

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K**

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

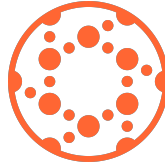
For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number 001-38360



Solid Biosciences Inc.

(Exact name of Registrant as specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

500 Rutherford Avenue, Third Floor

Charlestown, MA

(Address of principal executive offices)

90-0943402

(I.R.S. Employer
Identification No.)

02129

(Zip Code)

Registrant's telephone number, including area code: (617) 337-4680

Securities registered pursuant to Section 12(b) of the Act:

Title of each class
Common Stock \$0.001 par value per share

Trading Symbol
SLDB

Name of exchange on which registered
The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act:

None

(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐

Non-accelerated filer ☒

Emerging growth company ☐

Accelerated filer ☐

Smaller reporting company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). YES ☐ NO ☒

As of June 30, 2025, the last business day of the registrant’s most recently completed second fiscal quarter, the aggregate market value of the registrant’s common stock held by non-affiliates was \$317.7 million, based on the last reported sale price of such stock on the Nasdaq Global Select Market as of such date.

The number of shares of the registrant’s common stock outstanding as of March 16, 2026 was 98,391,314.

DOCUMENTS INCORPORATED BY REFERENCE

The registrant intends to file a definitive proxy statement for its 2026 Annual Meeting of Stockholders pursuant to Regulation 14A within 120 days of the end of the fiscal year ended December 31, 2025. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

	Page
<u>PART I</u>	1
Item 1. <u>Business</u>	1
Item 1A. <u>Risk Factors</u>	40
Item 1B. <u>Unresolved Staff Comments</u>	95
Item 1C. <u>Cybersecurity</u>	95
Item 2. <u>Properties</u>	95
Item 3. <u>Legal Proceedings</u>	95
Item 4. <u>Mine Safety Disclosures</u>	96
<u>PART II</u>	97
Item 5. <u>Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	97
Item 6. <u>Reserved</u>	98
Item 7. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	99
Item 7A. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	110
Item 8. <u>Financial Statements and Supplementary Data</u>	110
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	110
Item 9A. <u>Controls and Procedures</u>	110
Item 9B. <u>Other Information</u>	111
Item 9C. <u>Disclosure Regarding Foreign Jurisdictions that Prevent Inspections</u>	111
<u>PART III</u>	112
Item 10. <u>Directors, Executive Officers and Corporate Governance</u>	112
Item 11. <u>Executive Compensation</u>	112
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	112
Item 13. <u>Certain Relationships and Related Transactions, and Director Independence</u>	112
Item 14. <u>Principal Accountant Fees and Services</u>	112
<u>PART IV</u>	113
Item 15. <u>Exhibits and Financial Statement Schedules</u>	113
Item 16. <u>Form 10-K Summary</u>	117
<u>SIGNATURES</u>	118
<u>CONSOLIDATED FINANCIAL STATEMENTS</u>	F-3

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Annual Report on Form 10-K includes forward-looking statements, which involve risks and uncertainties. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “believe,” “estimate,” “project,” “anticipate,” “expect,” “seek,” “predict,” “aim,” “continue,” “possible,” “intend,” “may,” “might,” “will,” “could,” “would” or “should” or, in each case, their negative, or other variations or comparable terminology. These forward-looking statements include all matters that are not historical facts. They appear in a number of places throughout this Annual Report on Form 10-K. We derive many of our forward-looking statements from our operating budgets and forecasts, which are based upon many detailed assumptions. While we believe that our assumptions are reasonable, we caution that it is very difficult to predict the impact of known factors, and, of course, it is impossible for us to anticipate all factors that could affect our actual results. All forward-looking statements are based upon information available to us on the date of this Annual Report on Form 10-K.

The forward-looking statements in this Annual Report on Form 10-K include, among other things, statements about:

- the timing, progress, design and results of ongoing and planned preclinical studies and clinical trials for our neuromuscular (e.g., SGT-003, SGT-212), cardiac (e.g., SGT-401, SGT-501, SGT-601) or other future candidates;
- our ability to establish or maintain collaborations or strategic relationships;
- our ability to obtain and maintain U.S. and foreign regulatory approval of our neuromuscular (e.g., SGT-003, SGT-212), cardiac (e.g., SGT-401, SGT-501, SGT-601) or other future candidates, and the timing and scope thereof;
- the timing and outcomes of regulatory interactions;
- the size of the patient populations and potential market opportunity for our neuromuscular (e.g., SGT-003, SGT-212), cardiac (e.g., SGT-401, SGT-501, SGT-601) or other future candidates, if approved for commercial use;
- our manufacturing capabilities and strategy, including capacity constraints and the scalability and commercial viability of our manufacturing methods and processes;
- our plans to develop and commercialize our neuromuscular (e.g., SGT-003, SGT-212), cardiac (e.g., SGT-401, SGT-501, SGT-601) or other future candidates, if approved;
- the pricing and reimbursement of our neuromuscular (e.g., SGT-003, SGT-212), cardiac (e.g., SGT-401, SGT-501, SGT-601) or other future candidates we may develop, if approved;
- the establishment of sales, marketing and distribution capabilities and entry into agreements with third parties to market and sell our neuromuscular (e.g., SGT-003, SGT-212), cardiac (e.g., SGT-401, SGT-501, SGT-601) or other future candidates, if approved;
- the rate and degree of market acceptance and clinical utility of our neuromuscular (e.g., SGT-003, SGT-212), cardiac (e.g., SGT-401, SGT-501, SGT-601) or other future candidates, if approved;
- our plans to develop our platform technologies;
- our expectations related to our use of capital resources;
- our estimates regarding expenses, ongoing losses, future revenue, capital requirements, and need for and ability to obtain additional financing;
- our intellectual property position;
- our competitive and market position;
- developments relating to our competitors and our industry;
- our ability to continue as a going concern; and
- the impact of laws, regulations, and global political and economic developments, including the imposition of tariffs or other trade restrictions, on our business, operations, strategy and goals.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. We caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition, business and prospects may differ materially

from those made in or suggested by the forward-looking statements contained in this Annual Report on Form 10-K. In addition, even if our results of operations, financial condition, business and prospects are consistent with the forward-looking statements contained in this Annual Report on Form 10-K, those results may not be indicative of results to be expected in subsequent periods.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. The forward-looking statements contained in this Annual Report on Form 10-K are made as of the date of this Annual Report on Form 10-K, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

This Annual Report on Form 10-K includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities based on our analysis of these data, research, surveys and studies. All of the market data used in this Annual Report on Form 10-K involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our candidates include a number of key assumptions based on our industry knowledge, industry publications and third-party research, surveys and studies, which may be based on a small sample size and fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.

As used in this Annual Report on Form 10-K, the terms “Solid,” “the Company,” “we,” “us” and “our” refer to Solid Biosciences Inc., and its consolidated subsidiaries, unless the context indicates otherwise. Solid Biosciences Inc. was organized in March 2013 under the name SOLID Ventures Management, LLC and operated as a Delaware limited liability company until immediately prior to the effectiveness of its registration statement on Form S-1 on January 25, 2018, at which time it completed a statutory corporate conversion into a Delaware corporation and changed its name to Solid Biosciences Inc.

RISK FACTOR SUMMARY

Our business is subject to a number of risks that if realized could materially affect our business, operating results and financial condition and the trading price of our common stock could decline. These risks are discussed more fully below. These risks include the following:

- We have incurred significant net losses since inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.
- We will need additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.
- We have never generated revenue from product sales and do not expect to do so for the foreseeable future, if ever.
- Our limited operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.
- Unfavorable global economic conditions could harm our business, financial condition or results of operations.
- Our pipeline of gene transfer candidates, which we refer to collectively as our Candidates, utilize novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. To our knowledge, only a limited number of gene transfer products have been approved for commercialization in the United States and the European Union.
- One of our prior clinical trials had been placed on clinical hold by the Food and Drug Administration (“FDA”) in the past, and we cannot guarantee that similar events will not happen in ongoing, planned and future clinical trials for our Candidates.
- We have never completed a clinical trial and may be unable to do so for any Candidate, including SGT-003, SGT-212, SGT-501 and other Candidates.
- Our Candidates may cause one or more adverse events or other undesirable side effects or have properties that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more

restrictive label or the delay, denial or withdrawal of regulatory approval by the FDA or other comparable foreign regulatory authorities, limit the Candidates commercial potential or result in significant negative consequences following any potential marketing approval.

- Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials.
- Preliminary or interim data that we announce or publish from time to time may change as more data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.
- We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.
- We may find it difficult to enroll participants in our clinical trials, which could delay or prevent us from proceeding with clinical trials of SGT-003, SGT-212, SGT-501 or our other Candidates.
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our Candidates and the approval may be for a narrower indication than we seek.
- We face significant competition and our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our ability to develop, successfully market or commercialize our Candidates. Changes within the competitive landscape could lead us to alter our regulatory and/or clinical trial strategy, baseline eligibility criteria or make other modifications to clinical trial designs.
- We may not be successful in finding strategic collaborators for continuing development of our Candidates or platform technologies, or for successfully commercializing or competing in the market for certain indications.
- We have limited gene therapy manufacturing experience and could experience production problems and delays in obtaining regulatory approval of our manufacturing processes, which could result in delays in the development or commercialization of SGT-003, SGT-212, SGT-501, or our other Candidates. In addition, changes to manufacturing sites or processes, or formulations for our Candidates may result in additional cost or delay.
- We expect to utilize third parties to conduct our product manufacturing for the foreseeable future. Therefore, we are subject to the risk that these third parties may not perform satisfactorily or meet regulatory requirements.
- Our gene transfer approach utilizes capsids derived from a virus, which may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of gene transfer Candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our Candidates.
- We heavily rely on certain in-licensed patents and other intellectual property rights in connection with our development of our Candidates and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize our Candidates.
- If we are unable to obtain and maintain patent protection for our Candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our Candidates may be adversely affected.
- Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.
- The price of our common stock has been, and in the future is likely to be, volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.

PART I

Item 1. Business.

Overview

We are a life sciences company focused on advancing a portfolio of current and future gene therapy candidates, which we refer to collectively as our Candidates, including SGT-003 for the treatment of Duchenne muscular dystrophy (“Duchenne”), SGT-212 for the treatment of Friedreich’s ataxia (“FA”), SGT-501 for the treatment of Catecholaminergic polymorphic ventricular tachycardia (“CPVT”), SGT-601 for the treatment of TNNT2-mediated dilated cardiomyopathy (“TNNT2 DCM”), and additional assets for the treatment of genetic cardiac and neuromuscular diseases, at different stages of development, with varying levels of investment. We are advancing our diverse pipeline across rare neuromuscular and cardiac diseases, bringing together experts in science, technology, disease management and care. Patient-focused and founded by those directly impacted by Duchenne, our mission is to improve the daily lives of patients living with these devastating diseases.

Solid was purpose-built to advance the best science and accelerate the discovery and development of treatments that may benefit all patients with Duchenne. As we expand to bring meaningful treatments to patients living with other neuromuscular and cardiac diseases, the values and guiding principles that drive us continue. Our corporate vision is to build an innovation platform enabling the discovery and development of high-value genetic medicines for neuromuscular and cardiac diseases by integrating internal capabilities, including a vector core, use of validated animal models, optimized expression cassettes, novel capsids and regulatory expertise, and collaborations with leaders in related clinical and research fields. Our mission, which guides our operations, is to treat and change the course of neuromuscular and cardiac diseases at all stages. Underscoring this mission, our disease-focused business model is founded on the following fundamental principles:

- identify and develop meaningful therapies for underserved patients with sometimes fatal neuromuscular and cardiac diseases;
- build innovative libraries of delivery capsids and other enabling technologies with the potential to have broad impact on the gene therapy field at large;
- bring together the leading experts in neuromuscular and cardiac diseases, science, technology, disease management and care; and
- be guided by the needs of these patients.

Our Pipeline

We are focused on developing transformative treatments to improve the lives of patients with rare neuromuscular and cardiac diseases. The majority of our current programs are designed to treat these diseases with gene transfer products. Gene transfer, a type of gene therapy, is designed to address diseases caused by mutated genes through the delivery of functional versions of genes, called transgenes. The transgenes are then utilized by the body to produce proteins that act therapeutically to treat the condition. In addition to a transgene, our gene transfer Candidates include a viral capsid or vector (a protein shell utilized as a vehicle to deliver a transgene to cells in the body) and a promoter (a specialized DNA sequence that directs cells to produce the protein in specific tissues). The capsid is modified to no longer self-replicate yet still retain its ability to introduce new genetic material directly into patients’ cells. Adeno-associated virus (“AAV”) capsids have been approved for use to deliver transgenes to patients, including via systemic delivery as well as stereotactic neurosurgical administration to the brain. The use of AAV capsids to deliver gene therapies has also been extensively studied by third parties in human clinical trials for multiple disease indications.

The following pipeline chart summarizes the development stages of our Candidates:



Neuromuscular Programs

About Duchenne Muscular Dystrophy

Duchenne is a genetic muscle-wasting disease predominantly affecting boys, with symptoms that usually manifest between three and five years of age. Duchenne is a progressive, irreversible, and ultimately fatal disease that affects approximately one in every 5,000 live male births and has an estimated prevalence of 10,000 to 15,000 cases in the United States alone, with at least 400 annual Duchenne births. Duchenne is caused by mutations in the dystrophin gene, which result in the absence or near-absence of dystrophin protein. Dystrophin protein works to strengthen muscle fibers and protect them from daily wear and tear. Dystrophin protein also serves as the cornerstone of the dystrophin glycoprotein complex (“DGC”), a group of proteins that links the inner and outer components of muscle cells to ensure proper muscle function. Without functioning dystrophin and DGC, muscles suffer excessive damage from normal daily activities and are unable to regenerate, leading to the build-up of fibrotic, or scar, and fat tissue. More than 1,000 dystrophin gene mutations, which can be inherited or can occur spontaneously, have been identified in people with Duchenne. By their early teens, Duchenne patients typically lose their ability to walk and become dependent on a wheelchair for mobility. By their 20s, patients essentially become paralyzed from the neck down and require a ventilator to breathe. Though disease severity and life expectancy vary, a patient’s quality of life dramatically decreases over time, with death typically occurring by early adulthood from either cardiac or respiratory complications.

There is no cure for Duchenne. Glucocorticoid treatment, the current standard-of-care, has been shown to temporarily improve muscle strength, prolong the period of ambulation and slow the progression of Duchenne. However, glucocorticoid use is associated with well-known adverse side effects, including: severe weight gain, stunted growth, weakening of bone structure and metabolic dysfunctions, among others. The most commonly used glucocorticoids include prednisone and deflazacort (EMFLAZA).

Despite recent therapeutic advances, including the FDA approval of ELEVIDYS®, a gene transfer therapy for patients with Duchenne, we believe Duchenne represents a significant unmet medical need, in addition to a societal and economic burden. The economic burden includes costs associated with hospital admissions, medication, frequent doctor visits and investment in

assistive devices, as well as indirect costs related to productivity losses for the caregivers and costs due to pain, anxiety and social handicap. Only a small proportion of Duchenne patients are employed and many caregivers reduce their hours or stop working altogether to care for their children, who progressively require more help with everyday tasks, such as eating, dressing and using the bathroom. In some cases, patients also experience serious mental health issues that require additional support and treatment.

SGT-003

Background

Our lead neuromuscular, investigational gene transfer candidate, SGT-003, is designed to address the underlying genetic cause of Duchenne by delivering a synthetic transgene that produces microdystrophin, a dystrophin-like protein that retains critical components of the full-size dystrophin gene, yet is small enough to fit within AAV packaging constraints, and is primarily expressed in muscles of the body, including skeletal, cardiac and respiratory muscles. AAV-SLB101, the capsid used in SGT-003, was generated by modifying a naturally occurring, non-pathogenic virus called AAV, with the goal of enhancing its ability to efficiently enter skeletal, diaphragm and cardiac muscle tissues. In March 2026, we began using the mark POLARIS-101™ to represent our AAV-SLB101 capsid product (“POLARIS-101™”).

Our microdystrophin is based on three decades of development and optimization work at the University of Missouri and the University of Washington as well as other academic institutions. In preclinical studies, the laboratories of Jeffrey Chamberlain, Ph.D., from the University of Washington, and Dongsheng Duan, Ph.D., from the University of Missouri, identified a proprietary configuration of genetic components that, when administered systemically, produces functional microdystrophin protein expression that not only stabilizes muscle membranes and protects muscle against injury, but also simultaneously restores the localization of DGC to the muscle membrane, notably increasing neuronal Nitric Oxide Synthase, (“nNOS”) concentration. In published studies, Dr. Duan and Dr. Chamberlain demonstrated in animal models that, in comparison to earlier configurations, nNOS-restoring microdystrophins were more effective in improving muscle function and resistance to fatigue.

We believe the unique functionality of our proprietary microdystrophin has the potential to result in functional benefits including diminished muscle fatigue and protection against ischemic muscle damage, which can lead to loss of functional muscle.

The expression of our microdystrophin is regulated by a modified, synthetic muscle-specific promoter cassette called CK8, which is derived from the naturally occurring muscle creatine kinase promoter. Regulatory cassettes, such as CK8, are used to drive gene expression specifically in muscle tissues. In comparison to other regulatory cassettes, CK8 is small in size and is able to drive microdystrophin transgene expression in skeletal, diaphragm and cardiac muscle tissues. In our preclinical studies in small and large animal models, CK8 restricted microdystrophin transgene expression to these muscles.

SGT-003 is a clinical-stage gene therapy designed to preserve muscle function in Duchenne patients after a single administration. SGT-003 utilizes an updated construct, combining our proprietary microdystrophin containing nNOS with POLARIS-101™, a novel, rationally designed capsid derived from AAV9 and designed for enhanced muscle tropism, reduced liver uptake and to more selectively deliver the drug to target tissue. We believe the SGT-003 construct is meaningfully differentiated from other approved and in development gene transfer candidates and may provide differentiated clinical benefit.

Preclinical Development

Following in vitro studies in mouse and human muscle cells, POLARIS-101™ was evaluated in a head-to-head study against AAV9 with the CK8-microdystrophin construct in the dystrophin-negative mouse model of Duchenne (mdx mouse). Separate groups of mice were administered a single intravenous dose of either construct, and the biodistribution, microdystrophin protein expression, and biomarker analyses were performed at the conclusion of the study. Overall, the in vivo study mdx mouse data supported the results seen from in vitro assays and further demonstrated the potential benefits of SGT-003. The mdx mice dosed with the novel POLARIS-101™ capsid showed increased biodistribution (vector genome copies) in representative muscle tissues and increased microdystrophin expression compared to those administered the AAV9 capsid. Additionally, there were lower vector genome copies observed in the liver compared to AAV9-administered mice, with the data supporting a preferential distribution of the novel capsid towards muscle tissue and away from the liver. These data supported the proof of concept for the application of this novel capsid in Duchenne and formed a basis for establishing and advancing the SGT-003 program.

In April 2022, we released additional preclinical data from reporter transgene studies in non-human primates (“NHPs”) and both mdx and wild type mice suggesting that POLARIS-101™ may have meaningful advantages for the delivery of

muscle-related gene therapies. Data from the NHP study, which used a reporter transgene in POLARIS-101™ demonstrated increased muscle tropism, decreased liver biodistribution and improved efficiency compared with AAV9. The results from the NHP study are consistent with the data from the reporter transgene studies in both mdx and wild type mouse models, which suggested improved muscle tropism and reduced liver uptake.

Clinical Development and Regulatory Strategy

Based on our preclinical data, we submitted an investigational new drug application (“IND”) for SGT-003 to the FDA, which was cleared in November 2023. Participant dosing in the Phase 1/2 INSPIRE DUCHENNE trial of SGT-003 began in the second quarter of 2024. The INSPIRE DUCHENNE trial is a Phase 1/2 first-in-human, open-label, single-dose, multicenter trial designed to evaluate the safety, tolerability and efficacy of SGT-003 in pediatric patients with Duchenne at a dose of 1E14vg/kg. SGT-003 is administered as a one-time intravenous infusion. Since initiation of the INSPIRE DUCHENNE clinical trial, we amended the clinical trial protocol to increase the anticipated participant enrollment size, expand the participant cohort age groups, and extend the time points of certain secondary objective measurements. In connection with the expanded clinical trial, we have initiated work for additional Good Manufacturing Practices (“GMP”) batches of SGT-003.

Enrollment and dosing in the INSPIRE DUCHENNE trial is ongoing and being conducted at 15 clinical sites across the United States, Canada, Italy and the United Kingdom. We believe we have aligned with the FDA on SGT-003's potency assay strategy and will continue commercial-readiness CMC activities, with our process performance qualification manufacturing batches to be completed in 2026.

In October 2025, we activated the first clinical trial site and began screening participants for IMPACT DUCHENNE, a Phase 3 randomized, double-blind, placebo-controlled trial evaluating SGT-003. In February 2026, we announced positive feedback from a Type C meeting with the FDA where we reached alignment on the IMPACT DUCHENNE trial design, including: the patient population of ambulant participants 7 to <12 years of age, the primary endpoint of change from baseline in Time to Rise velocity from supine position evaluated at 18 months and other key secondary endpoints. The IMPACT DUCHENNE trial is currently planned to be conducted at sites in Australia, Canada, the European Union and the United Kingdom, and due to strong key opinion leader and community demand, we are also evaluating the potential to open clinical trial sites in the United States. Participant screening is underway and we anticipate dosing the first participant in the Phase 3 IMPACT DUCHENNE trial in April 2026.

In the first half of 2026, we plan to have additional meetings with the FDA to receive guidance on a potential accelerated approval pathway for SGT-003 and we expect to provide regulatory and clinical updates in mid-2026.

The FDA has granted Fast Track, Orphan Drug, and Rare Pediatric Disease designations for SGT-003 for the treatment of Duchenne. SGT-003 has been awarded an Innovation Passport by the new UK Innovative Licensing and Access Pathway, which aims to accelerate time to market and facilitate patient access to new medicines in the United Kingdom.

Updated Interim Clinical Data from INSPIRE DUCHENNE Trial of SGT-003

On March 11, 2026, we announced positive new interim data from the Phase 1/2 INSPIRE DUCHENNE clinical trial, a first-in-human, open-label, single-dose, multicenter trial designed to evaluate the safety, tolerability and efficacy of SGT-003 in pediatric participants with Duchenne at a dose level of 1E14vg/kg. SGT-003 is administered as a one-time intravenous infusion.

The interim clinical data reported is as of a February 23, 2026, data cutoff date. SGT-003 has been generally well tolerated in the 41 participants dosed as of March 18, 2026. The safety and tolerability profile observed in the INSPIRE DUCHENNE trial continued to be promising; SGT-003 is administered using a low-burden, steroid-only prophylactic immunomodulation regimen. As of March 18, 2026, there has been one treatment-related serious adverse event reported in the INSPIRE DUCHENNE trial. This serious adverse event was identified as a Grade 3 immune-mediated myositis which, importantly, was not associated with muscle pain or weakness, and occurred in a participant who had a large deletion in a region coded for by SGT-003's microdystrophin. The trial participant promptly responded to steroid treatment and the event has resolved. This serious adverse event was reviewed by the data and safety monitoring board (DSMB) with the recommendation to continue dosing without interruption.

Microdystrophin transduction and expression levels, beta-sarcoglycan localization and nNOS activity were evaluated by biopsy in 20 participants (ages 1-10 years) at Day 90 and in 3 participants at Day 360. Results demonstrated robust mean vector copies per nucleus and microdystrophin expression as well as properly localized and restored beta-sarcoglycan-positive fibers and nNOS activity-positive fibers. Beta-sarcoglycan and nNOS are critical components of the dystrophin-associated protein complex (“DAPC”). In Duchenne, the absence of dystrophin destabilizes the DAPC, triggering a cascade of structural, signaling and metabolic defects that impair muscle integrity. Reconstituting critical components of the DAPC,

including beta-sarcoglycan and nNOS, could suggest biologic correlation of SGT-003's treatment effect. Our microdystrophin construct is the only microdystrophin gene therapy, approved or investigational, that contains the R16/R17 binding domain, which uniquely localizes nNOS to the muscle.

Microdystrophin Expression and Other Measures at Day 90 (N=20 unless noted) and Day 360 (N=3)

	Day 90 (n=20 unless noted)	Day 360 (n=3)
Mean vector copies per nucleus	11	12
Mean microdystrophin expression by western blot (%)	60% (n=19)	91%
Mean microdystrophin expression by mass spectroscopy (%)	52% (n=17)	86%
Mean microdystrophin-positive fibers by immunofluorescence (%)	63%	69%
Properly localized and restored beta-sarcoglycan-positive fibers (%)	60%	69%
nNOS activity-positive fibers (%)	35%	33%

Western blot and mass spectrometry baselines were 0% mean normal dystrophin, microdystrophin-positive fibers by immunofluorescence was based on a manual count, as are beta-sarcoglycan and nNOS-positive fibers. These assays are conducted by multiple external vendors; at the time of analysis, one western blot sample and three mass spectrometry samples had not been received.

Additionally, we have identified an extensive biomarker panel to comprehensively evaluate treatment effect on muscle integrity. Collectively, these observed biomarker improvements at Day 90 and Day 360 suggest improved muscle fiber health and stability, reduced ongoing muscle damage, and an interruption of the chronic degeneration/regeneration cycle that is characteristic of Duchenne.

In particular, embryonic myosin heavy chain ("eMHC") is an informative predictor of disease progression. eMHC is typically expressed during fetal development but is also expressed when muscle satellite cells differentiate into muscle fibers, which in Duchenne occurs in response to muscle fiber damage. In the absence of functional dystrophin, newly generated muscle fibers also fail, leading to continued but ultimately futile satellite cell activation. A mean 44% observed reduction in eMHC-positive fibers seen at Day 90 (n=20) suggests that SGT-003 treatment has potentially disrupted this chronic and futile degeneration-regeneration cycle, stabilizing muscle fibers and preserving the reservoir of satellite cells.

Muscle Integrity Biomarker Evaluation at Day 90 (N=24 unless noted) and Day 360 (N=7 unless noted)

Serum Biomarkers	Day 90 Mean Reductions (n=24 unless noted)	Day 360 Mean Reductions (n=7 unless noted)
Serum creatine kinase (CK)	38%	37%
Serum alanine transaminase (ALT)	43%	27%
Serum aspartate aminotransferase (AST)	30%	32%
Serum lactate dehydrogenase (LDH)	46% (n=21)	38% (n=6)
Serum titin	22% (n=11)	25% (n=2)

Certain data from a subset of participants were not available at the time of analysis.

While cardiac assessments were initially included as safety evaluations, stabilization-to-improvement in systolic function continues to be observed as of the data cutoff date, as measured by left ventricular ejection fraction ("LVEF"). Observed improvements were driven largely by participants with low-normal baseline LVEF (defined as $\leq 60\%$). Cardiomyopathy is a leading cause of death in Duchenne, with 25% of individuals displaying evidence of cardiomyopathy by six years of age, increasing to 59% by 10 years of age.

About Friedrich's ataxia

Friedreich's ataxia ("FA") is a serious, life threatening, progressive multi system disease that is classically known to affect both cardiac and neurological systems but also involves endocrine, musculoskeletal and other organ systems. FA affects 1 in 40,000 people with an average onset between ages 10 and 15 and average lifespan of less than 40 years. It is estimated that approximately 5,000 to 7,000 patients in the United States and 25,000 patients in the European Union are affected by FA. The disease is due to autosomal recessive variants in the frataxin ("FXN") gene. Specifically, the majority of disease-causing variants are guanine-adenine-adenine expansion repeats located in intron 1 of the FXN gene on chromosome 9; the expansion range varies greatly from 70 to over 1700 repeats. This expansion causes a severe decrease in the expression of frataxin, a 210 amino-acid protein that is expressed as a precursor protein. Frataxin is imported into the mitochondrial matrix where it undergoes proteolytic cleavage to the 130 amino acid mature form, and is involved in iron-sulfur protein production, storage and transport. Alternatively, approximately 5% of patients will have another non-repeat variant in FXN. Frataxin, although

ubiquitously expressed, exhibits tissue-specific differences in the levels of expression that partially correlate with sites of disease pathology. Dorsal root ganglia (“DRG”), Purkinje and Granule cells in the cerebellum all exhibit high levels of expression. Frataxin expression is also high in non-neuronal tissues such as the heart and pancreas. FA is strongly associated with a high incidence of left ventricular (“LV”) wall thickening, cardiomyopathy and diabetes. Frataxin is also highly expressed in tissues not affected in FA, such as liver, kidney and brown fat. FA is associated with a wide range of clinical manifestations including neurological and cardiovascular impact.

Neurological symptoms are key features and are highly penetrant in FA with ataxia and dysarthria being prominent features of the disease. Cerebellar lesions and sensory neuropathy result in ataxia and loss of balance. Visual and hearing impairments also occur. It has been postulated that the onset of sensory neuropathy coincides with the beginning of inflammatory infiltration of the DRG. Modest reductions of frataxin are detrimental to the development of the spinal cord and DRG.

Cardiovascular complications are the most common cause of death in patients with FA, with comorbid cardiomyopathy found in at least 60% of fatalities. Cardiac involvement in FA manifests as cardiac LV wall thickening and resultant diastolic dysfunction. As the disease progresses, the heart becomes fibrotic and dilated, with damage to both the muscle and conduction system. Ultimately, FA cardiac involvement may result in reduced cardiac function (low ejection fraction), cardiac arrhythmias, heart failure, and death. As myocardial fibrosis is believed to be an irreversible end-stage complication, early intervention is key to preventing this most common cause of FA mortality.

There is no cure for FA. On February 28, 2023, Biogen’s SKYCLARYS® (omaveloxolone) was the first drug approved in the United States and European Union for people with FA. While SKYCLARYS® positively effects cellular energy production, there continues to be significant unmet needs for patients with FA and the underlying cause of the disease, FXN deficiency, is not addressed.

SGT-212

SGT-212 is an investigational gene therapy that utilizes a recombinant, non-replicating capsid, AAVhu68, containing a codon-optimized cDNA that encodes full-length FXN under control of the CB7 promoter and enhancer elements.

The vector capsid exhibits broad tissue tropism for effective transduction of a wide range of host cell types including cardiomyocytes and neurons. The expression of the cDNA is under the control of a ubiquitous CB7 promoter, which should lead to increased expression of FXN in many tissue types. Restoration of FXN levels is expected to address the underlying mitochondrial dysfunction, which is a hallmark of FA.

SGT-212 was designed to leverage a dual route of administration: intradentate nuclei (“IDN”) infusion using an FDA-approved neurosurgical device in a stereotactic, precision magnetic resonance imaging (“MRI”) guided technique, followed by an IV infusion to increase therapeutic FXN levels in the cerebellar dentate nuclei (“DN”), cardiomyocytes and other systemic tissues. By using this dual-route of administration approach, SGT-212 seeks to restore functional FXN levels and address the neurologic, cardiac and systemic manifestations of FA. Systemic administration alone in the non-clinical models resulted in poor penetration of the DN; therefore, we believe that a dual route of IDN and systemic IV infusion is needed to appropriately deliver the transgene to the desired tissues.

In January 2025, we announced that the FDA cleared our IND for SGT-212 for the treatment of FA. In October 2025, we activated the first clinical trial site and began screening participants for FALCON, an open-label, multi-center Phase 1b clinical trial of SGT-212, and in January 2026, we dosed the first participant in the trial. As of March 18, 2026, there have been no serious adverse events and no treatment-related adverse events reported in the FALCON trial. Intra-procedural MRI imaging demonstrated promising IDN targeting and coverage. The trial is expected to enroll approximately 10 non-ambulatory and ambulatory adult participants (aged 18-40) living with FA in up to three cohorts and is designed to evaluate the safety and tolerability of contemporaneous IDN and systemic IV infusion of SGT-212 with initial data anticipated in the second half of 2026, subject to participant enrollment. The FDA has granted Fast Track, Orphan Drug and Rare Pediatric Disease designations to SGT-212 for the treatment of FA.

Cardiac Programs

Genetic cardiac disease, or inherited cardiac conditions, is an umbrella term to describe cardiac diseases caused by mutations in one or more genes. Primary inherited arrhythmia syndromes present as abnormal cardiac arrhythmia, including life threatening ventricular arrhythmia, in the setting of structurally normal hearts and are in general genetically determined. Cardiomyopathy is a disease of the heart muscle that impairs the ability of the heart to pump blood to the rest of the body,

resulting in arrhythmias, backup of blood into the lungs and other parts of the body, and ultimately heart failure. Forms of cardiomyopathy include DCM, hypertrophic and arrhythmogenic cardiomyopathy.

About CPVT

Our lead cardiac program is directed to the primary inherited arrhythmia syndrome CPVT. CPVT is a rare, serious and life-threatening disease which primarily manifests in children in the first and second decades of life. CPVT is an inherited cardiac arrhythmia syndrome characterized by adrenergically induced polymorphic ventricular tachycardia in the presence of a normal resting sinus rhythm and a structurally normal heart. It is estimated that approximately 33,000 persons in the United States are affected by CPVT.

CPVT manifestations typically involve syncope, cardiac arrest and/or sudden cardiac death. The most common symptoms/signs include syncope (52-100%), cardiac arrest (8-48%), seizure-like events (40%), and hypoxic-ischemic encephalopathy (20%). CPVT is a significant cause of sudden death at a young age and historically has a high mortality rate of up to 50% by age 35. Data from the recent Pediatric and Congenital Electrophysiology Society CPVT registry suggest that three of every four children with CPVT present with life-threatening symptoms, which often occur during resting wakeful activities highlighting the unpredictable nature of CPVT.

To date, there are no medicines specifically approved for the treatment of CPVT and management is directed toward manifestations of the disease with the goal of reducing arrhythmias and eliminating the incidence of life-threatening arrhythmias. Current treatments for CPVT include lifestyle management changes, such as restriction of rigorous physical exercise and avoidance of emotional distress, which are very challenging in the pediatric population, as well as pharmacotherapies requiring strict compliance (e.g. beta-blockers and/or flecainide alone). Despite available pharmacotherapy options, the occurrence of breakthrough arrhythmia in approximately 30% of patients demonstrates that lifelong compliance is a critical problem. In addition, in some cases implantable cardioverter-defibrillators and/or left cardiac sympathetic denervation are used as treatment for symptomatic CPVT patients, but both are associated with attendant morbidity.

SGT-501

SGT-501 is a gene therapy candidate for the treatment of CPVT, which is typically caused by a gain of function mutation in the ryanodine receptor 2 (coded for by the RYR2 gene), referred to as RYR2-mediated CPVT. Mutations in RYR2 genes result in abnormal calcium ("Ca⁺⁺") flow from the sarcoplasmic reticulum into the cytoplasm through RYR channel in diastole, triggering abnormal heart beats and leading to arrhythmias.

Our approach focuses on AAV-mediated therapeutic overexpression, or augmentation, of CASQ2, a calcium-binding protein which, through its role in Ca⁺⁺ regulation, is integral to excitation-contraction coupling in the heart and in regulating the rate of heart beats. CASQ2 expression via AAV is intended to provide durable and continual protection from Ca⁺⁺ leaks seen in patients with RYR2-mediated CPVT.

SGT-501 uses AAV8, a muscle tropic capsid, to deliver a functional CASQ2 transgene. Collectively, overexpression of CASQ2 in CPVT patients converges on a mechanism that drives buffering of free sarcoplasmic reticulum luminal calcium such that diastolic calcium leaks through the RYR2 into the cytosol are less likely. This mechanism of action is intended to support maintenance of normal cardiac rhythm and protect against triggered activity and arrhythmias.

Non-clinical mouse studies have demonstrated proof of concept for CASQ2 gene replacement using a recombinant AAV8 serotype capsid encoding CASQ2 to mitigate effects associated with an RYR2 mutation.

We have conducted preclinical studies of SGT-501, including three and six-month good laboratory practices ("GLP") toxicology studies. IND-enabling GLP toxicology studies of SGT-501 in non-human primates, including in-life portion of the six-month toxicology study, were completed in the first quarter of 2025. SGT-501 was well tolerated with no adverse observations in non-human primates within the tested dose range through 6 months.

In July 2025, we announced that the FDA cleared our IND and that Health Canada approved our clinical trial application for SGT-501 for the treatment of CPVT. In January 2026, we announced that clinical trial sites have been activated and participant screening is underway in the ARTEMIS clinical trial, an open-label, multi-center Phase 1b clinical trial evaluating SGT-501 in adult participants with CPVT. The ARTEMIS trial is designed to evaluate the safety and tolerability of a single IV infusion of SGT-501. We anticipate dosing our first participant in the second quarter of 2026 with initial safety data anticipated in the second half of 2026, subject to participant enrollment.

The FDA has granted Fast Track, Orphan Drug and Rare Pediatric Disease designations to SGT-501 for the treatment of CPVT.

Other Cardiac Candidates

SGT-601

We are currently developing a preclinical stage product candidate, SGT-601, for the treatment of TNNT2 DCM. TNNT2 DCM is a rare cardiac disease characterized by mutations in the gene that codes for cardiac troponin T protein, which helps coordinate contraction of the heart muscle. TNNT2 gene mutations lead to reduced cardiac troponin T protein levels and DCM, which ultimately lead to heart failure. There are no approved therapies addressing the underlying cause of TNNT2 DCM. It is estimated that between 14,000 to 41,000 people in the United States are affected by TNNT2 DCM. TNNT2 DCM is typically diagnosed between ages 20 and 50, with approximately 50% of onset seen by age 30, and has a mortality rate of 50%.

Our approach utilizes an AAV-delivered human TNNT2 transgene with a cardiac-selective promoter designed to restore functional levels of the troponin T protein. Preclinical studies in mice demonstrated SGT-601's ability to elicit robust, dose-dependent, cardiac-selective expression of human TNNT2 that was properly localized to the heart cell sarcomere. Efficacy studies in mice suggest that SGT-601 treatment resulted in a restoration of ejection fraction function and a stabilization in cardiac function over time.

Other

We have two cardiac pipeline gene transfer programs, SGT-401 for BAG3-mediated DCM, which is in early preclinical development, and SGT-701 for RBM20 DCM, which is in the discovery stage.

BAG3-mediated DCM is a rare cardiac disease characterized by mutations in the BAG3 gene, which codes for the BCL-2-associated athanogene 3 ("BAG3") protein. Sufficient levels of functional BAG3 are required for healthy cardiac function. BAG3 gene mutations lead to reduced BAG3 protein levels and ultimately DCM. Deletions and truncations in the BAG3 protein that result in haplo-insufficiency have been associated with the development of DCM resulting from myofilament damage, poor contraction, left ventricular dysfunction, dilatation and heart failure.

RBM20 DCM is a rare inherited cardiac disease characterized by mutations in the RBM20 gene, a cardiac splicing factor that regulates alternative splicing and codes for RNA binding motif protein 20. RBM20 mutations can cause a clinically aggressive form of DCM that is correlated with high rates of heart failure, arrhythmias, and sudden cardiac death.

Additionally, in December 2024, we entered into a collaboration, patent and know-how license agreement with the Mayo Foundation for Medical Education and Research ("Mayo") to accelerate gene therapy innovation and advance development of cardiac gene therapies. As part of the collaboration, we will be providing manufactured viral materials and chemistry, manufacturing and controls know-how to Mayo while Mayo will be responsible for supporting all preclinical research through IND-enabling studies for six undisclosed programs. We will then be responsible for the clinical development of programs chosen by us to develop.

Platform Technologies

In addition to our gene transfer candidates, we have development programs focusing on platform technologies, including novel capsid libraries, genetic regulators including promoters, untranslated regions, and introns, immunomodulation technologies, manufacturing purity, and dual gene expression, a technology that allows us to package multiple transgenes into one capsid. These programs are part of our ongoing research efforts to develop innovative technologies that we believe may hold potential to translate into meaningful treatments, and drive future pipeline expansion, which we may seek to out-license to or develop through partnerships and collaborations with other biotechnology companies.

Novel Capsid Programs

Our novel capsid programs are directed toward developing capsid libraries designed to enhance skeletal muscle and/or cardiac muscle tropism. POLARIS-101™ is our rationally designed, proprietary capsid used in SGT-003 for Duchenne, which has been generally well tolerated as of March 18, 2026 (N=41) in the INSPIRE DUCHENNE clinical trial, and was also well tolerated in nonclinical NHP and mouse models. We aim to license POLARIS-101™ broadly to corporations, institutions and academic labs pursuing neuromuscular and cardiac rare disease research, with more than 50 agreements including licenses executed.

We developed a scalable, high-throughput platform for next-generation capsid design that aims for rapid translation from discovery to application. By leveraging a deep understanding of capsid structure, we aim to systematically combine enhancements without compromising capsid stability or manufacturability. This approach has uncovered multiple modifications that improve tissue targeting and expression. Additional performance gains are achieved through peptide

insertions and purpose-built libraries. Identification of key human receptors further accelerates optimization using generative AI and affinity maturation. Together, these integrated capabilities drive step-change improvements in biodistribution and expression, enabling the identification of potential first-in-class and best-in-class capsids with clear differentiation potential.

To investigate translational reliability, we assess capsid performance across multiple relevant species cell lines—providing a predictable path from discovery to development. Importantly, candidates are validated in human-relevant systems, such as iPSC-derived cardiomyocytes and engineered cell lines expressing human receptors, to assess clinical relevance. Collectively, these studies demonstrate improvements in biodistribution and expression relative to POLARIS-101™, establishing a strong foundation for next-generation, differentiated gene therapy programs

We are building cardiac and neuromuscular next-generation capsid and promoter libraries with capsid selection from the first library anticipated in the second half of 2026.

Manufacturing and Supply

Currently, we are working to develop and optimize a transient transfection manufacturing process for producing drug product for our current and future Candidates. This process will build on industry-wide accepted practices and is expected to increase the yield, robustness and scalability of our current methods.

SGT-003, SGT-212 and SGT-501 are manufactured using transient transfection which requires processing steps that are more complex than those required for most chemical pharmaceuticals. We also intend to use transient transfection manufacturing for our other Candidates. We selected a manufacturing process that we believe will be scalable to support clinical and commercial production needs for SGT-003, SGT-212 and SGT-501. The transient transfection process was selected to efficiently advance SGT-003, SGT-212 and SGT-501 along their respective development timelines.

We currently rely on third-party manufacturers for supply of SGT-003, SGT-212 and SGT-501 and plan to rely on third-party manufacturers for our other Candidates. In October 2021, we announced a partnership with a cell and gene therapy-focused contract development and manufacturing organization for the development and clinical stage manufacture of SGT-003. As part of our recently completed asset purchase from FA212 LLC (“FA212”), we also acquired sufficient GMP clinical materials from FA212 to supply the ongoing Phase 1b clinical trial for SGT-212.

We are supplying, and expect to continue to supply, our ongoing and future preclinical and clinical development programs with drug produced at a current Good Manufacturing Practice (“cGMP”) compliant facility located at one of our contract manufacturing organizations. We ultimately intend to establish the capability and capacity to supply Candidates at commercial scale in alignment with program timeframes.

Intellectual Property

Our commercial success depends in part on our ability to obtain and maintain proprietary or intellectual property protection for our pipeline programs, our platform technologies and other know-how, to operate without infringing, misappropriating or otherwise violating the intellectual property rights of others, and to prevent others from infringing, misappropriating or otherwise violating our intellectual property rights. We also rely on patents, trade secrets, know-how, confidentiality procedures and agreements, and continuing technological innovation to develop and maintain our proprietary and intellectual property position.

We own and in-license various patents, patent applications, know-how and trade secrets relating to the development and commercialization of our gene therapy candidates and platform technologies. As of February 6, 2026, our patent portfolio includes both owned and in-licensed patent families relating to our gene therapy programs and platform technologies.

Substantive prosecution of some of our patent applications has not yet commenced at the U.S. Patent and Trademark Office (“USPTO”) or in the patent offices of ex-U.S. jurisdictions. We cannot predict whether such pending patent applications will result in the issuance of patents that effectively protect our candidates and our platform technologies, or if such issued patents or any of our licensor’s issued patents will effectively prevent others from commercializing competitive products. In any event, patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the patent offices in various jurisdictions are often significantly narrowed by the time they issue, if they issue at all.

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent or patent application. The term of a patent that covers a drug or biological product may also be eligible for patent term extension when FDA approval is granted, subject to certain limitations and provided statutory

and regulatory requirements are met (for more information, please see “Business— Government Regulation and Product Licensure —U.S. Patent Term Restoration”). In the future, if and when our candidates receive approval from the FDA or foreign regulatory authorities, we expect to apply for patent term extensions on issued patents we may obtain covering those products, depending upon the length of the clinical trials for each product and other factors. There can be no assurance that any of our pending patent applications will issue or that we will benefit from any patent term extension or favorable adjustment to the term of any of our patents.

As with other biotechnology and pharmaceutical companies, our ability to maintain and solidify our proprietary and intellectual property position for our candidates will depend on our success in obtaining effective patent claims and enforcing those claims if granted. However, our owned and licensed pending patent applications, and any patent applications that we may in the future file or license from third parties may not result in the issuance of patents. We also cannot predict the breadth of claims that may be allowed or enforced in our patents. Any issued patents that we may receive in the future may be challenged, invalidated or circumvented. Further, third parties may have patents or be granted patents that may block our ability to develop or commercialize our gene therapy candidates and platform technologies. In addition, because of the extensive time required for clinical development and regulatory review of a candidate we may develop, it is possible that, before any of our candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby limiting protection such patent would afford the respective product or products and any competitive advantage such patent may provide.

In addition to patents, we rely upon unpatented trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by executing confidentiality agreements with our collaborators and scientific advisors, and non-competition, non-solicitation, confidentiality, and invention assignment agreements with our employees and consultants. We have also executed agreements requiring assignment of inventions with selected scientific advisors and collaborators. The confidentiality agreements we enter into are designed to protect our proprietary information, and the agreements or clauses requiring assignment of inventions to us are designed to grant us ownership of technologies that are developed through our relationship with the respective counterparty. We cannot guarantee, however, that these agreements will afford us adequate protection of our intellectual property and proprietary information rights.

We also seek trademark protection in the United States and internationally where available and when appropriate. We currently own U.S. federal registrations for the marks SOLID, SOLID BIOSCIENCES and SOLID BIOSCIENCES logo, as well as registrations in the European Union, United Kingdom, Japan, and Hong Kong for the mark SOLID BIOSCIENCES, registrations in the European Union and United Kingdom for the marks SOLID BIOSCIENCES logo and SOLID GT.

Duchenne

Exclusive of our platform technologies, our Duchenne program includes three patent families with respect to microdystrophin and promoter sequences. We have filed one pending international patent application, one pending U.S. non-provisional patent application, and eleven pending patent applications in foreign jurisdictions, and have also exclusively licensed four issued U.S. patents, one pending U.S. non-provisional patent application, and 21 granted patents and seven pending patent applications in foreign jurisdictions. The issued U.S. patents are projected to expire between 2028 and 2036, excluding any patent term adjustments and any patent term extensions, and any U.S. patents that may issue from the pending U.S. non-provisional patent applications would be projected to expire between 2036 and 2042, excluding any patent term adjustments and any patent term extensions.

FA

Exclusive of our platform technologies, our FA program includes eight patent families. We have filed one pending U.S. non-provisional patent application, and have also exclusively licensed three U.S. patents, six pending U.S. non-provisional patent applications, 15 granted patents and 43 pending patent applications in foreign jurisdictions. We have also licensed one pending international patent application. The issued U.S. patents are projected to expire between 2036 and 2038, excluding any patent term adjustments and any patent term extensions, and any U.S. patents that may issue from the pending U.S. non-provisional patent applications would be projected to expire between 2036 and 2044, excluding any patent term adjustments and any patent term extensions.

CPVT

Exclusive of our platform technologies, our CPVT program includes two patent families. We have one pending international patent application and have exclusively licensed one pending U.S. non-provisional patent application and 3 granted patents and five pending patent applications in foreign jurisdictions. Any U.S. patents that may issue from the pending U.S.

non-provisional patent applications currently pending would be projected to expire in 2039, excluding any patent term adjustments and any patent term extensions.

Platform Technologies

We own or license patents, patent applications and know-how related to various platform technologies. Certain of these technologies may be applicable to one or more of our current or future gene therapy candidates.

Our capsid program includes three patent families related to modified AAV capsids. We have filed or licensed two pending U.S. patent applications, 15 pending patent applications and one granted patent in foreign jurisdictions, and one pending international patent application. Any U.S. patents that may issue from the pending U.S. non-provisional patent application would be projected to expire in 2040, excluding any patent term adjustments and any patent term extensions.

Strategic Partnerships and Collaborations/Licenses

We have certain obligations under licensing agreements with third parties that include annual maintenance fees and payments that are contingent upon achieving various development, commercial and regulatory milestones. Pursuant to many of these license agreements, we are required to make milestone payments if certain development, regulatory and commercial sales milestones are achieved, and may have certain additional research funding obligations. Also, pursuant to the terms of many of these license agreements, when and if commercial sales of a licensed product commence, we must pay royalties to our licensors on net sales of the respective licensed products.

FA212 LLC Asset Purchase Agreement

In September 2024, we entered into a purchase agreement with FA212 for the purchase of certain intellectual property, including patents and assigned licenses, related to a preclinical drug candidate, which we now refer to as SGT-212, assigned manufacturing contracts as well as research and development materials such as manufactured materials and samples. The assets include an exclusive license for the gene therapy underlying SGT-212 from the University of Pennsylvania.

SGT-212 is designed as a dual-route administration AAV gene therapy aimed at treating the major manifestations of FA. SGT-212 is designed to be delivered via both IV and IDN infusion administration, which offers a novel approach to address FA's complex pathology.

Under the terms of the agreement, we made an upfront payment of \$1.0 million to FA212. Additionally, FA212 is eligible to receive development milestone payments of up to \$34.0 million and cumulative sales milestone payments of up to \$21.0 million, upon achievement of specified milestone events, and tiered royalties on net sales in the low-single-digits. Certain development milestone payments are payable in either cash, equity, or a combination of both at our discretion. We also assumed from FA212 contingent development milestone payments of up to \$4.2 million, regulatory milestone payments of up to \$13.0 million, cumulative sales milestone payments of up to \$27.5 million, and tiered royalties on worldwide net sales in the mid-single digits, each of which are payable to the University of Pennsylvania.

In February 2025, we made the first milestone payment of 975,496 shares of our common stock to FA212 following the FDA's clearance of our IND for SGT-212 for the treatment of FA. In January 2026, we made the second milestone payment of 1,316,899 shares of our common stock to FA212 following the dosing of the first participant in the Phase 1b FALCON clinical trial of SGT-212.

As part of the asset purchase, we also acquired sufficient GMP clinical materials from FA212 to supply the ongoing Phase 1b clinical trial of SGT-212.

Maugeri License Agreement

In June 2023 we entered into a license agreement (the "Maugeri License Agreement") with ICS Maugeri S.p.A. SB ("Maugeri") to focus on our development and commercialization of cardiac-related products based on Maugeri's inventions. Pursuant to the Maugeri License Agreement, Maugeri granted us an exclusive worldwide sublicensable license in certain Maugeri patent rights, including existing patent rights, and those in any improvements or know-how made in performance of the Maugeri License Agreement, and a non-exclusive worldwide sublicensable license in certain Maugeri know-how, including existing know-how, and on any improvement thereto, in each case, subject to certain conditions, that is necessary or reasonably useful to develop licensed products under the terms of the Maugeri License Agreement. We will conduct certain activities agreed to by the parties with respect to the research and development of licensed products. A condition

precedent to the effectiveness of the Maugeri License Agreement was regulatory review in Italy, which was completed in the third quarter of 2023 and, upon the completion of the condition precedent, the Maugeri License Agreement became effective.

We paid Maugeri an upfront license fee of €1.5 million, which was recorded as research and development expense during the second quarter of 2023. Additionally, we agreed to cumulative developmental, regulatory, and commercial milestone payments of up to €15.0 million, cumulative sales milestone payments of up to €15.0 million, upon achievement of specified milestone events, and tiered royalties on worldwide net sales in the low-to-mid-single-digits. Under the Maugeri License Agreement, we paid a €1.0 million milestone payment to Maugeri in August 2025. There were no milestones achieved during the year ended December 31, 2024.

The Maugeri License Agreement continues until the latest expiry of (i) the last valid claim (as defined in the Maugeri License Agreement), (ii) regulatory exclusivity, and (iii) all payment obligations. Either party may terminate the Maugeri License Agreement for the other party's uncured material breach. We may also terminate the Maugeri License Agreement in our sole discretion upon 60 days' prior written notice to Maugeri and payment of a fee.

University of Washington License Agreement

In 2015, we entered into a license agreement with the University of Washington, acting through UW CoMotion, under which we obtained an exclusive, royalty-bearing, sublicensable, worldwide license under certain patent applications owned by the University of Washington relating to novel micro-dystrophins to develop, manufacture, and commercialize products for use in the treatment of Duchenne and related disease indications caused by a lack of functional dystrophin. We have the right to grant sublicenses to third parties contingent upon written approval by the University of Washington prior to executing such sublicense, which approval may not be unreasonably withheld.

In consideration for the rights granted by the agreement, we paid a one-time, non-refundable license fee, which was recorded as a research and development expense in 2015. We are required to reimburse the University of Washington for costs incurred in applying for, prosecuting and maintaining patents and pay up to an aggregate of approximately \$1 million upon the achievement of certain milestones. There were no milestones achieved during the years ended December 31, 2025 and 2023. In October 2017, the first milestone was achieved under this agreement. The milestone payment was recorded as a research and development expense in the fourth quarter of 2017. In October 2020, the license agreement was amended such that we were required to pay the University of Washington \$375 thousand in connection with the execution of the collaboration and license agreement ("the Collaboration Agreement") with Ultragenyx Pharmaceutical Inc. ("Ultragenyx") in October 2020. This payment was recorded as a research and development expense in the fourth quarter of 2020. The license agreement was also amended such that we are required to pay an aggregate of approximately \$3.4 million upon the achievement of certain milestones. We must also pay royalties of a low single digit percentage of future sales by us and our sublicensees of products developed under the licensed patent rights. In addition, we must pay an annual maintenance fee until certain milestones are achieved, at which time a minimum annual royalty requirement will replace such maintenance fee and will apply to us and our sublicensees.

We are obligated to use our commercially reasonable efforts, consistent with sound and reasonable business practices and judgment, to commercialize the inventions covered by the licensed patent rights and to make and sell products based on that patent as soon as practicable and maximize sales thereof.

The University of Washington controls the prosecution and maintenance of the licensed patents in consultation with us and at our expense. In countries in which we have not requested prosecution or maintenance of licensed patents, the University of Washington may prosecute and maintain such licensed patents at its own cost. We have the first right to enforce such licensed patents at our expense. However, we may not enter into any settlement in any manner relating to the licensed patents without the University of Washington's prior written consent.

The license agreement remains in effect until the expiration of the last-to-expire patent licensed under the agreement. We may terminate the agreement at any time upon providing sixty days' written notice to the University of Washington. The University of Washington may terminate the agreement upon our uncured, material breach of the agreement or if we enter into an insolvency-related event.

The University of Missouri License Agreement

In 2015, we entered into a license agreement with the Curators of the University of Missouri (the "University of Missouri"), a public corporation of Missouri, under which we obtained an exclusive, royalty-bearing, sublicensable, worldwide license under certain patents and patent applications owned by the University of Missouri relating to a novel synthetic

microdystrophin gene to make, sell and distribute products for use in the treatment of Duchenne and related disease indications resulting from a lack of functional dystrophin.

In consideration for the rights granted by the agreement, we paid a one-time, non-refundable license fee, which was recorded as a research and development expense in 2015. We were required to reimburse the University of Missouri for costs incurred in applying for, prosecuting and maintaining the licensed patents and pay up to an aggregate of approximately \$1 million upon the achievement of certain milestones for each product developed based on the licensed patents.

Under the agreement, in the event we grant a sublicense to another party, we are required to pay the University of Missouri a percentage of the consideration received. The license agreement was amended such that we were required to pay, and did pay, the University of Missouri \$0.8 million in February 2021 and \$1.3 million in February 2022 as a result of the execution of the Collaboration Agreement with Ultragenyx in October 2020. These amounts were recorded as a research and development expense in the fourth quarter of 2020. The license agreement was also amended such that we are required to make aggregate milestone payments of approximately \$1.9 million upon the achievement of certain milestones.

There were no material milestones achieved during the years ended December 31, 2025 and 2024. We must pay a royalty of a low single digit percentage of future sales or by its sublicensees of products developed using the licensed patents. In addition, we must pay an annual maintenance fee until certain milestones are achieved, after which time a minimum annual royalty will replace such maintenance fee.

Under the agreement, we granted the University of Missouri a non-exclusive, royalty-free, irrevocable, paid-up license, with the right to grant sublicenses to non-profit, academic, educational or governmental institutions, to practice and use improvements made by us using the licensed patent rights, solely for non-commercial research purposes.

We are obligated to use our reasonable best efforts to introduce products based on the licensed patent rights into the commercial market as soon as possible, consistent with sound and reasonable business practices and judgment, and thereafter to keep such products reasonably available to the public.

The University of Missouri controls the prosecution and maintenance of the licensed patents in consultation with us and at our expense. In countries in which we have not requested prosecution or maintenance of licensed patents, the University of Missouri may prosecute and maintain such licensed patents at its own cost. We have the first right to enforce such licensed patents at our expense. However, any settlement, consent judgment or other voluntary disposition of litigation that materially limits the scope, validity or enforceability of the licensed patent or admits fault or wrongdoing on the part of the University of Missouri must be pre-approved in writing by the University of Missouri. The license agreement remains in effect until the expiration of the last-to-expire patent or the abandonment of the last to be abandoned patent application licensed under the agreement. The University of Missouri may terminate the agreement, or render the license granted thereunder non-exclusive, in individual countries if we and our sublicensees fail to achieve certain milestones. We may terminate the license agreement at any time upon providing six months' written notice to the University of Missouri and paying a termination fee. Each of the University of Missouri and we may also terminate the agreement for an uncured default or breach of the agreement by the other party. Our ability to cure such breach only applies to the first two notices of such breach provided by the University of Missouri, and thereafter, the University of Missouri may terminate the agreement for our default or breach of the agreement upon thirty days' written notice without an opportunity to cure such default or breach.

University of Florida License Agreements

We, and our subsidiary AavantiBio Inc. ("AavantiBio"), have entered into several license agreements with the University of Florida Research Foundation, Inc. ("UFRF"). Broadly, the agreements relate to FA and certain early-stage cardiac candidates, including SGT-401, SGT-601 and SGT-701. Under each agreement we obtained an exclusive, royalty-bearing, sublicensable, world-wide license to certain patents and patent applications and a royalty-bearing non-exclusive license under the know-how, to make, have made, use, see, have sold, import and export licensed products. UFRF retains the right to practice the patent rights and know-how for internal non-commercial research, including research sponsored by commercial entities, and educational purposes.

In consideration for the rights granted under each agreement, AavantiBio paid a one-time non-refundable license fee. In connection with each agreement, we are required to pay an annual license maintenance fee until the first commercial sale of a licensed product after which time a minimum annual royalty will replace such maintenance fees. Under each agreement, we are required to reimburse UFRF for costs incurred in applying for, prosecuting and maintaining patents, pay up to an aggregate of approximately \$2.9 million upon the achievement of certain intellectual property, clinical and regulatory milestones for each licensed product under the agreement and pay a low, single digit royalty on annual net sales by us and our sublicensees of licensed products on a licensed-product-by-licensed product basis. For any licensed product covered by both of these agreements, we are only obligated to make one payment for each milestone achieved and royalty payment

due. Under each agreement, in the event we grant a sublicense to another party, we are required to pay UFRF a percentage of the consideration received. Under each agreement, we have the right to grant sublicenses to third parties through multiple tiers, to the extent we are in compliance with our diligence obligations under the agreement and that sublicensee is subject to the terms of such agreement.

Under each agreement, we are obligated to use commercially reasonable efforts to develop and commercialize products covered by the licensed patent rights or know-how and to achieve certain regulatory and commercialization milestones within estimated time periods. Under the agreements entered in 2023 and 2024, we agreed to pay to UFRF cumulative sales milestones of up to \$8.5 million and \$27.0 million, respectively upon achievement of specified milestone events and tiered royalties on worldwide net sales in the low-to-mid-single digits.

Under each agreement, UFRF controls the prosecution and maintenance of the licensed patents in consultation with us and at our expense. In countries in which we have not requested prosecution or maintenance of licensed patents in a particular country or jurisdiction, the license granted to such patent rights will terminate in such country or jurisdiction. We have the first right to enforce such licensed patents at our expense.

Each of the agreements terminates on a licensed product-by-licensed product basis on the later of: (i) expiration of the patent rights covering such licensed product or (ii) ten (10) years from the first commercial sale of such licensed product. After five years, we may terminate an agreement for any reason giving advance written notice and reason for termination. UFRF may terminate an agreement for our uncured default or breach of the agreement. UFRF may immediately terminate an agreement if we bring or assist others in bringing a patent challenge against the licensed patent rights. If UFRF sends us a written demand to terminate a sublicense agreement due to such sublicensee bringing or assisting a patent challenge, UFRF may terminate such agreement if we do not terminate the license with such sublicensee.

Mayo Clinic Collaboration and License Agreement

In December 2024, we entered into a collaboration, patent and know-how license agreement with Mayo to further advance our research and development efforts in the field of genetic therapies, particularly for rare and debilitating cardiac diseases. This partnership focuses on leveraging Mayo's expertise in clinical research and our cutting-edge gene therapy platforms to explore innovative treatment options.

As part of the collaboration, we will be providing manufactured viral materials and chemistry, manufacturing and controls know-how to Mayo while Mayo will be responsible for supporting all preclinical research through IND-enabling studies for six programs. We will then be responsible for the clinical development of programs chosen by us to develop. Under the terms of the collaboration, we and Mayo agreed to share intellectual property rights arising from the collaboration, while we retain exclusive rights to commercialize any resulting approved therapies.

In connection with the entry into the agreement, we made a one-time upfront payment of \$0.6 million in cash to Mayo and issued 364,990 shares of our common stock to Mayo in December 2024. Additionally, Mayo is eligible to receive cumulative developmental and regulatory milestones of \$7.0 million, cumulative sales milestone payments of up to \$18.0 million, upon achievement of specified milestone events, and tiered royalties on worldwide net sales in the low-to-high-single-digits for each licensed product developed by us under the agreement. We have also agreed to pay an annual \$0.6 million know-how access fee to Mayo.

The agreement also includes provisions for the potential sublicensing of certain intellectual property rights. We will also be responsible for reimbursing Mayo for costs incurred in the prosecution and maintenance of any patents resulting from the collaboration.

The collaboration remains in effect for the duration of the intellectual property rights associated with any therapies developed under the agreement. Either party may terminate the agreement with proper notice should specific terms be breached or should an insolvency-related event occur.

Outlicensing Agreements

From time to time, we enter into non-exclusive license and collaboration agreements for the out-licensing of POLARIS-101TM, our proprietary, rationally designed capsid technology used in SGT-003, to both companies and academic institutions pursuing treatments for rare diseases. These arrangements may entitle us receive non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost reimbursement arrangements, product supply and royalty payments as a percentage of worldwide license product sales. At December 31, 2025, potential future milestone payments we may be entitled to under these agreements totaled an aggregate of \$97.1 million.

Competition

The biotechnology and pharmaceutical industries are characterized by rapidly changing technologies, significant competition and a strong emphasis on intellectual property. This is also true in treatments of neuromuscular diseases, such as Duchenne and FA, cardiac diseases, such as CPVT, as well as in gene therapy. While we believe that our focus, strength of team, expertise in gene therapy, scientific knowledge and intellectual property provide us with competitive advantages, we face competition from several different sources, including large and small biopharmaceutical companies, academic research institutions, government agencies and public and private research institutions. Not only must we compete with other companies that are focused on gene transfer technology, but any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, clinical trials, regulatory approvals and product marketing than we do. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, enrolling patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

We are aware of a number of companies and research institutions developing gene transfer programs progressing in Duchenne. For example, in June 2023, Sarepta Therapeutics, Inc. (“Sarepta”) received accelerated approval for its gene therapy candidate ELEVIDYS® for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne. In June 2024, Sarepta announced an expanded US approval of ELEVIDYS® for patients who are at least 4 years of age including full approval for ambulatory Duchenne patients and accelerated approval for non-ambulatory Duchenne patients. Following two reported cases of acute liver failure resulting in death, Sarepta agreed with FDA to a boxed warning for acute liver injury and acute liver failure and the removal of the non-ambulatory population from the Indication and Usage section of the Prescribing Information for ELEVIDYS®.

We are also aware of several companies and research institutions conducting clinical trials of product candidates focused on systemic gene transfers for Duchenne, including Genethon with a product candidate currently being evaluated in a Phase 1/2/3 clinical trial, REGENXBIO Inc. with a product candidate in Phase 1/2/3 clinical development and Insmid Incorporated, with product candidate INS1201 currently being evaluated in a Phase 1 clinical trial.

There are other approaches to treat Duchenne that are either currently marketed or in development including antisense oligonucleotides, histone deacetylase (“HDAC”) inhibitors, myosin inhibitors, cell therapies and gene editing. Notably, Sarepta has received accelerated approval for three therapies including Exondys 51, Vyondys 53 and Amondys 45 targeting exons 51, 53 and 45, respectively; Nippon Shinyaku received accelerated approval for Viltepso to treat exon 53 amenable patients; Avidity Biosciences is developing Del-zota to treat exon 44; Wave Life Sciences is developing WVE-N531 to treat exon 53 amenable patients; Dyne Therapeutics is developing DYNE-251 to treat exon 51 amenable patients; BioMarin Pharmaceutical is developing BMN 351 to treat exon 51 amenable patients; and Entrada Therapeutics is developing ENTR-601-44, ENTR-601-45, ENTR-601-50, and ENTR-601-51 for exon 44, 45, 50 and 51 amenable patients, respectively.

Italfarmaco received FDA approval for its HDAC inhibitor, Givinostat, in Duchenne patients who are at least 6 years of age. Edgewise Therapeutics is developing Sevasemten, a fast skeletal myosin inhibitor, for Duchenne and Becker muscular dystrophies. Capricor Therapeutics is developing Deramiciocel, an allogeneic cardiosphere-derived cell therapy product candidate. Satellos Bioscience is developing SAT-3247, an oral small molecule product candidate. Precision BioSciences is in preclinical development for gene editing product candidate, PBGENE-DMD.

We are also aware of a number of companies and research institutions developing gene transfer programs in FA. For example, Lexeo Therapeutics is developing an IV gene therapy to treat the cardiac manifestations of FA. Other competitors currently developing gene therapies to treat FA are in preclinical development, including Neurocrine Biosciences in collaboration with Voyager Therapeutics and Capsida Biotherapeutics. We are also aware of other companies developing non-gene therapies for FA, such as Design Therapeutics, Larimar Therapeutics, PTC Therapeutics and Papillon Therapeutics. Biogen’s SKYCLARYS® (omaveloxolone) was approved for the treatment of FA in adults and adolescents aged 16 and older by the FDA and the European Commission in February 2023 and February 2024, respectively.

We are also aware of several companies and research institutions conducting clinical trials in small molecule product candidates focused on CPVT, including Cardurion Pharmaceuticals, Inc. with an orally administered CAMKII-delta inhibitor candidate in a Phase 2 clinical trial.

Government Regulation and Product Licensure

U.S. Government Regulation and Product Licensure

In the United States, biologic products including gene therapy products, such as our lead candidates, are licensed for marketing by the FDA under the Public Health Service Act (“PHS Act”), and regulated by the FDA under the Federal Food, Drug, and Cosmetic Act (“FD&C Act”), as well as by other federal, state and local statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding rules and regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, recordkeeping, distribution, marketing, pricing, post-approval monitoring, reporting, advertising and other promotional practices involving biologic products. FDA approval must be obtained before conducting human clinical testing of biologic products. FDA must license a biologic product before it may be marketed within the United States.

U.S. Biologic Products Development Process

A company, institution, or organization which takes responsibility for the initiation and management of a clinical development program for such products is referred to as a sponsor. A sponsor seeking approval to market and distribute a new biological product in the United States must typically secure the following:

- completion of preclinical laboratory tests and in vivo studies according to the FDA’s GLP requirements and applicable requirements for the humane use of laboratory animals or other applicable regulations;
- design of a clinical protocol and submission to the FDA of an application for an IND, which allows human clinical trials to begin unless the FDA objects within 30 days;
- approval by an institutional review board (“IRB”), reviewing each clinical site before each clinical trial may be initiated;
- approval by an institutional biosafety committee (“IBC”), assessing the safety of the clinical research and identifying any potential risk to public health or the environment;
- performance of adequate and well controlled human clinical trials according to the FDA’s regulations commonly referred to as good clinical practices (“GCPs”), and any additional requirements for the protection of human research subjects and their health information, to establish the safety, potency and purity of the proposed biologic product for each of its intended uses;
- preparation and submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity and potency from results of preclinical testing and clinical trials, and detailed information about the chemistry, manufacturing and controls (“CMC”) for the product, reports of the outcomes and full data sets of the clinical trials and proposed labeling and packaging for the product;
- review of the product candidate by an FDA advisory committee, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biologic product candidate is produced to assess compliance with cGMP requirements and to assure that the facilities, methods and controls are adequate to preserve the biologic product candidate’s identity, safety, strength, quality and purity;
- potential FDA audit of the non-clinical and clinical trial sites that generated the data in support of the BLA;
- payment of user application and program fees;
- FDA review and licensure of the BLA for particular indications in the United States; and
- compliance with any approval or post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy (“REMS”) and the potential requirement to conduct post-approval studies.

Preclinical Studies and Investigational New Drug Application

Before testing any biologic product candidate in humans, including a gene therapy product candidate, the product candidate must undergo preclinical testing. Preclinical tests, also referred to as non-clinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as *in vivo* studies to assess the potential safety and activity of the product candidate and to establish a rationale for therapeutic use. These studies are generally referred to as IND-enabling studies. The conduct of certain non-clinical studies must comply with federal regulations and requirements, including GLPs and the U.S. Department of Agriculture's Animal Welfare Act, if applicable.

The clinical trial sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted. With passage of the FDA's Modernization Act 2.0 in December 2022, Congress eliminated provisions in both the FD&C Act and PHS Act that required animal testing in support of a BLA. While animal testing may still be conducted, the FDA was authorized to rely on alternative non-clinical tests, including cell-based assays, microphysiological systems or bioprinted or computer models. In April 2025, the FDA released a roadmap to replace animal testing in preclinical safety studies with scientifically validated new approach methodologies, such as organ-on-a-chip systems, computational modeling, and advanced *in vitro* assays.

An IND is an exemption from the FD&C Act that allows an unapproved product to be shipped in interstate commerce for use in an investigational clinical trial and a request for FDA authorization to administer an investigational product to humans. Such authorization must be secured prior to interstate shipment and administration of any product candidate that is not the subject of an approved BLA. In addition to reviewing an IND to assure the safety and rights of patients, the FDA also focuses on any CMC issues and the quality of the investigation. Some preclinical tests may continue even after the IND is submitted.

The IND becomes effective 30 days after receipt by the FDA, unless the FDA notifies the sponsor of deficiencies that require correction before human studies can begin. The sponsor cannot initiate studies until the FDA notifies the sponsor that the submitted corrections are satisfactory. The FDA may also place the clinical trial on a full clinical hold or partial clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

In addition, following the clearance of an IND, the FDA may impose a full or partial clinical hold at any time during clinical trials. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND (e.g., a specific protocol or part of a protocol is not allowed to proceed; however, other protocols or parts of the protocol are allowed to proceed under the IND). If the FDA requires that progress to the next study is contingent on (i) FDA review of additional data and (ii) subsequent specific permission for the study to proceed, this represents a partial clinical hold.

Human Clinical Trials Under an IND

Clinical trials involve the administration of the biologic product candidate to healthy volunteers or subjects under the supervision of qualified investigators, generally physicians not employed by, or under the control of, the trial sponsor. Clinical trials are conducted under written study protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent.

Further, each clinical trial must be reviewed and approved by an IRB at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative, reviews and approves the study protocol and must monitor the clinical trial until completed.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring committee ("DMC"). This group provides authorization as to whether or not a trial may move forward at designated check points based on access that only the group maintains to available data from the study. Clinical trials involving recombinant DNA also must be reviewed by an IBC a local institutional committee that reviews and oversees basic and clinical research and utilizes recombinant DNA at that institution. The IBC assesses the safety of the research and identifies any potential risk to public health or the environment.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The investigational biologic product is initially introduced into a small group of healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion and, if possible, to gain an early understanding of its effectiveness. In the case of some product candidates for severe or life-threatening diseases, especially when the product candidate may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients. Phase 1 clinical trials of gene therapies are typically conducted in patients rather than healthy volunteers.
- *Phase 2.* The biologic product candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- *Phase 3.* Phase 3 clinical trials are commonly referred to as “pivotal” studies, which typically denotes a study that presents the data that the FDA or other relevant regulatory agency will use to determine whether or not to approve a biologic product. In Phase 3 clinical trials, the investigational biologic product is administered to an expanded patient population, generally at multiple geographically dispersed clinical trial sites in adequate and well controlled clinical trials to generate sufficient data to statistically confirm the potency and safety of the product for approval. These clinical trials are intended to establish the overall risk/benefit ratio of the product candidate and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes also referred to as post-marketing clinical trials, may be conducted after initial approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

A clinical trial may combine the elements of more than one phase and the FDA often requires more than one Phase 3 trial to support marketing approval of a product candidate. A company’s designation of a clinical trial as being of a particular phase is not necessarily indicative that the study will be sufficient to satisfy the FDA requirements of that phase because this determination cannot be made until the protocol and data have been submitted to and reviewed by the FDA. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need.

In December 2022, with the passage of Food and Drug Omnibus Reform Act (“FDORA”), Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other “pivotal study” of a new biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, action plans must include the sponsor’s goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In January 2024, the FDA issued draft guidance setting out its policies for the collection of race and ethnicity data in clinical trials. Unlike most guidance documents issued by the FDA, the diversity action plan guidance, when finalized, will have the force of the law because FDORA specifically dictates that the form and manner for submission of diversity action plans are specified in FDA guidance. In January 2025, in response to an executive order issued by President Trump on Diversity, Equity and Inclusion programs, the FDA removed this draft guidance from its website. That action, along with similar actions by the Trump administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. In July 2025, the U.S. District Court for the District of Columbia ruled that the Trump administration’s actions to remove these webpages, including the draft diversity action plan guidance, are unlawful under the Administrative Procedure Act. The court ordered the restoration of many of these webpages. In late July 2025, the FDA restored the draft diversity action plan guidance to its website with a statement that information on the webpage may be modified and/or removed in the future subject to the terms of the court’s order and implemented in accordance with applicable law. Accordingly, there is considerable uncertainty surrounding the draft guidance and how the FDA will consider diversity action plans in connection with its review of BLAs.

In September 2025, the FDA issued final guidance with updated recommendations for GCPs aimed at modernizing the design and conduct of clinical trials. The updates are intended to help pave the way for more efficient clinical trials to facilitate the development of medical products. The final guidance is adopted from the International Council for Harmonisation’s updated E6(R3) draft guideline that was developed to enable the incorporation of rapidly developing technological and methodological innovations into the clinical trial enterprise.

The FDA or the sponsor or its DSMB/DMC may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the biologic product candidate has been associated with unexpected serious harm to patients.

Finally, sponsors of certain clinical trials are required to register and disclose certain clinical trial information on a public registry (clinicaltrials.gov) maintained by the NIH. In particular, information related to the product, patient population, phase

of investigation, study sites and investigators and other aspects of the clinical trial is made public as part of the registration of the clinical trial. The PHSA grants the Secretary of Health and Human Services (the “HHS”), authority to issue a notice of noncompliance to a responsible party to failure to submit clinical trial information as required. The responsible party, however, is allowed 30 days to correct the noncompliance and submit the required information. Although sponsors are also obligated to disclose the results of their clinical trials after completion, disclosure of the results can be delayed in some cases for up to two years after the date of completion of the trial. As of December 30, 2025, the FDA has issued eight notices of non-compliance, signaling the government’s willingness to enforce these requirements against non-compliant clinical trial sponsors. While these notices of non-compliance did not result in civil monetary penalties, the failure to submit clinical trial information to clinicaltrials.gov, as required, is a prohibited act under the FD&C Act with violations subject to potential civil monetary penalties of up to \$10,000 for each day the violation continues. Violations may also result in injunctions and/or criminal prosecution or disqualification from federal grants.

Interactions with the FDA During the Clinical Development Program

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data and clinical trial investigators. Written IND safety reports must be promptly submitted to the FDA, the IRB and the investigators for serious and unexpected adverse events, any findings from other trials, in vivo laboratory tests or in vitro testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor’s initial receipt of the information. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA.

In addition, sponsors are given opportunities to meet with the FDA at certain points in the clinical development program. Specifically, sponsors may meet with the FDA prior to the submission of an IND, or pre-IND application meeting, at the end of a Phase 2 clinical trial, or EOP2 meeting, and before a BLA is submitted, or pre-BLA meeting. Meetings at other times may also be requested. There are five types of meetings that occur between sponsors and the FDA. Type A meetings are those that are necessary for an otherwise stalled product development program to proceed or to address an important safety issue. Type B meetings include pre-IND application and pre-BLA meetings, as well as Type B EOP2 meetings. A Type C meeting is any meeting other than a Type A or Type B meeting regarding the development and review of a product. A Type D meeting is focused on a narrow set of issues (and should be limited to no more than two focused topics) and should not require input from more than three disciplines or divisions. Finally, INTERACT meetings are intended for novel products and development programs that present unique challenges in the early development of an investigational product.

These meetings provide an opportunity for the sponsor to share information about the data gathered to date with the FDA and for the FDA to provide advice on the next phase of development. At the conclusion of these meetings, the FDA will typically provide its responses to questions posed by the sponsor regarding the clinical development program. The FDA will not indicate whether an NDA or BLA will be approved, but it will provide guidance to the sponsor on various questions, including whether an application should be submitted in the first place on the basis of the studies and data proposed by the sponsor. The agency may also generally express support for the sponsor’s approach in the clinical development program but indicate that questions concerning whether the data support approval will be subject to review by the agency following its acceptance for filing of the NDA or BLA. The FDA has indicated that its responses, as conveyed in meeting minutes and advice letters, only constitute mere recommendations and/or advice made to a sponsor and, as such, sponsors are not bound by such recommendations and/or advice. Nonetheless, from a practical perspective, a sponsor’s failure to follow the FDA’s recommendations for design of a clinical program may put the program at significant risk of failure.

Clinical Studies Outside the United States in Support of FDA Approval

In connection with our clinical development program, we may conduct trials at sites outside the United States. When a foreign clinical trial is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical trial is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval. Specifically, the studies must be conducted in accordance with GCP requirements, including undergoing review and receiving approval by an independent ethics committee and seeking and receiving informed consent from subjects. GCP requirements encompass both ethical and data integrity standards for clinical trials. The FDA’s regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical trials, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign trials are conducted in a manner comparable to that required for IND studies.

The acceptance by the FDA of study data from clinical trials conducted outside the United States in support of U.S. approval may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the U.S., the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted.

Expanded Access to an Investigational Drug for Treatment Use

Expanded access, sometimes called “compassionate use,” is the use of investigational new drug products outside of clinical trials to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options. The rules and regulations related to expanded access are intended to improve access to investigational drugs for patients who may benefit from investigational therapies. FDA regulations allow access to investigational drugs under an IND by the company or the treating physician for treatment purposes on a case-by-case basis for: individual patients (single-patient IND applications for treatment in emergency settings and non-emergency settings); intermediate-size patient populations; and larger populations for use of the drug under a treatment protocol or Treatment IND Application.

When considering an IND application for expanded access to an investigational product with the purpose of treating a patient or a group of patients, the sponsor and treating physicians or investigators will determine suitability when all of the following criteria apply: patient(s) have a serious or immediately life-threatening disease or condition, and there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition; the potential patient benefit justifies the potential risks of the treatment and the potential risks are not unreasonable in the context or condition to be treated; and the expanded use of the investigational drug for the requested treatment will not interfere with initiation, conduct, or completion of clinical trials that could support marketing approval of the product or otherwise compromise the potential development of the product.

There is no obligation for a sponsor to make its investigational products available for expanded access; however, as required by the 21st Century Cures Act (“the Cures Act”), passed in 2016, if a sponsor has a policy regarding how it responds to expanded access requests, it must make that policy publicly available. Sponsors are required to make such policies publicly available upon the earlier of initiation of a Phase 2 or Phase 3 trial; or 15 days after the drug or biologic receives designation as a breakthrough therapy, fast track product, or regenerative medicine advanced therapy. In October 2025, the FDA issued final guidance further clarifying the statutory and regulatory requirements governing expanded access.

In addition, on May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Special Regulations and Guidance governing Gene Therapy Products

The FDA has defined a gene therapy product as one that mediates its effects by transcription and/or translation of transferred genetic material and/or by integrating into the host genome and which is administered as nucleic acids, viruses, or genetically engineered microorganisms. The products may be used to modify cells in vivo or transferred to cells ex vivo prior to administration to the recipient.

Within the FDA, the Center for Biologics Evaluation and Research (“CBER”) regulates gene therapy products. CBER’s Office of Therapeutic Products is responsible for the review of gene therapy and related products, and the FDA has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its reviews. The NIH also advises the FDA on gene therapy issues and other issues related to emerging technologies. The FDA and the NIH have published guidance documents with respect to the development and submission of gene therapy protocols.

If a gene therapy trial is conducted at, or sponsored by, institutions receiving NIH funding for recombinant DNA research, prior to the submission of an IND to the FDA, a protocol and related documents must be submitted to, and the study registered with, the NIH Office of Biotechnology Activities, pursuant to the NIH Guidelines for Research Involving Recombinant DNA Molecules (“NIH Guidelines”). Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA. However, many companies and other institutions, not otherwise subject to the NIH Guidelines, voluntarily follow them.

The FDA has issued various guidance documents regarding gene therapies, including final guidance documents released in January 2020 relating to chemistry, manufacturing and controls information for gene therapy INDs, gene therapies for rare diseases and gene therapies for retinal disorders, a final guidance in October 2022 for Human Gene Therapy for Neurodegenerative Diseases, as well as a draft guidance in July 2023 on comparability requirements for manufacturing changes in gene therapy products. In December 2023, a draft guidance on potency assurance for cellular and gene therapy products was released. Although the FDA has indicated that these and other guidance documents it previously issued are not legally binding, we believe that our compliance with them is likely necessary to gain approval for any gene therapy product candidate we may develop. The guidance documents provide additional factors that the FDA will consider at each of the above stages of development and relate to, among other things, the proper preclinical assessment of gene therapies; the chemistry, manufacturing, and control information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND or BLA application; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high. Further, for AAV capsids specifically, the FDA typically recommends that sponsors continue to monitor participants for potential gene therapy-related adverse events for up to a 5-year period. Other types of gene therapy or gene editing products may require longer follow up, potentially up to a maximum 15-year period.

Finally, for a gene therapy product and where applicable, the FDA also will not approve the product if the manufacturer is not in compliance with good tissue practices (“GTP”). These standards are found in FDA regulations and guidance that govern the methods used in, and the facilities and controls used for, the manufacture of human cells, tissues, and cellular and tissue-based products (“HCT/Ps”), which are human cells or tissue intended for implantation, transplant, infusion, or transfer into a human recipient. The primary intent of the GTP requirements is to ensure that T-cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission, and spread of communicable disease. FDA regulations also require tissue establishments to register and list their HCT/Ps with the FDA and, when applicable, to evaluate donors through screening and testing.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003 (“PREA”), a BLA or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the sponsor plans to conduct, including study objectives and design, any deferral or waiver requests, and other information required by regulation. The sponsor, the FDA, and the FDA’s internal review committee must then review the information submitted, consult with each other, and agree upon a final plan. The FDA or the sponsor may request an amendment to the plan at any time.

For products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of a sponsor, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors and FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than 90 days after the FDA’s receipt of the study plan.

The FDA may, on its own initiative or at the request of the sponsor, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. The FDA is required to send a PREA Non-Compliance letter to sponsors who have failed to submit their pediatric assessments required under PREA, have failed to seek or obtain a deferral or deferral extension or have failed to request approval for a required pediatric formulation. It further requires the FDA to publicly post the PREA Non-Compliance letter and sponsor’s response. Unless otherwise required by regulation, the pediatric data requirements do not apply to products with orphan designation, although FDA has recently taken steps to limit what it considers abuse of this statutory exemption. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the Food and Drug Administration Safety and Innovation Act (“FDASIA”). The FDA also maintains a list of diseases that are exempt from the requirements PREA, due to low prevalence of disease in the pediatric population. In May 2023, the FDA issued new draft guidance that further describes the pediatric study requirements under the PREA.

Compliance with cGMP Requirements

Manufacturers of biologics must comply with applicable cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Manufacturers and others involved in the manufacture and distribution of such products also must register their establishments with the FDA and certain state agencies. Both domestic and foreign manufacturing establishments must register and provide additional information to the FDA upon their initial participation in the manufacturing process. Establishments may be subject to periodic, unannounced inspections by government authorities to ensure compliance with cGMP requirements and other laws. Discovery of problems may result in a government entity placing restrictions on a product, manufacturer or holder of an approved BLA, and may extend to requiring withdrawal of the product from the market. The PREVENT Pandemics Act, which was enacted in December 2022, clarifies that foreign drug manufacturing establishments are subject to registration and listing requirements even if a biologic undergoes further manufacture, preparation, propagation, compounding, or processing at a separate establishment outside the United States prior to being imported or offered for import into the United States.

Concurrent with clinical trials, companies usually complete additional preclinical studies and must also develop additional information about the physical characteristics of the biologic product candidate as well as finalize a process for manufacturing the product candidate in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents or of causing other adverse events with the use of biologic products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other requirements, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biologic product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the biologic product candidate does not undergo unacceptable deterioration over its shelf life.

Submission and Filing of a BLA

After the completion of clinical trials of a biologic product, FDA licensure of a BLA must be obtained before commercial marketing of the biologic product. The BLA must include results of product development, laboratory and animal studies, human studies, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biologic product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers.

Under the Prescription Drug User Fee Act (“PDUFA”), as amended, each BLA must be accompanied by a significant user fee. Under federal law, the submission of most BLAs is subject to an application user fee, which for federal fiscal year 2026 is approximately \$4.7 million for an application requiring clinical data. The sponsor of an approved BLA is also subject to an annual program fee, which for federal fiscal year 2025 is currently \$442,213 per eligible prescription product. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for product candidates designated as orphan drugs, unless the product candidate also includes a non-orphan indication.

The FDA reviews a BLA within 60 days of submission to determine if it is substantially complete before the agency accepts it for filing, and it must so notify the sponsor of that determination within the 60 days. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In the event that FDA determines that an application does not satisfy this standard, it will issue a Refuse to File (“RTF”) determination to the sponsor. The BLA may be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. In October 2025, the FDA issued internal guidance clarifying that “materially incomplete or inadequately organized” applications that would not permit timely, efficient and complete review will be the subject of a RTF determination. The internal guidance also provides that the agency will issue a RTF determination for an application that relies on a single adequate and well-controlled investigation to support approval if prior communications with the FDA determined the need for more than one clinical study and any justification for a single investigation is inadequate. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA.

With filing of the application, the FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product’s identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biologic products or biologic products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation

and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Moreover, the FDA will review a sponsor's financial relationship with the principal investigators who conducted the clinical trials in support of the BLA. That is because, under certain circumstances, principal investigators at a clinical trial site may also serve as scientific advisors or consultants to a sponsor and receive compensation in connection with such services. Depending on the level of that compensation and any other financial interest a principal investigator may have in a sponsor, the sponsor may be required to report these relationships to the FDA. The FDA will then evaluate that financial relationship and determine whether it creates a conflict of interest or otherwise affects the interpretation of the trial or the integrity of the data generated at the principal investigator's clinical trial site. If so, the FDA may exclude data from the clinical trial site in connection with its determination of safety and efficacy of the investigational product.

During the biologic product approval process, the FDA also will determine whether a REMS, is necessary to assure the safe use of the biologic product. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events and whether the product is a new molecular entity. A REMS could include medication guides, physician communication plans and elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

In connection with its review of a BLA, the FDA will inspect the facilities at which the product candidate is manufactured. The FDA will not approve the product candidate unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND study requirements and GCP requirements to ensure the integrity of the clinical data. cGMP, GLP and GCP compliance requires significant expenditure of time, money and effort in the areas of training, recordkeeping, production and quality control.

With passage of FDORA, Congress clarified FDA's authority to conduct inspections by expressly permitting inspection of facilities involved in the preparation, conduct, or analysis of clinical and non-clinical studies submitted to FDA as well as other persons holding study records or involved in the study process.

Decisions on a BLA

After evaluating the application and all related information, including the advisory committee recommendations, if any, and inspection reports of manufacturing facilities and clinical trial sites, the FDA will issue either a Complete Response Letter ("CRL") or an approval letter. To reach this determination, the FDA must determine that the expected benefits of the proposed product outweigh its potential risks to patients. This "benefit-risk" assessment is informed by the extensive body of evidence about the product in the BLA.

A CRL indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. A CRL generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes; or major, for example, requiring additional clinical trials. Additionally, the CRL may include recommended actions that the sponsor might take to place the application in a condition for approval. If a CRL is issued, the sponsor may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. For those seeking to challenge FDA's CRL decision, the agency has indicated that sponsors may request a formal hearing on the CRL or they may file a request for reconsideration or a request for a formal dispute resolution. While CRLs were previously treated by the FDA as confidential and were only disclosed in action packages for approved products, the FDA announced in September 2025 that it will now release CRLs promptly after they are issued to sponsors. Since that announcement, the FDA has posted a number of CRLs on its website.

If a product receives regulatory approval, the FDA will issue an approval letter. The approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post-marketing clinical trials, designed to further assess a biologic product's safety, purity and potency, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

The FDA has agreed to specified performance goals in the review of BLAs under the PDUFA. One such goal is to review standard BLAs in ten months after the FDA accepts the BLA for filing, and priority BLAs in six months, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

Biosimilars and Reference Product Exclusivity

The Patient Protection and Affordable Care Act and the companion Health Care and Education Reconciliation Act (“Health Care Reform Law”), which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009 (“BPCIA”). That Act established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. To date, the FDA has approved a number of biosimilars and it has also issued numerous guidance documents outlining its approach to reviewing and licensing biosimilars and interchangeable biosimilars under the PHS Act.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. In December 2022, Congress clarified through FDORA that FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the first day on which such a product is approved as interchangeable with the reference product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of first licensure of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was first licensed. Even if a product is considered to be a reference product eligible for regulatory exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. There have been recent government proposals to reduce the 12-year reference product regulatory exclusivity period, but none has been enacted to date. Since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products.

As of December 27, 2020 (enacted as part of the Consolidated Appropriations Act, 2021), the “patent dance” lists became public information as listed in the Purple Book (FDA’s “Database of Licensed Biological Products”). In particular, reference product BLA holders must submit to the FDA within 30 days of exchanging a patent list (patents with expiry dates) with a biosimilar applicant, as well as any supplemental lists. This information was previously maintained as confidential as between the BLA holder and biosimilar applicant. Despite publication of these lists, a BLA holder may assert other patents against future filers, and does not exclude enforcement of newly granted patents.

Additionally, under the Act, the FDA must now publish in the Purple Book the following information about patented biological products:

- a list of each biological product, by nonproprietary name, for which a biologics license is in effect;
- the date of licensure and the application number;
- the licensure status and, as available, the marketing status; and
- exclusivity periods.

The FDA must publish in the Purple Book all of the above information in the first instance within 180 days of enactment and update every 30 days.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent exclusivity in the United States and, if granted, provides for the attachment of an additional six months of regulatory exclusivity to the term of any existing regulatory exclusivity, including reference

product and orphan exclusivity. This six-month exclusivity may be granted if an application sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of exclusivity cover the product are extended by six months. Thus, pediatric exclusivity adds six months to existing exclusivity periods applicable to biological products under the BPCIA—namely, the four-year period during which the FDA will not consider an application for a biosimilar product, and the 12-year regulatory exclusivity period during which the FDA will not approve a biosimilar application.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a biologic product as an “orphan drug” if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a biologic product available in the United States for treatment of the disease or condition will be recovered from sales of the product). Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, meaning that the FDA may not approve any other applications to market the same drug or biologic product for the same indication for seven years, except in limited circumstances, such as if the party holding the exclusivity fails to assure the availability of sufficient quantities of the drug to meet the needs of patients with the disease or condition for which the drug was designated. In addition, the FDA may not approve other applications to market the same drug or biologic product for the same indication for seven years unless the sponsor of the other product demonstrates that its product is clinically superior to the product with orphan drug exclusivity. Under Omnibus legislation enacted in December 2020, this clinical superiority requirement applies to drugs and biologics that received orphan drug designation before enactment of the FDA Reauthorization Act in 2017, but have not yet been approved or licensed by FDA.

Orphan exclusivity does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different indications. In particular, the concept of what constitutes the “same drug” for purposes of orphan drug exclusivity remains in flux in the context of gene therapies, and the FDA issued final guidance in September 2021 suggesting that it would not consider two gene therapy products to be different drugs solely based on minor differences in the transgenes or capsids. If a product designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity. Orphan medicinal product status in the European Union has similar, but not identical, benefits.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. In February 2025, in a case challenging the scope of orphan drug exclusivity, a federal district court in Washington, D.C. fully embraced the reasoning of a prior decision from the Court of Appeals for the 11th Circuit holding that the term “same disease or condition” in the statute means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” In April 2025, the FDA appealed this decision to the U.S. Court of Appeals for the D.C. Circuit. The implications of this decision, and its impact on the FDA's implementation of the Orphan Drug Act, are unclear at this point.

Expedited Development and Review Programs

The FDA is authorized to expedite the review of BLAs in several ways. Under the Fast Track program, the sponsor of a biologic product candidate may request the FDA to designate the product for a specific indication as a Fast Track product concurrent with or after the filing of the IND. Biologic products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product candidate and the specific indication for which it is being studied. In addition to other benefits, such as the ability to have greater interactions with the FDA, the FDA may initiate review of sections of a Fast Track BLA before the application is complete, a process known as rolling review.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as breakthrough therapy designation, priority review and accelerated approval.

- *Breakthrough therapy designation.* To qualify for the breakthrough therapy program, product candidates must be intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence must indicate that such product candidates may demonstrate substantial improvement on one or more clinically significant

endpoints over existing therapies. The FDA will seek to ensure the sponsor of a breakthrough therapy product candidate receives intensive guidance on an efficient drug development program, intensive involvement of senior managers and experienced staff on a proactive, collaborative and cross-disciplinary review and rolling review.

- *Priority review.* A product candidate is eligible for priority review if it treats a serious condition and, if approved, it would be a significant improvement in the safety or effectiveness of the treatment, diagnosis or prevention compared to marketed products. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. FDA aims to complete its review of priority review applications within six months as opposed to 10 months for standard review.
- *Accelerated approval.* Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials.

With passage of FDORA, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months (until the study is completed) and use expedited procedures to withdraw accelerated approval of a BLA if certain conditions are not met, including where the confirmatory trial fails to verify the product's clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval trial of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the FDA Commissioner or the Commissioner's designee and a written appeal, among other things. In March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidance relating to accelerated approval. This guidance describes the FDA's views on what it means to conduct a confirmatory trial with due diligence and how the agency plans to interpret whether such a study needs to be underway at the time of approval. While this guidance is currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

- *Regenerative advanced therapy.* With passage of the Cures Act in December 2016, Congress authorized the FDA to accelerate review and approval of products designated as regenerative advanced therapies. A product is eligible for this designation if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product candidate has the potential to address unmet medical needs for such disease or condition. The benefits of a regenerative advanced therapy designation include early interactions with the FDA to expedite development and review, benefits available to breakthrough therapies, potential eligibility for priority review and accelerated approval based on surrogate or intermediate endpoints.

None of these expedited programs change the standards for approval but they may help expedite the development or approval process of product candidates. Even if a product candidate qualifies for one or more of these designations or programs, there is no guarantee it would result in approval of our marketing applications or that such approval, if granted, would be on an expedited basis.

Rare Pediatric Disease Designation and Priority Review Vouchers

In 2012, Congress enacted the FDASIA, requiring the FDA to award priority review vouchers ("PRVs") to sponsors of certain rare pediatric disease product applications. This program is designed to encourage development of new drug and biological products for prevention and treatment of "rare pediatric diseases" by, upon initial approval of an application

meeting certain specified criteria, providing companies with a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease product receiving a PRV may sell or otherwise transfer the voucher to another company. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted an application relying on the priority review voucher. The FDA may also revoke any PRV if the rare pediatric disease product for which the voucher was awarded is not marketed in the United States within one year following the date of approval.

In order to receive a PRV upon BLA approval, the product must receive designation from the FDA as a product for a rare pediatric disease prior to submission of the marketing application. A “rare pediatric disease” is a disease that is serious or life-threatening, in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and affects fewer than 200,000 people in the United States, or affects more than 200,000 people in the United States but there is no reasonable expectation that the cost of developing and making available in the United States a product for such disease or condition will be recovered from sales in the United States of such product. In addition to receiving rare pediatric disease designation, in order to receive a PRV, the BLA must be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a product that does not include a previously approved active ingredient.

The Rare Pediatric Disease PRV program was scheduled to expire after September 30, 2020. After that, only drugs designated as rare pediatric treatments and approved by the FDA by October 1, 2022, could receive a voucher. In December 2020, however, Congress renewed the program as part of the 2021 Coronavirus Response and Relief Supplemental Appropriations Act through the federal fiscal year 2024. Thus, under the current statutory sunset provisions, FDA may only award PRVs for approved rare pediatric disease product applications if sponsors have rare pediatric disease designation for the drug granted by September 30, 2024. The FDA may not award any rare pediatric disease PRVs after September 30, 2026.

Commissioner’s National Priority Voucher

In June 2025, the FDA created a new voucher program called the Commissioner’s National Priority Voucher (“CNPV”), to expedite the development and approval of new drug products. Vouchers may reportedly be redeemed by sponsors to shorten the review time of a BLA from approximately 10-12 months to 1-2 months. The FDA has indicated that the new CNPV process will convene experts from the FDA’s offices for a team-based review rather than using the standard review system of a drug application being sent to numerous FDA offices. Clinical information will be reviewed by a multidisciplinary team of physicians and scientists who will pre-review the submitted information and convene for a 1-day meeting.

Post-Approval Requirements

After regulatory approval of a product is obtained, there may be a number of post-approval requirements. For example, as a condition of approval of a BLA, the FDA may require post-marketing testing and surveillance to monitor the product’s safety or efficacy. In addition, holders of an approved BLA are required to keep extensive records, to report certain adverse reactions and production problems to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling for their products. Also, quality control and manufacturing procedures must continue to conform to cGMP regulations and practices, as well as the manufacturing conditions of approval set forth in the BLA. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior regulatory approval before being implemented. Regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon us and any third-party manufacturers that we may decide to use. The FDA periodically inspects manufacturing facilities to assess compliance with cGMP requirements, which impose certain procedural, substantive and recordkeeping requirements. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

Further, although physicians may prescribe legally available products for unapproved uses or patient populations, which are commonly referred to as “off-label uses,” manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. In September 2021, the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a biologic. If a company is found to have promoted off-label uses, it may become subject to administrative and judicial enforcement by the FDA, the Department of Justice (“DOJ”), or the Office of the Inspector General of the HHS, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

It may be permissible, under very specific, narrow conditions, for a manufacturer to engage in nonpromotional, non-misleading communication regarding off-label information, such as distributing scientific or medical journal information. For example, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product. Moreover, with passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Previously, such communications were permitted under FDA guidance but the new legislation explicitly provides protection to sponsors who convey certain information about products in development to payors, including unapproved uses of approved products.

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA") and its implementing regulations, as well as the Drug Supply Chain Security Act ("DSCSA"), which regulate the distribution and tracing of prescription drug samples at the federal level, and set minimum standards for the regulation of drug distributors by the states. The PDMA, its implementing regulations and state laws limit the distribution of prescription pharmaceutical product samples, and the DSCSA imposes requirements to ensure accountability in distribution and to identify and remove counterfeit and other illegitimate products from the market. Manufacturers were required by November 2023 to have such systems and processes in place to comply with the DSCSA, but, so as not to disrupt supply chains, the FDA has granted certain exemptions from enhanced drug distribution security requirements for eligible trading partners for particular periods of time. For wholesale drug distributors, the final DSCSA deadline was August 27, 2025, marking the date for mandatory transition to a fully electronic, interoperable system for tracking prescription drugs at the package level throughout the United States.

U.S. Patent Term Restoration

Depending upon the timing, duration and specifics of FDA approval of product candidates, some of a sponsor's U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent terms lost during product development and FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period generally is one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application. Only one patent applicable to an approved biologic product is eligible for the extension, the application for the extension must be submitted prior to the expiration of the patent, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Moreover, a given patent may only be extended once based on a single product. The USPTO in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Federal and State Data Privacy Laws

There are multiple privacy and data security laws that may impact our business activities, in the United States and in other countries where we conduct trials or where we may do business in the future. These laws are evolving and may increase both our obligations and our regulatory risks in the future. In the health care industry generally, under The Health Insurance Portability and Accountability Act ("HIPAA"), the HHS has issued regulations to protect the privacy and security of protected health information used or disclosed by covered entities including certain healthcare providers, health plans, and healthcare clearinghouses. HIPAA also regulates standardization of data content, codes and formats used in healthcare transactions and standardization of identifiers for health plans and providers. HIPAA also imposes certain obligations on the business associates of covered entities that obtain protected health information in providing services to or on behalf of covered entities. HIPAA may apply to us in certain circumstances and may also apply to our business partners in ways that may impact our relationships with them. Our clinical trials will be regulated by the Common Rule, which also includes specific privacy-related provisions. In addition to federal privacy regulations, there are a number of state laws governing confidentiality and security of health information that may be applicable to our business. In addition to possible federal civil and criminal penalties for HIPAA violations, state attorneys general are authorized to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state attorneys general (along with private plaintiffs) have brought civil actions seeking injunctions and damages resulting from alleged violations of HIPAA's privacy and security rules. State attorneys general also have authority

to enforce state privacy and security laws. New laws and regulations governing privacy and security may be adopted in the future as well.

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the FTC Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. We will need to account for the FTC’s evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements. Finally, both the FTC and HHS’s enforcement priorities (as well as those of other federal regulators) may be impacted by the change in administration and new leadership. These shifts in enforcement priorities may also impact our business.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, in 2024, Congress passed H.B. 815, which included the Protecting Americans’ Data from Foreign Adversaries Act of 2024. This law creates certain restrictions for entities that disclose sensitive data (including potential health data) to countries such as China. Failure to comply with these rules can lead to a potential FTC enforcement action. Additionally, the DOJ recently finalized a rule implementing Executive Order 14117, which creates similar restrictions related to the transfer of sensitive US data to countries such as China. These data transfer restrictions (and others that may pass in the future) may create operational challenges and legal risks for our business.

In 2018, California passed into law the California Consumer Privacy Act (the “CCPA”), which took effect on January 1, 2020, and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA’s requirements are similar to those found in the General Data Protection Regulation (“GDPR”), including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of “sales” of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act (“CPRA”), which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency—the California Privacy Protection Agency—whose sole responsibility is to enforce the CPRA, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime over the next several years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of “sensitive” data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws that will go into effect over the next several years. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, the State of Washington passed the My Health My Data Act in 2023 which specifically regulated health information that is not otherwise regulated by the HIPAA rules, and the law also has a private right of action, which further increases the relevant compliance risk. Some states have also passed similar laws regulating consumer health data, and more states are considering such legislation. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs’ lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available under such laws, it is possible that some of our current or future business activities, including certain clinical research, sales and marketing practices, and the provision of certain items and services to our customers, could be subject to challenge under one or more of such privacy and data security laws. The heightening compliance environment and the need to build and maintain robust and secure systems to comply with different privacy compliance and/or reporting requirements in multiple jurisdictions could increase the possibility that a healthcare company may fail to comply fully with one or more of these requirements. If our operations are found to be in violation of any of the privacy or data security laws or regulations described above that are applicable to us, or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil, and administrative penalties, damages, fines, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a consent decree or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any product candidates we may develop, once approved, are sold in a foreign country, we may be subject to similar foreign laws.

Government Regulation Outside of the U.S.

In addition to regulations in the United States, a manufacturer is subject to a variety of regulations in foreign jurisdictions to the extent it chooses to sell any products in those foreign countries. Even if a manufacturer obtains FDA approval of a product, it must still obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Because biologically sourced materials are subject to unique contamination risks, their use may also be restricted in some countries. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained. Similar to the United States, the various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls.

With the exception of the European Union and European Economic Area (“EEA”), applying the harmonized regulatory rules for medicinal products, the approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly between countries and jurisdictions and can involve additional testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

Non-clinical Studies

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical (pharmacotoxicological) studies must be conducted in compliance with the principles of good laboratory practice as set forth in EU Directive 2004/10/EC (unless otherwise justified for certain particular medicinal products – e.g., radio-pharmaceutical precursors for radio-labeling purposes). In particular, non-clinical studies, both in vitro and in vivo, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical Trial Approval in the European Union

On January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 (“CTR”) became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one Member State of the European Union (“EU Member State”) will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public.

Beyond streamlining the process, CTR includes a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors, and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical

trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the CTR.

The CTR did not change the preexisting requirement that a sponsor must obtain prior approval from the competent national authority of the EU Member State in which the clinical trial is to be conducted. If the clinical trial is conducted in different EU Member States, the competent authorities in each of these EU Member States must provide their approval for the conduct of the clinical trial. Furthermore, the sponsor may only start a clinical trial at a specific study site after the applicable ethics committee has issued a favorable opinion.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive were governed by said directive until January 31, 2025. Beginning January 31, 2025, all clinical trials (including those which are ongoing) are subject to the provisions of the CTR. The failure to transition ongoing clinical trials to the Clinical Trials Regulation can result in corrective measures under Article 77 of the Clinical Trials Regulation, including revocation of the authorization of the clinical trial or suspension of the clinical trial as well as criminal sanctions and fines under national law of EU Member States.

Parties conducting certain clinical trials must post clinical trial information in the European Union at EudraCT website: <https://eudract.ema.europa.eu>.

PRIME Designation

In March 2016, the EMA, launched the PRIority MEdicines (“PRIME”) initiative to foster research and development of medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. PRIME aims to strengthen clinical trial designs to facilitate the generation of high-quality data for the evaluation of an application for marketing authorization. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on preclinical and/or early clinical data. These medicines are considered priority medicines within the European Union.

After an investigational candidate has been selected for PRIME, developers are assigned a rapporteur from the Committee for Human Medicinal Products (“CHMP”), to provide continuous support and help to build knowledge ahead of a marketing authorization application (“MAA”). A multidisciplinary group of experts will provide broader guidance on the overall development plan and regulatory strategy of the product. Companies are also eligible for accelerated assessment at the time of their regulatory application.

Pediatric Studies

Sponsors developing a new medicinal product must agree upon a Pediatric Investigation Plan (“PIP”) with the EMA’s pediatric committee (“PDCO”), and must conduct pediatric clinical trials in accordance with that PIP, unless a waiver applies (e.g., because the relevant disease or condition occurs only in adults). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the drug for which marketing authorization is being sought. The marketing authorization application for the product must include the results of pediatric clinical trials conducted in accordance with the PIP, unless a waiver applies, or a deferral has been granted by the PDCO of the obligation to implement some or all of the measures of the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults, in which case the pediatric clinical trials must be completed at a later date.

Marketing Authorization

In the European Union, marketing authorizations for medicinal products may be obtained through several different procedures founded on the same basic regulatory process.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid across the European Economic Area (i.e., the European Union as well as Iceland, Liechtenstein and Norway). The centralized procedure is compulsory for medicinal products produced by certain biotechnological processes, products designated as orphan medicinal products, and products with a new active substance indicated for the treatment of certain diseases. It is optional for those products that are highly innovative or for which a centralized process is in the interest of patients. Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the sponsor in response to questions asked by the CHMP. Accelerated evaluation may be granted by the CHMP in exceptional cases. These are defined as circumstances in which a medicinal product is expected to be of a “major public health interest.” Three cumulative criteria

must be fulfilled in such circumstances: the seriousness of the disease, such as severely disabling or life-threatening diseases, to be treated; the absence or insufficiency of an appropriate alternative therapeutic approach; and anticipation of high therapeutic benefit. In these circumstances, the EMA ensures that the opinion of the CHMP is given within 150 days.

The EMA's Committee for Advanced Therapies ("CAT") is responsible for assessing the quality, safety and efficacy of advanced-therapy medicinal products. Advanced-therapy medical products include gene therapy medicine, somatic cell therapy medicines and tissue-engineered medicines. The role of the CAT is to prepare a draft opinion on an application for marketing authorization for a gene therapy medicinal candidate that is submitted to the EMA. In the European Union, the development and evaluation of a gene therapy medicinal product must be considered in the context of the relevant EU guidelines. The EMA may issue new guidelines concerning the development and marketing authorization for somatic cell therapy medicinal products and require that we comply with these new guidelines. Similarly, complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. As a result, the procedures and standards applied to gene therapy products and cell therapy products may be applied to any of our gene therapy or genome editing candidates, but that remains uncertain at this point.

Specifically, the grant of marketing authorization in the European Union for products containing viable human tissues or cells such as gene therapy medicinal products is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC includes specific rules concerning the authorization, supervision, and pharmacovigilance of gene therapy medicinal products, somatic cell therapy medicinal products, and tissue engineered products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety, and efficacy of their products to EMA which provides an opinion regarding the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by EMA.

The decentralized procedure provides for approval by one or more other concerned EU Member States of an assessment of an application for marketing authorization conducted by one EU Member State, known as the reference EU Member State. In accordance with this procedure, a sponsor submits an application for marketing authorization to the reference EU Member State and the concerned EU Member States. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU Member State prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid application. The resulting assessment report is submitted to the concerned EU Member States which, within 90 days of receipt, must decide whether to approve the assessment report and related materials.

If a concerned EU Member State cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the European Commission, whose decision is binding on all EU Member States. In accordance with the mutual recognition procedure, the sponsor applies for national marketing authorization in one EU Member State. Upon receipt of this authorization the sponsor can then seek the recognition of this authorization by other EU Member States. Authorization in accordance with either of these procedures will result in authorization of the medicinal product only in the reference EU Member State and in the other concerned EU Member States.

A marketing authorization may be granted only to a sponsor established in the European Union. Regulation No. 1901/2006 provides that, prior to obtaining a marketing authorization in the European Union, a sponsor must demonstrate compliance with all measures included in a PIP approved by the PDCO, covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

Conditional Marketing Authorization

In specific circumstances, European Union legislation on Conditional Marketing Authorizations for Medicinal Products for Human Use, or conditional marketing authorization, enables sponsors to obtain a conditional marketing authorization prior to obtaining the comprehensive clinical data required for an application for a full marketing authorization. Such conditional approvals may be granted for product candidates (including medicines designated as orphan medicinal products) if the risk-benefit balance of the product candidate is positive, it is likely that the sponsor will be in a position to provide the required comprehensive clinical trial data, the product fulfills unmet medical needs and the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization may contain specific obligations to be fulfilled by the marketing authorization holder, including obligations with respect to the completion of ongoing or new studies, and with respect to the collection of pharmacovigilance data.

Conditional marketing authorizations are valid for one year, and may be renewed annually, if the risk-benefit balance remains positive, and after an assessment of the need for additional or modified conditions and/or specific obligations. The timelines for the centralized procedure described above also apply with respect to the review by the CHMP of applications for a conditional marketing authorization.

Exceptional Circumstances

A marketing authorization may also be granted “under exceptional circumstances” when the applicant can show that it is unable to provide comprehensive data on the efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. This may arise in particular when the intended indications are very rare and, in the present state of scientific knowledge, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. This marketing authorization is similar to the conditional marketing authorization as it is reserved to medicinal products to be approved for severe diseases or unmet medical needs and the applicant does not hold the complete data set legally required for the grant of a marketing authorization. However, unlike the conditional marketing authorization, the applicant does not have to provide the missing data and will never have to. Although the marketing authorization “under exceptional circumstances” is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually and the MA is withdrawn in case the risk-benefit ratio is no longer favorable. Under these procedures, before granting the marketing authorization, the EMA or the competent authorities of the EU Member States make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety, and efficacy.

Orphan Drug Designation and Exclusivity

The criteria for designating an orphan medicinal product in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition, (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition. The term “significant benefit” is defined in Regulation (EC) 847/2000 to mean a clinically relevant advantage or a major contribution to patient care.

Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. During this ten year market exclusivity period, the EMA or the competent authorities of the Member States of the European Economic Area, (“EEA”) cannot accept an application for a marketing authorization for a similar medicinal product for the same indication. A similar medicinal product is defined as a medicinal product containing a similar active substance or substances as contained in an authorized orphan medicinal product, and which is intended for the same therapeutic indication. The application for orphan designation must be submitted before the application for marketing authorization. The sponsor will receive a fee reduction for the marketing authorization application if the orphan designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The ten-year market exclusivity in the European Union may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if: (1) the second sponsor can establish that its product, although similar, is safer, more effective or otherwise clinically superior; (2) the sponsor consents to a second orphan medicinal product application; or (3) the sponsor cannot supply enough orphan medicinal product.

Pediatric Exclusivity

Products that are granted a marketing authorization with the results of the pediatric clinical trials conducted in accordance with the PIP are eligible for a six month extension of the protection under a supplementary protection certificate (if any is in effect at the time of approval) even where the trial results are negative. In the case of orphan medicinal products, a two-year extension of the orphan market exclusivity may be available. This pediatric reward is subject to specific conditions and is not automatically available when data in compliance with the PIP are developed and submitted.

Brexit and the Regulatory Framework in the United Kingdom

The United Kingdom's withdrawal from the European Union took place on January 31, 2020. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency (the "MHRA") became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law whereas Northern Ireland continues to be subject to EU rules under the Northern Ireland Protocol as amended by the "Windsor Framework". As of January 1, 2025, the MHRA is responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. The MHRA relies on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended) (the "HMR") as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of EU law instruments governing medicinal products that pre-existed prior to the UK's withdrawal from the European Union.

As of January 1, 2024, a new international recognition procedure ("IRP") applies which intends to facilitate approval of pharmaceutical products in the UK. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators ("RRs"). The RR notably include EMA and regulators in the EEA member states for approvals in the EU centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the U.S.). The RR assessment must have undergone a full and standalone review. RR assessments based on reliance or recognition cannot be used to support an IRP application. A CHMP positive opinion or a positive end of procedure outcome is an RR authorization for the purposes of IRP.

As with other issues related to withdrawal of the UK from the European Union, there are open questions about how personal data will be protected in the UK and whether personal information can transfer from the European Union to the UK. Following the withdrawal of the UK from the European Union, the UK Data Protection Act of 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by the GDPR. While the Data Protection Act of 2018 in the UK that "implements" and complements the GDPR has achieved Royal Assent on May 23, 2018 and is now effective in the UK, it is still unclear whether transfer of data from the EEA to the UK will remain lawful under the GDPR. The UK government has already determined that it considers all EU and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the UK to the EU/EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the UK as being "essentially adequate" for purposes of data transfer from the European Union to the UK, although this decision may be re-evaluated in the future.

General Data Protection Regulation

The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the EU, including personal health data, is subject to the GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EU, including the U.S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

Compliance with the GDPR will be a rigorous and time-intensive process that may increase the cost of doing business or require companies to change their business practices to ensure full compliance. In July 2020, the Court of Justice of the European Union ("CJEU") invalidated the EU-U.S. Privacy Shield framework, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which would serve as a replacement to the EU-U.S. Privacy Shield. The European Commission initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. There is currently one pending litigation against the EU-U.S. Data Privacy Framework before the CJEU. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy

Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue may further impact our business operations in the EU.

Following the withdrawal of the United Kingdom from the European Union, the U.K. Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR, including in relation to data transfers.

Healthcare Law and Regulation

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching physicians and patient privacy laws and regulations and other healthcare laws and regulations that may constrain business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;
- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal false statements statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Health Care Reform Law, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services (“CMS”) within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians, other healthcare professionals and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Pharmaceutical Insurance Coverage and Health Care Reform

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated health care costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

By way of example, the United States and state governments continue to propose and pass legislation designed to reduce the cost of healthcare. In March 2010, the United States Congress enacted the Health Care Reform Law, which, among other things, includes changes to the coverage and payment for products under government health care programs. In addition, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013. Under current legislation, the actual reductions in Medicare payments may vary up to 4%.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our candidates for which we may obtain regulatory approval or the frequency with which any such candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%.

Since enactment of the Health Care Reform Law, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 ("TCJA"), Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the Patient Protection and Affordable Care Act ("PPACA") brought by several states without specifically ruling on the constitutionality of the PPACA. Litigation and legislation over the Health Care Reform Law are likely to continue, with unpredictable and uncertain results.

Pharmaceutical Prices

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been several U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America ("PhRMA"), but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of drugs from Canada. Several states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. In January 2024, the FDA approved Florida's plan for Canadian drug importation. Florida now has authority to import certain products from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each product selected for importation, which must be approved by the FDA. Florida will also need to relabel the products and perform quality testing of the products to meet FDA standards.

Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless

the price reduction is required by law. The final rule would also eliminate the current safe harbor for Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and pharmacy benefit manager service fees. It originally was set to go into effect on January 1, 2022, but with passage of the Inflation Reduction Act (the “IRA”), has been delayed by Congress to January 1, 2032.

The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Medicare Part D drugs in 2027, 15 Medicare Part B or Part D drugs in 2028, and 20 Medicare Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years. Drugs and biologics that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation. With passage of the One Big Beautiful Bill Act, or OBBBA, in July 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations. In August 2024, HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions and the prices will become effective January 1, 2026. In January 2025, CMS announced the next 15 drug and biologic prices that will be subject to the IRA’s price negotiation provisions. CMS issued a public statement on January 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated \$2,000 a year beginning in 2025.

The IRA includes a provision exempting orphan drugs from Medicare price negotiation but this exclusion has been interpreted by CMS in final guidance issued in July 2023 to apply only to those orphan drugs with an approved indication (or indications) for a single rare disease or condition. The final guidance clarifies that CMS will consider only active designations/approvals when evaluating a drug for the exclusion, such that designations/indications withdrawn before the selected drug publication date will not be considered. CMS also clarified that, if a drug loses its orphan drug exclusion status, the agency will use the earliest date of approval/licensure to determine whether the product is a qualifying single source drug subject to price negotiations.

In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or “catastrophic period” of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

On June 6, 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA’s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including pharmaceutical companies, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. HHS has generally won the substantive disputes in these cases, and various federal district court judges have expressed skepticism regarding the merits of the legal arguments being pursued by the pharmaceutical industry. Most of these cases are now on appeal. In October 2024, the Court of Appeals for the Third Circuit heard oral argument in three of these cases, and in April 2025, the U.S. Court of Appeals for the Second Circuit and the U.S. Court of Appeals for the Third Circuit heard arguments in an additional three cases. In May 2025, the U.S. Court of Appeals for the Third Circuit rejected a challenge to the Medicare price negotiation program, finding that the program did not violate the company’s due process rights under the Constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

In April 2025, President Trump issued an executive order which directs HHS to take steps to reduce the prices of pharmaceutical products. The executive order repeats many of the proposals advanced during the first Trump Administration, including directing the FDA to streamline and improve its existing drug importation program so as to make it easier for states to obtain approval without sacrificing the safety or quality of drug products. Other provisions of the executive order relate to the 340B drug discount program. Specifically, one provision calls on the Secretary of HHS to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments and to consider and propose any appropriate adjustments for Medicare payment. With respect to the IRA's Medicare drug pricing program, the executive order, among other things, calls for alignment in "the treatment of small molecule prescription drugs with that of biological products, ending the distortion that undermines relative investment in small molecule prescription drugs, coupled with other reforms to prevent any increase in overall costs to Medicare and its beneficiaries."

Further, in May 2025, the President issued an additional executive order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The executive order directs the Secretary of HHS to communicate most-favored-nation, or MFN, price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. The executive order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the United States. Subsequently, HHS indicated that the proposed MFN pricing will apply only to brand products without generic or biosimilar competition and the referenced foreign countries will include only those in which the branded product similarly does not have generic or biosimilar competition. HHS also indicated that the MFN target price will be the lowest price in a country that is a member of the Organization for Economic Co-operation and Development, or OECD, with a gross domestic product per capita of at least 60% of the U.S. gross domestic product per capita. Based on previous estimates, there are likely at least 22 OECD countries that would satisfy this criterion. The implications of these actions remain unclear and could result in litigation.

More recently, in July 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 2025 executive order and demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, repatriate increased revenues earned abroad to lower prices for American patients and provide for direct purchasing at MFN pricing. The letters also urged these companies to stipulate that they will not offer other developed nations lower prices for new drugs than the prices offered for such products in the United States. Virtually all of these pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, President Trump launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the administration's pricing agreements with pharmaceutical manufacturers.

Separately, on December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as Organisation for Economic Co-operation and Development countries with a gross domestic product of \$400 billion and a per capita GDP that is at least 60% of the US per capita GDP (an initial list of 19 reference countries is included in the proposed rule). These pilot programs are proposed to go into effect beginning October 1, 2026.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payors are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its EU Member States to restrict the range of products for which their national health insurance

systems provide reimbursement and to control the prices of medicinal products for human use. Member States may approve a specific price for a product, or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU Member States allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage health care expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on health care costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU Member States, and parallel trade, i.e., arbitrage between low-priced and high-priced EU Member States, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Environmental Regulations

We are also subject to regulation under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other present and potential federal, state or local regulations. These and other laws govern our use, handling and disposal of various biological and chemical substances used in, and waste generated by, our operations. Our research and development involves the controlled use of hazardous materials, chemicals and viruses.

Human Capital

We recognize that attracting, motivating and retaining talented employees is vital to our success. We value the health and wellness of our employees and their families. It is our goal to deliver innovative programs that provide choice, quality and value. We aim to create an equitable, inclusive and empowering environment in which our employees can grow and advance their careers, with the overall goal of developing, expanding and retaining our workforce to support our current pipeline and future business goals. Our success also depends on our ability to attract, engage and retain a talented group of employees. Our efforts to recruit and retain a talented and passionate workforce with different experiences, perspectives and backgrounds include providing competitive compensation and benefits packages.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. We offer a comprehensive benefits program that provides resources to help employees manage their health, finances, and life outside of work.

As of December 31, 2025, we employed 121 full-time employees, including 89 in research and development and 32 in general and administrative positions, and of which 26 of our employees hold Ph.D. or M.D. degrees.

Corporate Information

Our principal executive offices are located at 500 Rutherford Avenue, Third Floor, Charlestown, Massachusetts 02129 and our telephone number is (617) 337-4680. Our website address is www.solidbio.com. The information contained in, or accessible through, our website does not constitute a part of this Annual Report on Form 10-K.

We make available free of charge on our website our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act") as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, in addition to the other information contained in this Annual Report on Form 10-K, including the section of this report titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and related notes. If any of the events described in the following risk factors and the risks described elsewhere in this Annual Report on Form 10-K occurs, our business, operating results and financial condition could be seriously harmed and the trading price of our common stock could decline. This Annual Report on Form 10-K also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Annual Report on Form 10-K. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to our Financial Position and Need for Capital Requirements

We have incurred significant net losses since inception and anticipate that we will continue to incur net losses for the foreseeable future and may never achieve or maintain profitability.

Since inception, we have incurred significant net losses. Our net losses were \$174.3 million and \$124.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of \$957.8 million. Prior to our acquisition of AavantiBio, Inc. in December 2022 (the “Acquisition”) we devoted substantially all of our efforts to research and development, including clinical development of SGT-001, which we are no longer developing, and preclinical development of SGT-003, as well as to building out our management team and infrastructure. Following the Acquisition, we have devoted our efforts to the research and development of our other Candidates, including clinical development of SGT-003, SGT-212 and SGT-501, as well as building out our management team. We expect that it could be several years before we have a commercialized product, and we may never have a commercialized product. We expect to incur significant expenses and operating losses for the foreseeable future. We anticipate that our expenses will increase substantially if, and as, we:

- enroll participants in our INSPIRE DUCHENNE, IMPACT DUCHENNE, FALCON and ARTEMIS trials and advance clinical development of SGT-003, SGT-212 and SGT-501;
- advance our other Candidates into clinical trials;
- continue research and preclinical development of our Candidates and adjacent technologies such as assays;
- seek to identify additional Candidates;
- engage in regulatory interactions with the FDA and other regulatory authorities;
- submit regulatory filings relating to the development of our Candidates and seek marketing approvals for our Candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- scale up our manufacturing processes and arrange manufacturing for larger quantities of our Candidates for preclinical and clinical development and potential commercialization;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire and retain additional clinical, quality control and scientific personnel;
- build out new facilities or expand existing facilities to support our activities;
- acquire or in-license other drugs, drug candidates, technologies and intellectual property; and
- add operational, financial and management information systems and personnel.

We may never achieve or maintain profitability. To become and remain profitable, we must develop and eventually commercialize one or more Candidates with significant market potential. This will require us to be successful in a range of challenging activities, and our expenses will increase substantially as we enroll participants in and conduct the INSPIRE DUCHENNE, IMPACT DUCHENNE, FALCON and ARTEMIS trials and continue to develop our pipeline and complete ongoing and planned preclinical studies and clinical trials of our Candidates, obtain marketing approval for our Candidates, develop adjacent technologies such as assays, develop and validate commercial-scale manufacturing processes, manufacture,

market and sell any future Candidates for which we may obtain marketing approval and satisfy any post-marketing requirements. Moreover, the manufacturing process requires materials which may fluctuate in cost or be limited or unavailable to us, as well as relationships with contract development and manufacturing organizations (“CDMOs”) to facilitate the manufacturing process. We may never succeed in any of these activities and, even if we do, we may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause stockholders to lose all or part of their investment.

We will need additional funding, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development efforts or other operations.

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of, conduct clinical trials of, and seek marketing approval for our Candidates. In addition, if we obtain marketing approval for our Candidates, we expect to incur significant expenses related to product sales, marketing, manufacturing and distribution. We also expect to continue to incur additional costs associated with operating as a public company. While we believe that our cash, cash equivalents and available-for-sale securities as of December 31, 2025, together with the net proceeds from our private placement that closed in March 2026, will be sufficient to fund our operating expenses and capital requirements into the first half of 2028, we have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently anticipate. In order to continue to operate our business beyond that time, we will need to raise additional funds. However, there can be no assurance that we will be able to generate funds on terms acceptable to us, on a timely basis, or at all. In addition, we anticipate that we will need additional funding to complete the development of our Candidates.

Our future capital requirements will depend on many factors, including:

- the progress, costs and results of the INSPIRE DUCHENNE, IMPACT DUCHENNE, FALCON and ARTEMIS trials and any future clinical trials of our Candidates;
- the costs, timing and outcome of regulatory review of our Candidates;
- the scope, progress, results and costs of discovery, laboratory testing, manufacturing, preclinical development and clinical trials for our Candidates;
- the costs associated with manufacturing and use of third-party manufacturers;
- the revenue, if any, received from commercial sale of our Candidates, should any of our future Candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights and defending intellectual property-related claims;
- the outcome of any lawsuits filed against us;
- the terms of our current and any future license agreements and collaborations;
- our ability to establish and maintain additional strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones, royalties and other collaboration-based revenues, if any;
- the extent to which we acquire or in-license other candidates, technologies and intellectual property; and
- if and as we need to adapt our business in response to public health emergencies or pandemics and collateral consequences related thereto.

Identifying potential candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to submit a Biologics License Application (“BLA”) or obtain marketing approval and achieve product sales. In addition, our Candidates, if approved, may not achieve commercial success. Our product revenue, if any, will be derived from or based on sales of our Candidates that may not be commercially available for many years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all, and may be impacted by the economic climate and market conditions. Our ability to raise additional

funds may be adversely impacted by general economic conditions, both inside and outside the U.S., including disruptions to, and instability and volatility in, the credit and financial markets in the U.S. and worldwide, heightened inflation, interest rate and currency rate fluctuations, global trade programs, tariffs and economic slowdown or recession as well as concerns related to public health emergencies or pandemics and geopolitical events, including civil or political unrest. In addition, market instability and volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. Alternatively, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or Candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership of our common stock will be diluted and the terms may include liquidation or other preferences that adversely affect the rights of our current stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or Candidates, or grant licenses on terms unfavorable to us.

We have never generated revenue from product sales and do not expect to do so for the foreseeable future, if ever.

Our ability to generate revenue from product sales and achieve profitability depends on our ability, alone or with collaborative partners, to successfully complete the development of, and obtain the regulatory approvals necessary to commercialize our Candidates. We do not anticipate generating revenue from product sales for the foreseeable future, if ever. Our ability to generate future revenue from product sales depends heavily on our success in:

- completing research and development of our Candidates in a timely and successful manner;
- seeking and obtaining regulatory and marketing approvals for any of our Candidates for which we complete clinical trials;
- launching and commercializing Candidates for which we obtain regulatory and marketing approval by establishing a sales force and marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner;
- maintaining and enhancing a commercially viable, sustainable, scalable, reproducible and transferable manufacturing process for our Candidates that is compliant with cGMPs;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in terms of cost, amount and quality, products and services to support clinical development and the commercial demand for our Candidates, if approved;
- obtaining market acceptance, if and when approved, of our Candidates as a viable treatment option by patients, the medical community and third-party payors;
- qualifying for coverage and adequate reimbursement by government and third-party payors for our Candidates both in the U.S. and internationally;
- effectively addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations under such arrangements;
- maintaining, protecting, enforcing and expanding our portfolio of intellectual property rights, including patents, trademarks, trade secrets and know-how;
- avoiding and defending against intellectual property infringement, misappropriation and other claims;
- implementing additional internal systems and infrastructure, as needed; and
- attracting, hiring and retaining qualified personnel.

Our limited operating history may make it difficult for our stockholders to evaluate the success of our business to date and to assess our future viability.

Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, acquiring rights to our technology, conducting research and development activities, establishing research and development collaborations, identifying and acquiring Candidates, establishing manufacturing arrangements, undertaking preclinical studies and clinical trials, and licensing of our POLARIS-101TM capsid. As a company, we have limited experience in clinical development. We have not yet demonstrated the ability to complete clinical trials of any Candidate, obtain marketing approvals, manufacture at commercial-scale or conduct sales and marketing activities necessary for successful commercialization. Consequently, any predictions our stockholders make about our prospects may not be as accurate as they could be if we had a longer operating history or prior experience integrating acquired businesses into our existing business.

Unfavorable global economic conditions could harm our business, financial condition or results of operations.

Our results of operations could be harmed by general conditions in the global economy and in the global financial markets. A severe or prolonged economic downturn, including the impact of increased interest rates and inflation, and global trade programs and tariffs, could result in a variety of risks to our business, including weakened demand for our Candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could strain our manufacturers, possibly resulting in manufacturing disruption, or cause delays in payments for our services by third-party payors or our future collaborators. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could harm our business.

We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts that could be adversely affected if the financial institutions holding such funds fail.

We hold a portion of our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts at multiple financial institutions. The balance held in these accounts may exceed the Federal Deposit Insurance Corporation (“FDIC”) standard deposit insurance limit of \$250,000. If a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations, including payroll obligations.

For example, on March 10, 2023, Silicon Valley Bank (“SVB”) and Signature Bank, were closed by state regulators and the FDIC was appointed receiver for each bank. The FDIC created successor bridge banks and all deposits of SVB and Signature Bank were transferred to the bridge banks under a systemic risk exception approved by the United States Department of the Treasury, the Federal Reserve and the FDIC. If financial institutions in which we hold funds for working capital and operating expenses were to fail, we cannot provide any assurances that such governmental agencies would take action to protect our uninsured deposits or investments in a similar manner.

We also maintain investment accounts with other financial institutions in which we hold our investments and marketable securities and, if access to the funds we use for working capital and operating expenses is impaired, we may not be able to sell investments or transfer funds from our investment accounts to other operating accounts on a timely basis sufficient to meet our operating expense obligations.

Risks Related to the Development of our Candidates

Our pipeline of gene transfer Candidates utilize novel technology, which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval. To our knowledge, only a limited number of gene transfer products have been approved for commercialization in the United States and the European Union.

Our future success depends on our successful development of our Candidates. Our risk of failure is high. We had experienced problems and delays in developing SGT-001, which we are no longer developing, and may in the future experience problems or delays in developing our Candidates. Any such problems or delays would cause unanticipated costs, and any development problems may not be solved. For example, we or another party may uncover a previously unknown risk associated with our Candidates, the AAV capsid, construct or other issues resulting in toxicity or lack of efficacy that may be more problematic than we currently believe and this may prolong the period of observation required for obtaining, or result in the failure to obtain, regulatory approval or may necessitate additional clinical testing.

In addition, our ability to conduct and complete our preclinical development testing and studies is contingent on our ability to source animals and other supplies required for the conduct of such testing and studies and the performance of animal models.

If we are unable to obtain all necessary animals and other supplies required for the conduct of our preclinical testing and studies, or the animal models do not perform as expected, we may be unable to complete such preclinical development testing and studies in a timely manner or at all. For example, some of our IND-enabling toxicology and other studies require certain NHPs that may be imported from countries in which trade relation with the U.S. are or may become challenging or through vendors who may not be able to timely source certain NHPs or at all, which may impair our ability to complete preclinical development testing and studies to support IND or similar applications or delay submission of such applications. Additionally, we may fail to demonstrate adequate Candidate efficacy and/or safety as required by regulatory authorities. We may fail to access relevant, adequate, or necessary animal models, including genetic models of disease and non-human primates in particular, for use in such studies as requested by regulatory authorities. We may also experience substantial delays as a result of our reliance on contract research organizations (“CROs”) to conduct all animal model experimentation necessary to assess the efficacy and safety of our Candidates. Any of these factors may result in delays to Candidate progression, inability to obtain regulatory approval, and/or substantial increases in Candidate development costs.

In addition, the product specifications and the clinical trial requirements of the FDA, the European Commission, the European Medicines Agency (the “EMA”) and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of such product candidate. The regulatory approval process for novel product candidates such as ours is unclear and can be more expensive and take longer than for other, better known or more extensively studied product candidates. To our knowledge, only a limited number of gene transfer products have been approved for commercialization in the United States and the European Union. As a result, it is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our gene transfer Candidates in either the United States or the European Union, if at all. Approvals by the European Commission may not be indicative of what the FDA may require for approval and vice versa.

Our Candidates may cause undesirable side effects or have other properties that could delay or prevent their clinical development, regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.

During the conduct of clinical trials, participants may experience changes in their health, including illnesses, injuries, discomforts or a fatal outcome. Often, it is not possible to determine whether the Candidate being studied caused these conditions. For instance, we reported a serious adverse event in IGNITE DMD, which resulted in a clinical hold in November 2019, which has since been resolved. In April 2021, a participant treated with SGT-001 in IGNITE DMD experienced a systemic inflammatory response classified as a serious adverse event and considered by the investigator to be drug related. In addition, there has been one treatment-related serious adverse event reported in the INSPIRE DUCHENNE trial, identified as a Grade 3 immune-mediated myositis.

In addition, it is possible that as we test Candidates in larger, longer and more extensive clinical programs, or as use of these Candidates becomes more widespread if they receive regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier clinical trials, as well as conditions that did not occur or went undetected in previous clinical trials, will be reported by subjects. Many times, side effects are only detectable after investigational products are tested in large-scale, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. If additional clinical experience indicates that a Candidate has side effects or causes serious or life-threatening side effects, the development of the Candidate may fail or be delayed, or, if the Candidate has received regulatory approval, such approval may be withdrawn.

There have been several significant adverse side effects in gene therapy treatments in the past, including reported cases of leukemia and death seen in other clinical trials. The FDA convened the Cellular, Tissue, and Gene Therapies Advisory Committee in September 2021 to discuss toxicity risks of AAV based gene therapy products and discussed risks including oncogenicity risks due to capsid genome integration, hepatotoxicity, thrombotic microangiopathy, and neurotoxicity (especially related to dorsal root ganglion toxicity). While new recombinant capsids have been developed with the intent to reduce these side effects, gene therapy is still a relatively new approach to disease treatment and additional adverse side effects could develop. There have been reports of significant adverse side effects, including muscle weakness, myocarditis, and acute liver injury, in clinical trials of other gene therapy treatments for Duchenne that may be related to the type and location of the specific gene mutation causing the disease. In another gene therapy treatment, there have been reports of AAV mediated acute liver failure leading to death in non-ambulatory boys with Duchenne in the setting of commercially available product. There also is the potential risk of delayed adverse events following exposure to gene therapy products due to persistent biologic activity of the genetic material or other components of products used to carry the genetic material. Possible adverse side effects that may occur with treatment with gene therapy products include an immunologic reaction early after administration that could substantially limit the effectiveness of the treatment or represent safety risks for patients. Additionally, in previous clinical trials involving AAV capsids for gene therapy, some subjects experienced the development of a positive ELISPOT test associated with T-cell responses, which is of unclear clinical translatability. If T-cells are

activated, the cellular immune response system may trigger the removal of transduced cells. If our gene transfer Candidates demonstrate a similar effect or other undesirable side effects, we may decide or be required to halt or delay further clinical development of our Candidates involving AAV capsids for gene therapy.

Adverse side effects may be observed following administration of any AAV gene therapy, including SGT-003 or other Candidates. Not all contemplated AAV delivery systems have been validated in human clinical trials previously, such as POLARIS-101TM, which is a novel capsid. If a delivery system does not meet the safety criteria or cannot provide the desired efficacy results, then we may be forced to suspend or terminate our development of SGT-003 or other Candidates. If certain adverse side effects were to occur in the future and we are unable to demonstrate that they were not caused by the administration process or related procedures, the FDA, the European Commission, the EMA or other regulatory authorities could order us to cease further development of, or deny approval of, SGT-003 or other Candidates for any or all targeted indications. Even if we are able to demonstrate that any serious adverse events are not product-related, such occurrences could affect participant recruitment or the ability of enrolled participants to complete the clinical trial. Participants will also create antibodies to the AAV capsid and a second administration of gene transfer might not be safe or successful.

Additionally, if one or more of our Candidates receive marketing approval, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy (“REMS”) to ensure that the benefits outweigh the risks, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients and a communication plan to health care practitioners. Furthermore, if we or others later identify undesirable side effects caused by our Candidates, several potentially significant negative consequences could result, including:

- regulatory authorities may suspend or withdraw approvals of such a Candidate;
- regulatory authorities may require additional warnings on the label;
- we may be required to change the way a Candidate is administered or conduct additional clinical trials;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

One of our prior clinical trials had been placed on clinical hold by the FDA in the past, and we cannot guarantee that similar events will not happen in ongoing, planned and future clinical trials for our Candidates.

In November 2019, the FDA placed a clinical hold on our clinical trial of SGT-001 following a serious adverse event in IGNITE DMD. The third participant in the 2E14 vg/kg cohort of IGNITE DMD, dosed in late October 2019, experienced a serious adverse event deemed related to the study drug that was characterized by complement activation, thrombocytopenia, decrease in red blood cell count, acute kidney injury, and cardio-pulmonary insufficiency. In April 2021, an eighth participant was treated with SGT-001. The participant experienced a systemic inflammatory response which has since fully resolved. The event was classified as a serious adverse event and considered by the investigator to be drug related. While SGT-003 utilizes POLARIS-101TM, a different capsid than was utilized in SGT-001, and includes other changes to the construct and manufacturing process to help avoid or mitigate any such events, we cannot guarantee that similar serious adverse events or clinical holds will not happen in ongoing and future clinical trials of SGT-003. We also cannot guarantee that similar serious adverse events or clinical holds will not happen in planned and future clinical trials of any of our other Candidates.

Delays in the completion of, or our inability to conduct, any clinical trial of SGT-003 or any other Candidate, as a result of similar serious adverse events or clinical holds or otherwise, will increase our costs, slow down or cease our Candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of SGT-003 or other Candidates.

We have never completed a clinical trial and may be unable to do so for any Candidate, including SGT-003, SGT-212, SGT-501 and other Candidates.

We are early in our development efforts and we have never completed a clinical trial. We are conducting our INSPIRE DUCHENNE trial of SGT-003, our IMPACT DUCHENNE trial of SGT-003, our FALCON trial of SGT-212 and our ARTEMIS trial of SGT-501. Our other current Candidates are still in the preclinical and discovery stages of development. Preclinical studies involve a lengthy and expensive process with an uncertain outcome. There are many potential preclinical models to test for different disease states, and we could fail to choose the best or a predictive preclinical model to determine proof of concept and potential safety and efficacy of our Candidates. We may decide to suspend further testing on our Candidates or technologies if, in the judgment of our management and advisors, the preclinical test results do not support further development.

We will need to successfully initiate our planned clinical trials and complete our ongoing clinical trials in order to obtain FDA approval to market SGT-003, SGT-212, SGT-501 and other Candidates. We have limited experience in preparing, submitting and prosecuting regulatory submissions, and have not previously submitted a BLA for any Candidate. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin or to begin as proposed, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Carrying out later-stage clinical trials and the submission of a successful BLA is a complicated process. This may be particularly true for design of a pivotal trial for the treatment of Duchenne as the FDA has not given clear guidance as to the necessary endpoints for approval of a treatment for Duchenne. In addition, we cannot be certain how many clinical trials of SGT-003, SGT-212, SGT-501 or other Candidates will be required or how such trials should be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA submission and approval of SGT-003, SGT-212, SGT-501 or other Candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of Candidates that we develop. Failure to commence or complete, or delays in, clinical trials could prevent us from or delay us in commercializing SGT-003, SGT-212, SGT-501 and other Candidates.

Success in preclinical studies or early clinical trials may not be indicative of results obtained in later trials.

Results from preclinical studies or early clinical trials are not necessarily predictive of results from future clinical trials and are not necessarily indicative of final results. Our preclinical studies for certain Candidates in animals have been limited. There is a high failure rate for gene therapy and biologic products proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials even after achieving promising results in preclinical testing and earlier-stage clinical trials. Data obtained from preclinical studies and clinical trials are subject to varying interpretations, which may delay, limit or prevent regulatory approval. We also may experience regulatory delays or rejections as a result of many factors, including due to changes in regulatory policy during the period of our Candidate development. Our Candidates may fail to show the desired safety and efficacy in clinical development despite positive results in preclinical studies. This failure could cause us to abandon any of our Candidates.

Preliminary or interim data that we announce or publish from time to time may change as more data becomes available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may announce or publish preliminary or interim data from clinical trials. Positive preliminary or interim data may not be predictive of such trial's subsequent or overall results. Preliminary or interim data are subject to the risk that one or more of the outcomes may materially change as more data becomes available. Additionally, preliminary or interim data are subject to the risk that one or more of the biologic or clinical outcomes may materially change as participant enrollment continues and more participant data becomes available. Therefore, positive preliminary or interim data in any ongoing clinical trial, including the INSPIRE DUCHENNE trial, may not be predictive of such results in the completed trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully evaluate all data. As a result, preliminary or interim data that we report may differ from future results from the clinical trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Preliminary or interim data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or interim data we previously published. As a result, preliminary or interim data should be viewed with caution until the final data are available. Material adverse changes in the final data compared to preliminary or interim data could significantly harm our business prospects.

We may encounter substantial delays in our clinical trials or we may fail to demonstrate safety and efficacy to the satisfaction of applicable regulatory authorities.

Before obtaining marketing approval from regulatory authorities for the sale of our Candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the Candidate for its intended indications. Clinical testing is expensive, time consuming and uncertain as to outcome. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing. Events that may prevent successful or timely completion of clinical development include:

- delays in obtaining animals in sufficient quantities to run our preclinical studies;
- delays in reaching a consensus with regulatory authorities on trial design;
- delays in reaching agreement with the appropriate external parties on dose escalation;
- delays in enrolling participants in clinical trials;

- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites;
- delays in opening clinical trial sites or obtaining required institutional review board or independent ethics committee approval at each clinical trial site;
- delays in recruiting suitable subjects to participate in our clinical trials, including because such trials have restrictive eligibility criteria or may be placebo-controlled trials and participants are not guaranteed to receive treatment with our Candidates, or as a result of alternative therapies or competing trials;
- difficulty in finding suitable animal models to demonstrate a disease specific phenotype;
- failure by us, any CROs we engage or any other third parties to adhere to clinical trial requirements;
- failure to perform in accordance with FDA good clinical practices (“GCPs”) or applicable regulatory guidelines in the European Union and other countries;
- delays in the testing, validation, manufacturing and delivery of our Candidates to the clinical sites, including delays by third parties with whom we have contracted to perform certain of those functions;
- delays in subjects completing participation in a trial or returning for post-treatment follow-up;
- clinical trial sites or subjects dropping out of a trial;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- imposition of a clinical hold by regulatory authorities as a result of a serious adverse event, or after an inspection of our clinical trial operations, trial sites or manufacturing facilities or otherwise;
- occurrence of serious adverse events in trials of the same class of agents conducted by other sponsors;
- delays as a result of public health emergencies or pandemics or other global instability; or
- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols.

Additionally, if the results of any clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our Candidates, we may:

- interrupt or halt clinical development;
- be delayed or fail in obtaining marketing approval for our Candidates;
- obtain approval for indications or patient populations that are not as broad as we intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to changes in the way our products, if approved, are administered;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the product or impose restrictions on its distribution in the form of a modified REMS;
- be sued and held liable for harm caused to participants; or
- experience damage to our reputation.

In addition, the FDA’s and other regulatory authorities’ policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Our product development costs will increase if we experience delays in testing or marketing approvals. In addition, if we make manufacturing or other changes to our Candidates, we may need to conduct additional studies to bridge our modified Candidates to earlier versions. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, which we have done in the past and which could result in delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our Candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our Candidates.

If our third-party clinical trial vendors fail to comply with strict regulations, any clinical trials for our Candidates may be delayed or unsuccessful.

We do not have the personnel capacity to conduct or manage the clinical trials that will be necessary for the development of our Candidates. We are relying on third parties to manage, monitor and conduct our INSPIRE DUCHENNE, IMPACT DUCHENNE, FALCON and ARTEMIS trials and we expect we will rely, on third parties to assist us in managing, monitoring and conducting any planned or future clinical trials. If these third parties fail to comply with applicable regulations or do not adequately fulfill their obligations under the terms of our agreements with them, we may not be able to enter into alternative arrangements without undue delay or additional expenditures and, therefore, clinical trials for SGT-003, SGT-212, SGT-501 or other Candidates may be delayed or unsuccessful.

Furthermore, the FDA can be expected to inspect some or all of the clinical sites participating in our clinical trials to determine if our clinical trials are being conducted according to GCPs. If the FDA determines that these clinical sites are not in compliance with applicable regulations, we may be required to delay, repeat or terminate the clinical trials.

We may find it difficult to enroll participants in our clinical trials, which could delay or prevent us from proceeding with clinical trials of SGT-003, SGT-212, SGT-501 or our other Candidates.

Identifying and qualifying participants to participate in any clinical trials of SGT-003, SGT-212, SGT-501 and our other Candidates are critical to our success. Because of our primary focus on rare diseases, we may have difficulty enrolling a sufficient number of eligible participants. The timing of any clinical trials depends on our ability to recruit participants to participate as well as complete required follow-up periods. If participants are unwilling or unable to participate in our gene therapy clinical trials, including because of negative publicity from adverse events related to our Candidates, other approved therapies, or due to competitive clinical trials or approvals for similar participant populations, clinical trials in products employing our capsid or our platform or for other reasons, the timeline for recruiting participants, conducting clinical trials and obtaining regulatory approval of SGT-003, SGT-212, SGT-501 or other Candidates may be delayed. We may also experience delays if participants withdraw from the clinical trial or do not complete the required monitoring period. Furthermore, we may face difficulties in recruiting participants to enroll in, or once enrolled, retaining participants in future clinical trials if they or their caretakers are affected by public health emergencies or pandemics or are fearful of traveling to, or are unable to travel to, our clinical trial sites because of public health emergencies or pandemics or other unforeseen events. These delays could result in increased costs, delays in advancing SGT-003, SGT-212, SGT-501 or other Candidates, delays in testing the effectiveness of our Candidates or termination of clinical trials altogether.

We may not be able to identify, recruit and enroll a sufficient number of participants, or those with required or desired characteristics, to complete any clinical trials in a timely manner. Participant enrollment and trial completion is affected by many factors, including:

- size of the participant population and the process for identifying subjects;
- design of the trial protocol;
- eligibility and exclusion criteria, including age, size and functional ability and pre-existing antibodies to AAV capsids that preclude subjects from being able to receive AAV-mediated gene transfer;
- restrictions on our ability to conduct clinical trials, including full and partial clinical holds on ongoing or planned clinical trials;
- perceived risks and benefits of the Candidate under study;
- perceived risks and benefits of gene therapy-based approaches to the treatment of diseases;
- release or disclosure of data from our completed or ongoing clinical trials;
- availability of competing therapies and clinical trials;

- severity of the disease;
- proximity and availability of clinical trial sites for prospective subjects;
- ability to obtain and maintain subject consent;
- risk that enrolled subjects will drop out before completion of the trial;
- patient referral practices of physicians;
- ability to monitor subjects adequately during and after treatment; and
- in the case of pivotal trials, the risk that participants may opt not to enroll because they are not assured treatment with our Candidate.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act (“FDORA”), Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other “pivotal study” of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse participant populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance when finalized will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance. On January 27, 2025, in response to an executive order issued by the President earlier in January 2025 on Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the current U.S. presidential administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. In late July 2025, the FDA restored the draft DAP guidance to its website with a statement that “information on this page may be modified and/or removed in the future subject to the terms of the court’s order and implemented consistent with applicable law.” Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of marketing applications.

We plan to conduct clinical trials at sites outside the United States. The FDA may not accept data from trials conducted in such locations, and the conduct of trials outside the United States could subject us to additional delays and expense.

We plan to conduct clinical trials, including the INSPIRE DUCHENNE, IMPACT DUCHENNE and ARTEMIS trials, with one or more trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted at sites outside the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, where data from foreign clinical trial sites are not intended to serve as the sole basis for approval in the United States, the FDA will not accept the data as support for a marketing application unless the clinical trial was well designed and conducted in accordance with GCP requirements. The FDA must also be able to validate the data from the trial through an onsite inspection, if necessary. Where data from foreign clinical trial sites are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, these clinical trials are subject to the applicable local laws of the jurisdictions where the trials are conducted. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

In addition, conducting clinical trials outside the United States could have a significant adverse impact on us. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct our clinical trials;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange fluctuations;

- diminished protection of intellectual property in some countries; and
- interruptions or delays resulting from geopolitical events, such as wars.

The EU Clinical Trials Regulation (“CTR”) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR aims to simplify and streamline the authorization, conduct and transparency of clinical trials in the European Union. We have only recently secured authorization to conduct clinical trials in the European Union pursuant to the CTR and, accordingly, there is a risk that we may be delayed in commencing any such studies. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our Candidates and the approval may be for a narrower indication than we seek.

We cannot commercialize our Candidates until the appropriate regulatory authorities have reviewed and approved the Candidate. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state and local statutes and regulations require the expenditure of substantial time and financial resources and we may not be able to obtain the required regulatory approvals. Even if our Candidates meet their safety and efficacy endpoints in clinical trials, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA advisory committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action or changes in regulatory authority policy during the period of product development, clinical trials and the regulatory review process.

Further, under the Pediatric Research Equity Act of 2003, a BLA or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness of the biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic Candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our Candidates for which we are seeking regulatory approval in the U.S. or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action, invalidation of the marketing application, and/or financial penalties. Our collaborators are also subject to similar requirements outside of the United States and the European Union and thus the attendant risks and uncertainties.

Even if we receive regulatory approval, regulatory authorities may approve a Candidate for more limited indications than requested or they may impose significant limitations in the form of narrow indications, warnings or a REMS. Regulatory authorities may require precautions or contra-indications with respect to conditions of use or they may grant approval subject to the performance of costly post-marketing clinical trials. In addition, regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our Candidates. Any of the foregoing scenarios could materially harm the commercial prospects for our Candidates.

Even if we obtain regulatory approval for a Candidate, our Candidates will remain subject to regulatory oversight.

Even if we obtain any regulatory approval for any of our Candidates, we will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our Candidates may also be subject to a REMS, limitations on the approved indicated uses for which the product may be marketed or conditions of approval, or requirements for potentially costly post-marketing testing and surveillance to monitor the safety, purity, and potency of the biologic product. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have various consequences, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions and warnings on the labeling or marketing of a product;

- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; or
- litigation involving patients using our products.

In addition, manufacturers of approved products and those manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs applicable to drug manufacturers or quality assurance standards applicable to medical device manufacturers, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, any contract manufacturers we may engage in the future, our future collaborators and their contract manufacturers will also be subject to other regulatory requirements, including submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements regarding the distribution of samples to clinicians, recordkeeping, and costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product such as the requirement to implement a REMS.

Finally, our ability to develop and market new drug products may be impacted by litigation challenging the FDA's approval of another company's drug product. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the Supreme Court reversed that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states filed an amended complaint in the U.S. District Court for the Northern District of Texas challenging the FDA's actions. On January 16, 2025, the District Court agreed to allow these states to file an amended complaint and continue to pursue this challenge. Thereafter, on September 30, 2025, the District Court declined to dismiss the case and, instead, transferred it to federal District Court in the Eastern District of Missouri. Depending on the outcome of this litigation our ability to develop new drug Candidates and to maintain approval of existing drug products could be delayed, undermined or subject to protracted litigation.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Further, similar restrictions apply to approved products in the European Union. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the EU's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union and are also subject to EU Member State laws.

Accordingly, assuming we, or our collaborators, receive marketing approval for one or more of our Candidates, we, and our collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and our

collaborators, are not able to comply with post-approval regulatory requirements, our or our collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

Any regulatory approval to market our products will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, Medicines and Healthcare products Regulatory Agency ("MHRA"), and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug product. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product.

In addition, we could be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency, such as the FDA, acted within its statutory authority under the Administrative Procedure Act (the "APA"). Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and Centers for Medicare & Medicaid Services (the "CMS"), that we rely on. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services ("HHS"), the FDA, the Federal Trade Commission ("FTC"), and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Even if we obtain and maintain approval of one or more of our Candidates from the FDA, we may never obtain approval for our Candidates outside of the United States, which would limit our market opportunities and adversely affect our business.

Even if we receive FDA approval of one or more of our Candidates in the United States, approval of a Candidate in the United States by the FDA does not ensure approval of such Candidate by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Future sales of our Candidates outside of the United States will be subject to foreign regulatory requirements governing clinical trials, manufacturing and marketing approval. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and more onerous than, those in the United States, including additional preclinical studies or clinical trials. In many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. If we submit a marketing authorization application (“MAA”) to the EMA for approval of SGT-003, SGT-212, SGT-501 or other Candidates in the European Union, obtaining such approval from the European Commission following the opinion of the EMA is a lengthy and expensive process. Regulatory authorities in countries outside of the United States and the European Union also have requirements for approval of product candidates with which we must comply prior to marketing in those countries. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our Candidates in certain countries.

Further, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries. Also, regulatory approval for our Candidates may be withdrawn. If we fail to comply with the regulatory requirements, our target market will be reduced, and our ability to realize the full market potential of our Candidates will be harmed.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the MHRA is responsible for approving all medicinal products destined for the UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. On April 28, 2025, the United Kingdom Parliament adopted amendments to improve and strengthen the United Kingdom’s clinical trials regulatory regime, which are scheduled to take effect on April 28, 2026. Any delay in obtaining, or an inability to obtain, any marketing authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for our Candidates, which could significantly and materially harm our business.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission’s proposal for revision of several legislative instruments related to medicinal products (including potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023, with several amendments requested in April 2024. In December 2025, the European Parliament and European Council reached a provisional political agreement on the revision of EU pharmaceutical legislation, which is expected to be adopted by mid-2026. Key changes include updating regulatory data exclusivity to a new system with a regulatory data protection period of eight years and a reduced market exclusivity period of one year (which can be extended if specific conditions are fulfilled), adding launch/supply obligations, incentivizing antibiotic innovation with transferable vouchers, and streamlining approval procedures in the EU. If the legislation is finalized in line with the provisional political agreement, it will have a significant impact on the pharmaceutical industry.

We expect that we will be subject to additional risks in commercializing any of our Candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

Changes in and uncertainty surrounding U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

In 2025, the Trump Administration imposed a series of tariffs against U.S. trading partners pursuant to the International Emergency Economic Powers Act. On February 20, 2026, the U.S. Supreme Court ruled these tariffs unlawful. The Trump Administration immediately imposed new global tariffs pursuant to Section 122 of the Trade Act of 1974, which allows for tariffs of up to 15% for a period of up to 150 days.

Separately, in April 2025, the Department of Commerce announced an investigation under Section 232 of the Trade Expansion Act of 1962 into imports of pharmaceuticals and pharmaceutical ingredients, including finished products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the United States would face a 100% tariff. At the same time, President Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the United States. Thereafter, President Trump delayed the October 1, 2025 effective date of the tariffs on branded or patented pharmaceutical products announcing that the Trump Administration had now “begun preparing” tariffs on manufacturers that do not build in the United States or enter into a most-favored-nation drug pricing agreement with the Trump Administration. A host of other U.S. tariff actions remain possible, including additional 25% tariffs on products from countries that do certain business with Iran or Cuba.

As a result of changes in tariffs that have been announced and/or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact to our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and platform materials, affect the demand for our product candidates (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidates used in our preclinical studies and clinical trials. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries, in particular, China, will impose and maintain quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Regulatory requirements governing gene therapy products are periodically updated and may continue to change in the future.

Regulatory requirements governing gene therapy products have changed frequently and will likely continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of gene therapy products. For example, in the United States, the FDA has established the Office of Therapeutic Products within the Center for Biologics Evaluation and Research (“CBER”) to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. Gene therapy clinical trials may also be subject to review and oversight by an institutional biosafety committee, a local institutional committee that reviews and oversees basic and clinical research conducted at the institution participating in the clinical trial. Although the FDA decides whether individual gene therapy protocols may proceed, the review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical trial, even if the FDA has reviewed the trial and approved its initiation.

The FDA has issued various guidance documents regarding gene therapies, including final guidance documents released in January 2020 relating to chemistry, manufacturing and controls information for gene therapy INDs, gene therapies for rare diseases and gene therapies for retinal disorders, a final guidance in October 2022 for Human Gene Therapy for Neurodegenerative Diseases, as well as a draft guidance in July 2023 on comparability requirements for manufacturing changes in gene therapy products. In December 2023, a draft guidance on potency assurance for cellular and gene therapy products was released. Although the FDA has indicated that these and other guidance documents it previously issued are not legally binding, we believe that our compliance with them is likely necessary to gain approval for any gene therapy Candidate we may develop. The guidance documents provide additional factors that the FDA will consider at each of the above stages of development and relate to, among other things, the proper preclinical assessment of gene therapies; the chemistry, manufacturing, and control information that should be included in an IND application; the proper design of tests to measure product potency in support of an IND or BLA application; and measures to observe delayed adverse effects in subjects who have been exposed to investigational gene therapies when the risk of such effects is high. Further, for AAV capsids

specifically, the FDA typically recommends that sponsors continue to monitor participants for potential gene therapy-related adverse events for up to a 5-year period. Other types of gene therapy or gene editing products may require longer follow up, potentially up to a maximum 15-year period.

Similarly, the EMA may issue new guidelines concerning the development and marketing authorization for gene therapy products and require that we comply with these new guidelines. The grant of marketing authorization in the European Union for gene therapy products is governed by Regulation 1394/2007/EC on advanced therapy medicinal products, read in combination with Directive 2001/83/EC of the European Parliament and of the Council, commonly known as the Community code on medicinal products. Regulation 1394/2007/EC includes specific rules concerning the authorization, supervision, and pharmacovigilance of gene therapy medicinal products. Manufacturers of advanced therapy medicinal products must demonstrate the quality, safety, and efficacy of their products to the EMA, which provides an opinion regarding the MAA. The European Commission grants or refuses marketing authorization in light of the opinion delivered by the EMA.

Finally, ethical, social and legal concerns about gene therapy, genetic testing and genetic research could result in additional regulations or prohibiting the processes we may use. Federal and state agencies, congressional committees and foreign governments have expressed their intentions to further regulate biotechnology. More restrictive regulations or claims that our Candidates are unsafe or pose a hazard could prevent us from commercializing any products. New government requirements may be established that could delay or prevent regulatory approval of our Candidates under development. It is impossible to predict whether legislative changes will be enacted, regulations, policies or guidance changed, or interpretations by agencies or courts changed, or what the impact of such changes, if any, may be.

As we advance our Candidates through clinical development, we will be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. These regulatory review committees and advisory groups and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of Candidates or lead to significant post-approval limitations or restrictions. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue.

We may not be able to obtain orphan drug exclusivity for one or more of our Candidates, and even if we do, that exclusivity may not prevent the FDA or the EMA from approving other competing products.

Under the Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is a drug or biologic intended to treat a rare disease or condition. A similar regulatory scheme governs approval of orphan products by the EMA in the European Union. Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for a similar product for the same therapeutic indication for that time period. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, in particular if the product is sufficiently profitable so that market exclusivity is no longer justified.

The FDA has granted orphan drug designation to SGT-003 for the treatment of Duchenne, SGT-212 for the treatment of FA and to SGT-501 for the treatment of CPVT.

In order for the FDA to grant orphan drug exclusivity to one of our products, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which orphan drug exclusivity is sought does not meet this standard. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition.

In addition, under the FDA September 2021 guidance for interpreting sameness of gene therapy products under the orphan drug regulations, even after an orphan drug is approved, the FDA can subsequently approve a similar product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA Reauthorization Act of 2017 (“FDARA”) requires that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. FDARA reverses prior precedent holding that the Orphan Drug Act unambiguously requires that the FDA recognize the orphan exclusivity period regardless of a showing of clinical superiority.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term “same disease or condition” means the designated “rare disease or condition” and could not be interpreted by the FDA to mean the “indication or use.” Thus, the Court of Appeals concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the “indication or use.” Although there have been legislative proposals to overrule this decision, they have not been enacted into law. In January 2023, the FDA announced that, in matters beyond the scope of that court order, FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA or Congress may make to its orphan drug regulations and policies, our business could be adversely impacted.

We may seek a breakthrough therapy designation for one or more of our Candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

We may seek a breakthrough therapy designation for one or more of our Candidates; however, we cannot assure our stockholders that one or more of our Candidates will meet the criteria for that designation. A breakthrough therapy is defined as a therapy that is intended, alone or in combination with one or more other therapies, to treat a serious condition, and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For therapies and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of participants placed in ineffective control regimens. Therapies designated as breakthrough therapies by the FDA may also be eligible for priority review if supported by clinical data at the time the BLA is submitted to the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our Candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive breakthrough therapy designation, the receipt of such designation for a Candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our Candidates qualifies as a breakthrough therapy, the FDA may later decide that the Candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Accelerated approval by the FDA, even if granted for one or more of our Candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our Candidates will receive marketing approval.

We may seek approval of one or more of our Candidates using the FDA’s accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition and generally provides a meaningful advantage over available therapies. In addition, it must demonstrate an effect on a surrogate or intermediate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (“IMM”) that is reasonably likely to predict an effect on IMM or other clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate or intermediate endpoint is reasonably likely to predict long-term clinical benefit. Given that expression of microdystrophin has not yet been established to predict long-term clinical benefit, it is not currently accepted, and it is possible the FDA and/or other applicable regulatory agencies could decide never to accept it, as a surrogate endpoint for the accelerated approval pathway for the treatment of Duchenne.

As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. These confirmatory trials must be completed with due diligence and may be required to be initiated prior to submission of the BLA. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Further, with passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to FDA every six months (until the study is completed) and use expedited procedures to withdraw accelerated approval of a BLA after the confirmatory trial fails to verify the product’s clinical benefit.

There can be no assurance that the FDA or comparable foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our clinical trials, or that we will decide to pursue or submit any additional application for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval. Furthermore, for any submission of an application for accelerated approval or application under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted for filing or that any expedited development, review or approval will be granted on a timely basis, or at all.

A failure to obtain accelerated approval or any other form of expedited development, review or approval for our Candidates, or withdrawal of a Candidate, would result in a longer time period until commercialization of such Candidate, could increase the cost of development of such Candidate and could harm our competitive position in the marketplace.

A potential regenerative medicine advanced therapy designation by the FDA for our Candidates may not lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our Candidates will receive marketing approval.

We may seek a regenerative medicine advanced therapy designation for some of our Candidates. A regenerative medicine advanced therapy is defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells, that lead to a durable modification of cells or tissues may meet the definition of a regenerative medicine therapy. The regenerative medicine advanced therapy program is intended to facilitate efficient development and expedite review of regenerative medicine advanced therapies, which are intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition. A BLA for a regenerative medicine advanced therapy may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long-term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with the FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A regenerative medicine therapy that is granted accelerated approval and is subject to post-approval requirements may fulfill such requirements through the submission of clinical evidence, clinical trials, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post-approval monitoring of all participants treated with such therapy prior to its approval.

Designation as a regenerative medicine advanced therapy is within the discretion of the FDA. Accordingly, even if we believe one of our Candidates meets the criteria for designation as a regenerative medicine advanced therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a regenerative medicine advanced therapy designation for a Candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our Candidates qualify as regenerative medicine advanced therapies, the FDA may later decide that the biological products no longer meet the conditions for qualification.

We may seek PRIME Designation in the EU for one or more of our Candidates, but we might not receive such designations and, even if we do, such designations may not lead to a faster development or regulatory review or approval process.

In the EU, we may seek PRIME designation for our Candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the sponsor intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims.

The benefits of a PRIME designation include the appointment of a Committee for Medicinal Products for Human Use rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables a sponsor to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our Candidates, the designation may not result in a

materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

We may seek a Rare Pediatric Disease Designation for our Candidates. However, a BLA for such Candidates may not meet the eligibility criteria for a priority review voucher upon approval.

With enactment of the Food and Drug Administration Safety and Innovation Act in 2012, Congress authorized the FDA to award priority review vouchers to sponsors of certain rare pediatric disease product applications that meet the criteria specified in the law. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives an approval for a drug or biologic for a "rare pediatric disease" may qualify for a voucher that can be redeemed to receive a priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product receiving a priority review voucher may transfer (including by sale) the voucher to another sponsor. The voucher may be further transferred any number of times before the voucher is used, as long as the sponsor making the transfer has not yet submitted the application.

In order to receive a priority review voucher upon BLA approval, the product must receive designation from the FDA as a product for a rare pediatric disease prior to approval of the marketing application. A "rare pediatric disease" is a disease that is serious or life-threatening, in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and affects fewer than 200,000 people in the United States, or affects more than 200,000 people in the United States but there is no reasonable expectation that the cost of developing and making available in the United States a product for such disease or condition will be recovered from sales in the United States of such product. In addition to receiving rare pediatric disease designation, in order to receive a priority review voucher, the BLA must be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a product that does not include a previously approved active ingredient.

Under the current statutory sunset provisions for the Rare Pediatric Disease Priority Review Voucher Program, after September 30, 2024, the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024.

After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. If we do not obtain approval of a BLA by these dates, and if the Rare Pediatric Disease Priority Review Voucher Program is not further extended by congressional action, we may not receive a Priority Review Voucher.

The FDA has granted rare pediatric disease designation to SGT-003 for the treatment of Duchenne, SGT-212 for the treatment of FA and SGT-501 for the treatment of CPVT.

We may seek a fast track designation for one or more of our Candidates. However, such designation may not actually lead to a faster development or regulatory review or approval process. We might not receive such designation for one or more of our Candidates.

If a therapy is intended for the treatment of a serious condition and non-clinical or clinical data demonstrates the potential to address unmet medical need for this condition, a drug sponsor may apply for FDA fast track designation. However, fast track designation does not ensure that we will receive marketing approval or that approval will be granted within any particular timeframe. The FDA has broad discretion with respect to whether or not to grant fast track designation to a product candidate, so even if we believe a particular Candidate is eligible for such designation, the FDA may decide not to grant it. Moreover, we may not experience a faster development or regulatory review or approval process with fast track designation compared to conventional FDA procedures. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program or if the unmet need has been fulfilled with the approval of another product. Fast track designation alone does not guarantee qualification for the FDA's priority review procedures.

The FDA has granted fast track designation to SGT-003 for the treatment of Duchenne, SGT-212 for the treatment of FA and SGT-501 for the treatment of CPVT.

We may seek priority review designation for one or more of our Candidates, but we might not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

If the FDA determines that a product candidate offers a treatment for a serious condition and, if approved, the product would provide a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard

review period of ten months. We may request priority review for our Candidates, however, we cannot assume that one or more of our Candidates will meet the criteria for that designation. The FDA has broad discretion with respect to whether or not to grant priority review status to a product candidate, so even if we believe a particular Candidate is eligible for such designation or status, the FDA may decide not to grant it. Moreover, a priority review designation does not necessarily mean a faster development or regulatory review or approval process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. Receiving priority review from the FDA does not guarantee approval within the six-month review cycle or at all.

Disruptions and delays at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development program and develop and secure approval of our Candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions play an important role in the development of our Candidates by providing guidance on our clinical development programs and reviewing our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted, then correspondingly our ability to develop and secure timely approval of our Candidates could be impacted in a negative manner.

Further, there is substantial uncertainty as to how measures being implemented by the US government administration will impact the FDA, CMS and other federal agencies with jurisdiction over our activities. If oversight and review activities by the FDA and comparable foreign regulatory authorities are disrupted due to funding cuts, personnel losses, reductions in force, regulatory reform or government shutdown, then our ability to develop and/or secure timely approval of our product candidates could be impacted in a negative manner. For example, the recent loss of FDA leadership and personnel, including due to a significant reduction in force, could lead to disruptions and delays in FDA guidance, review and approval of our product candidates. There are also ongoing deliberations within the administration and Congress over potentially substantial proposed cuts to the overall budget for HHS and funding of the FDA for the 2026 federal fiscal year. Similarly, efforts by the new administration to substantially reduce or delay research funding by the National Institutes of Health of medical research could have substantial direct or indirect impacts on our research activities.

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the agency's review and processing of our regulatory submissions, including INDs and BLAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

We face significant competition and our competitors may achieve regulatory approval before us or develop therapies that are more advanced or effective than ours, which may adversely affect our ability to develop, successfully market or commercialize our Candidates. Changes within the competitive landscape could lead us to alter our regulatory and/or clinical trial strategy, baseline eligibility criteria or make other modifications to clinical trial designs.

We operate in a highly competitive segment of the biopharmaceutical market. We face competition from many different sources, including larger and better-funded pharmaceutical, specialty pharmaceutical and biotechnology companies, as well as from academic institutions, government agencies and private and public research institutions. Our Candidates, if successfully developed and approved, will compete with established therapies as well as with new treatments that may be introduced by our competitors. There are a variety of product candidates, including gene therapies, in development for Duchenne, CPVT,

other cardiomyopathies or FA. Many of our competitors have significantly greater financial, product candidate development, manufacturing and marketing resources than we do. Large pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and mergers and acquisitions within these industries may result in even more resources being concentrated among a smaller number of larger competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, enrolling participants in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

We are aware of a number of companies and research institutions developing gene transfer programs progressing in Duchenne. For example, in June 2023, Sarepta Therapeutics, Inc. (“Sarepta”) announced that it had received accelerated approval for its gene therapy candidate ELEVIDYS® for the treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne. In June 2024, Sarepta announced an expanded US approval of ELEVIDYS® for patients who are at least 4 years of age including full approval for ambulatory Duchenne patients and accelerated approval for non-ambulatory Duchenne patients. We are also aware of several companies and research institutions conducting clinical trials of product candidates focused on systemic gene transfers for Duchenne, including Genethon, with product candidate GNT0004 currently being evaluated in a Phase 1/2/3 clinical trial, REGENXBIO Inc., with product candidate RGX-202 currently being evaluated in a Phase 1/2/3 clinical trial and Insmed Incorporated, with product candidate INS1201 currently being evaluated in a Phase 1 clinical trial.

There are other approaches to treat Duchenne that are either currently marketed or in development including antisense oligonucleotides, histone deacetylase (“HDAC”) inhibitors, myosin inhibitors, cell therapies and gene editing. Notably, Sarepta has received accelerated approval for three therapies including Exondys 51, Vyondys 53 and Amondys 45 targeting exons 51, 53 and 45, respectively; Nippon Shinyaku received accelerated approval for Viltipso to treat exon 53 amenable patients; Avidity Biosciences is developing Del-zota to treat exon 44; Wave Life Sciences is developing WVE-N531 to treat exon 53 amenable patients; Dyne Therapeutics is developing DYNE-251 to treat exon 51 amenable patients; BioMarin Pharmaceutical is developing BMN 351 to treat exon 51 amenable patients; and Entrada Therapeutics is developing ENTR-601-44, ENTR-601-45, ENTR-601-50, and ENTR-601-51 for exon 44, 45, 50 and 51 amenable patients, respectively. Italfarmaco received FDA approval for its HDAC inhibitor, Givinostat, in Duchenne patients who are at least 6 years of age. Edgewise Therapeutics is developing Sevasemten, a fast skeletal myosin inhibitor, for Duchenne and Becker muscular dystrophies. Capricor Therapeutics is developing Deramiciel, an allogeneic cardiosphere-derived cell therapy product candidate. Satellos Biosciences is developing SAT-3247, an oral small molecule product candidate. Precision BioSciences is in preclinical development for gene editing product candidate, PBGENE-DMD.

We are also aware of a number of companies and research institutions developing gene transfer programs in FA. For example, Lexeo Therapeutics is developing an IV gene therapy to treat the cardiac manifestations of FA. Other competitors currently developing gene therapies to treat FA are in preclinical development, including Neurocrine Biosciences in collaboration with Voyager Therapeutics and Capsida Biotherapeutics. We are also aware of other companies developing non-gene therapies for FA, such as Design Therapeutics, Larimar Therapeutics, PTC Therapeutics and Papillon Therapeutics. Biogen’s SKYCLARYS® (omaveloxolone) was approved for the treatment of FA in adults and adolescents aged 16 and older by the FDA and the European Commission in February 2023 and February 2024, respectively.

We are also aware of several companies and research institutions conducting clinical trials in small molecule product candidates focused on CPVT, including Cardurion Pharmaceuticals Inc., with an orally administered CAMKII-delta inhibitor candidate in a Phase 2 clinical trial.

Our commercial opportunity could be reduced or eliminated if competitors develop and commercialize products that are first to market or are safer, more effective, have fewer or less severe side effects, have broader market acceptance, are more convenient or are less expensive than any Candidate that we may develop. Changes within the competitive landscape could lead us to alter regulatory and/or clinical trial strategy, baseline eligibility criteria or make other modifications to clinical trial designs.

We are aware of several companies focused on developing gene therapies in various indications, as well as several companies addressing other methods for modifying genes and regulating gene expression. Any advances in gene therapy technology made by a competitor may be used to develop therapies that could compete against Candidates we develop.

We may fail to capitalize on other potential Candidates that may represent a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to develop and commercialize our Candidates. Because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or Candidates or for indications that later

prove to have greater commercial potential than our Candidates. For example, in September 2022, we announced that we would be pausing activities for SGT-001, which we are no longer developing.

Our spending on current and future research and development programs may not yield any commercially viable Candidates. If we do not accurately evaluate the commercial potential for a particular Candidate, we may relinquish valuable rights to that Candidate through strategic collaborations, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such Candidate. Alternatively, we may allocate internal resources to a Candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon our development efforts with respect to a particular Candidate or fail to develop a potentially successful Candidate.

Risks Related to the Manufacturing and Commercialization of our Candidates

We have entered into, and may in the future enter into, collaborations with third parties for the development or commercialization of our Candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these Candidates and our business could be adversely affected.

While we have retained all necessary rights to and are developing on our own SGT-003, SGT-212, SGT-501 and other Candidates, we may in the future enter into development, distribution or marketing arrangements with third parties with respect to SGT-003, SGT-212, SGT-501 or other Candidates. Our likely collaborators for any such sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties in the future, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our Candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements.

Collaborations that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our Candidates or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may not pursue commercialization of any Candidates that achieve regulatory approval or may elect not to continue or renew commercialization programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that may divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a Candidate, repeat or conduct new clinical trials or require a new formulation of a Candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding Candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such Candidates on a discretionary basis;
- collaborators could develop products that compete directly or indirectly with our Candidates and products pursuant to the collaboration;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our Candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- Candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our Candidates;

- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a Candidate or product;
- a collaborator with marketing and distribution rights to one or more of our Candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of Candidates, might lead to additional responsibilities for us with respect to Candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable Candidates.

Collaboration agreements may not lead to development or commercialization of Candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of our Candidates could be delayed and we may need additional resources to develop our Candidates. All of the risks relating to product development, regulatory approval and commercialization described herein also apply to the activities of our collaborators.

Additionally, subject to its contractual obligations to us, if a collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any Candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected.

We may not be successful in finding strategic collaborators for continuing development of our Candidates or platform technologies, or for successfully commercializing or competing in the market for certain indications.

We may seek to establish strategic partnerships for developing Candidates or platform technologies due to capital costs required to develop, manufacture and commercialize our Candidates or platform technologies. We may not be successful in our efforts to establish strategic partnerships or other alternative arrangements because, among other things, our research and development pipeline may be insufficient, Candidates or platform technologies may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our Candidates or platform technologies as having the requisite potential to demonstrate safety and efficacy. We cannot be certain that, following a strategic transaction, we will achieve an economic or business benefit that justifies such transaction. If we seek to but are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail, reduce or delay the development of a Candidate, delay its potential commercialization, reduce the scope of any sales or marketing activities or increase our expenditures and undertake development, manufacturing or commercialization activities independently. If we elect to fund our own independent development or commercialization activities, we will need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development, manufacturing and commercialization activities, we may not be able to further develop our Candidates or platform technologies.

We have limited gene therapy manufacturing experience and could experience production problems and delays in obtaining regulatory approval of our manufacturing processes, which could result in delays in the development or commercialization of SGT-003, SGT-212, SGT-501, or our other Candidates. In addition, changes to manufacturing sites or processes, or formulations for our Candidates may result in additional cost or delay.

We have limited experience manufacturing SGT-003, SGT-212, SGT-501 and our other Candidates. The manufacturing process we have used historically and the manufacturing process we plan to use in the future to produce product for our

Candidates are complex and our processes have not been validated for commercial use. As Candidates progress through preclinical studies and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to enhance safety, quality, efficacy, yield, manufacturing batch size, minimize costs and achieve consistent results. For example, we have moved to a transient transfection-based manufacturing process for SGT-003 and while we have observed early positive results in preclinical studies and in our ongoing INSPIRE DUCHENNE trial using this new manufacturing process, any further changes in manufacturing or formulation may result in effects and results that are different from those observed in our completed studies to date. Similarly, in the future we may further alter our existing process or introduce an alternative process or formulation of one or more of our Candidates during the course of our planned preclinical studies or clinical trials. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our Candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay initiation or completion of clinical trials, require the conduct of bridging studies or clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay approval of our Candidates and jeopardize our ability to commercialize our Candidates, if approved, and generate revenue.

The production of SGT-003, SGT-212 and SGT-501 uses a transient transfection-based process which requires processing steps that are more complex than those required for most chemical pharmaceuticals. We also intend to use transient transfection manufacturing for our other Candidates. Moreover, unlike chemical pharmaceuticals, the physical and chemical properties of a gene therapy candidate such as ours generally cannot be fully characterized. As a result, assays of the finished product may not be sufficient to ensure that the product will perform in the intended manner. Accordingly, we have and will continue to employ multiple steps to control our manufacturing processes to assure that the process works and that SGT-003, SGT-212, SGT-501 and our other Candidates are made strictly and consistently in compliance with such processes. We must supply all necessary documentation in support of an IND, BLA or MAA on a timely basis and must adhere to the FDA's and the European Union's cGMP requirements before we can obtain marketing approval for SGT-003, SGT-212, SGT-501, and other Candidates. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with cGMP requirements, by performing extensive audits of contract laboratories, manufacturers and suppliers.

We currently rely on multiple third-party manufacturers for supply of SGT-003, SGT-212 and SGT-501 and plan to rely on third-party manufacturers for our other Candidates. In order to produce sufficient quantities of Candidates for clinical trials and initial U.S. commercial demand, we have and will continue to further optimize and increase the capacity of our manufacturing process at our third-party manufacturers. We may need to make changes to our manufacturing processes, beyond implementation of a transient transfection-based manufacturing process. We may not be able to produce sufficient quantities of drug product due to several factors, including capacity constraints, equipment malfunctions, facility contamination, material shortages or contamination, natural disasters, a public health issue (for example, an outbreak of a contagious disease such as the COVID-19 pandemic), disruption in utility services, human error or disruptions in the operations of our suppliers. We may experience variability with respect to the success and yield between lots that will require continued engagement in process development activities to improve the reproducibility, reliability, quality and consistency of yields of the manufacturing process. Additional manufacturing runs will be required to produce necessary or adequate supply for our future clinical trials and there is no guarantee that all of those runs will be within specifications or produce adequate supply. If we are not able to produce sufficient supply on the timeline expected, our overall development schedule for SGT-003, SGT-212, SGT-501 and other Candidates could be delayed, and we could incur additional expense. Any such failure could delay or prevent development and commercialization of SGT-003, SGT-212, SGT-501 or other Candidates.

If supply from a manufacturing facility is interrupted, including as a result of capacity constraints, equipment malfunctions, facility contamination, material shortages or contamination, natural disasters, public health emergencies or pandemics, such as the recent COVID-19 pandemic, disruption in utility services or human error, there could be a significant disruption in supply of SGT-003 or other Candidates. In such instance, we may need to locate appropriate replacement third-party manufacturers, and we may not be able to enter into arrangements with such additional third-party manufacturers on favorable terms or at all. Use of new third-party manufacturers could increase the risk of delays in production or insufficient supplies of our Candidates as we transfer our manufacturing technology to these manufacturers and as they gain experience manufacturing our Candidates.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, the FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable tests at any time. Under some circumstances,

the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a lot until the agency authorizes its release. Lot failures or product recalls could cause us to delay or abandon clinical trials or product launches.

We also may encounter problems hiring and retaining the experienced scientific, quality control and manufacturing personnel needed to oversee our manufacturing and quality control process, which could result in delays in our production or difficulties in maintaining compliance with applicable regulatory requirements.

Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including biotechnology and pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. Problems in our manufacturing process or facilities also could restrict our ability to meet market demand for our Candidates.

We expect to utilize third parties to conduct our product manufacturing for the foreseeable future. Therefore, we are subject to the risk that these third parties may not perform satisfactorily or meet regulatory requirements.

We do not independently manufacture material for our ongoing or planned clinical trials and we are utilizing and expect to utilize materials manufactured by cGMP-compliant third-party suppliers. If these third-party manufacturers do not successfully carry out their contractual duties, meet expected deadlines or manufacture our Candidates in accordance with quality and regulatory requirements or if there are disagreements between us and these third-party manufacturers, we may not be able to complete, or may be delayed in completing, the clinical trials required for approval of our Candidates. In such instances, we may need to locate an appropriate replacement third-party relationship, which may not be readily available or on acceptable terms, which would cause additional delay or increased expense prior to the approval of our Candidates.

Additionally, we rely on our third-party manufacturers for their compliance with the cGMP and their maintenance of adequate quality control, quality assurance and qualified personnel. Furthermore, all of our third-party suppliers and manufacturers are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes them to regulatory risks for the production of such materials and products. FDA inspections may identify compliance issues at third-party manufacturer facilities or at the facilities of third-party suppliers that may disrupt production or distribution, or require substantial resources to correct and prevent recurrence of any deficiencies, and could result in fines or penalties by regulatory authorities. In addition, discovery of problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action, including fines, injunctions, civil penalties, license revocations, seizure, total or partial suspension of production or criminal penalties, any of which could significantly and adversely affect supplies of our Candidates.

In addition, we do not currently have long-term supply or manufacturing arrangements in place for the production of our Candidates at commercial scale. Although we intend to establish additional sources for long-term supply, from one or more third-party manufacturers, if the gene therapy industry were to grow, we may encounter increasing competition for the materials necessary for the production of Candidates. We may experience difficulties in scaling up production beyond clinical batches. Furthermore, demand for third-party cGMP manufacturing facilities may grow at a faster rate than existing manufacturing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of our Candidates for future clinical trials or to meet initial commercial demand in the United States. We currently rely, and expect to continue to rely, on additional third parties to manufacture materials for our Candidates and to perform quality testing. We intend to maintain third-party manufacturers for these materials, as well as to serve as additional sources of our Candidates, which will expose us to risks including reduced control of manufacturing activities;

- the inability of certain CDMOs to produce our Candidates in the necessary quantities, or in compliance with current cGMP or in compliance with pertinent regulatory requirements and within our planned time frame and cost parameters;
- the inability of our CDMOs to pass regulatory inspections and supply commercial material, which could impact our commercialization timelines;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturer and our and their suppliers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier, natural disasters or public health issues.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our Candidates. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of product manufacture.

If we are unable to establish sales, distribution and marketing capabilities or enter into agreements with third parties to market and sell our Candidates, we will be unable to generate any product revenue.

We currently have no sales, distribution or marketing organization. To successfully commercialize any Candidate that may result from our development programs, we will need to develop these capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract sales force to market any Candidate we may develop will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may enter into collaborations regarding our Candidates with other entities to utilize their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any future collaborators do not commit sufficient resources to commercialize our Candidates, or we are unable to develop the necessary capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We compete with many companies that currently have extensive, experienced and well-funded sales, distribution and marketing operations to recruit, hire, train and retain marketing and sales personnel. We will also face competition in our search for third parties to assist us with the sales and marketing efforts of any future products. Without an internal team or the support of a third party to perform marketing and sales functions, we will be unable to compete successfully against these more established companies.

If we are unable to establish medical affairs capabilities, we will be unable to establish an educated market of physicians to administer any future products.

We currently have no medical affairs team. If we are unable to successfully build a medical affairs team to address scientific and medical questions and provide expert guidance and education in the application, administration and utilization of any future products to physicians, we may not be able to establish an educated market for our products. The establishment and development of our own medical affairs team will be expensive and time-consuming and could delay any product launch. Moreover, we cannot be certain that we will be able to successfully develop this capability.

If the market opportunities for any of our future products are smaller than we believe they are, our revenue prospects may be adversely affected and our business may suffer.

We currently focus our research and product development on treatments for rare genetic neuromuscular and cardiac indications. Our understanding of the patient population with these diseases is based on estimates in published literature and by disease-focused foundations. These estimates may prove to be incorrect and new studies may reduce the estimated incidence or prevalence of these diseases. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our Candidates or patients may become increasingly difficult to identify and access.

Further, there are several factors that could contribute to reducing the actual number of patients who could receive our Candidates less than the potentially addressable market. These include the lack of widespread availability of, and limited reimbursement for, new therapies in many underdeveloped markets. Further, the severity of the progression of a degenerative disease such as Duchenne and FA up to the time of treatment will likely diminish the therapeutic benefit conferred by a gene therapy due to irreversible cell damage.

Certain patients' immune systems might prohibit the successful delivery of certain gene therapy products, thereby potentially limiting the population of patients amenable to gene transfer.

As with many AAV-mediated gene therapy approaches, certain patients' immune systems might prohibit the successful delivery of certain gene therapy products, thereby potentially limiting the population of patients amenable to gene transfer. While we are working to better understand the prevalence of antibodies to AAV, or seroprevalence, as it relates to gene therapy, the exact seroprevalence is currently unknown and varies by AAV serotype and age. We may not be able to address these potentially limiting factors for gene therapy as a treatment for certain patients.

The commercial success of any of our Candidates, if approved, will depend upon market acceptance by physicians, patients, third-party payors and others in the medical community.

Even with the requisite approvals from the FDA in the United States, the European Commission in the European Union and other regulatory authorities internationally, the commercial success of our Candidates will depend, in part, on the acceptance of physicians, patients and health care payors of gene therapy products in general, and, in particular for each of our current and future Candidates, as medically necessary, cost-effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community due to ethical, social, medical and legal concerns. If our products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of gene therapy products and, in particular, our current and future Candidates, if approved for commercial sale, will depend on multiple factors, including:

- the efficacy and safety of our current and future Candidates as demonstrated in clinical trials;
- the efficacy and potential and perceived advantages of our Candidates over alternative treatments;
- the cost of treatment relative to alternative treatments;
- the clinical indications for which our Candidates are approved by the FDA, the European Commission or other regulatory authorities, as applicable;
- the willingness of physicians to prescribe new therapies;
- the willingness of the target patient population to try new therapies;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA, the EMA or other regulatory authorities, including any limitations or warnings contained in a product's approved labeling;
- relative convenience and ease of administration;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of products to meet market demand;
- publicity concerning our Candidates or competing products and treatments;
- any restrictions on the use of our products together with other medications; and
- favorable third-party payor coverage and adequate reimbursement.

Even if a potential Candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after it is launched.

Our efforts to educate the medical community and third-party payors on the benefits of our Candidates may require significant resources and may never be successful. Such efforts may require more resources than are typically required due to the complexity and uniqueness of our potential Candidates. If our Candidates are approved but fail to achieve market acceptance among physicians, patients or third-party payors, we will not be able to generate significant revenue from any such product.

Our gene transfer approach utilizes capsids derived from a virus, which may be perceived as unsafe or may result in unforeseen adverse events. Negative public opinion and increased regulatory scrutiny of gene therapy may damage public perception of the safety of gene transfer Candidates and adversely affect our ability to conduct our business or obtain regulatory approvals for our Candidates.

Gene transfer remains a novel technology that faces many challenges imposed by the humoral immune response. The immunogenicity of AAV gene transfers is a very complex process that we and others continue to work understand through the extensive clinical experience that now exists over a broad spectrum of therapeutic areas and indications. Marked inflammatory toxicities have been observed, including complement activation, cytopenias, severe hepatotoxicity as well as transgene related toxicities representing part of the continuum of diverse aspects of clinical immune responses that can be observed post gene transfer.

In particular, our success will depend upon physicians who specialize in the treatment of our pipeline indications, prescribing treatments that involve the use of viral capsids in lieu of, or in addition to, other treatments with which they are more familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion may

delay or impair the development and commercialization or demand for any Candidate we may develop. A public backlash developed against gene therapy following the death of a participant in 1999 during a gene therapy clinical trial of research subjects with ornithine transcarbamylase (“OTC”) deficiency, a rare disorder in which the liver lacks a functional copy of the OTC gene. The death of the clinical trial subject was due to complications of adenovirus capsid administration. Dr. James M. Wilson, former chair of our Scientific Advisory Board, was a co-investigator of the 1999 trial while he was Director of the Institute for Human Gene Therapy of the University of Pennsylvania. Serious adverse events in our clinical trials, including the events that led to the previously-lifted clinical holds on IGNITE DMD or other clinical trials involving gene transfer products or our competitors’ products, even if not ultimately attributable to the relevant Candidates, and the resulting publicity, could result in increased government regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our Candidates, stricter labeling requirements for our Candidates, if approved, and a decrease in demand for our Candidates.

Any contamination in our manufacturing process, shortages of materials or failure of any of our key suppliers to deliver necessary components could result in interruption in the supply of our Candidates and delays in our clinical development or commercialization schedules.

Given the nature of biologics manufacturing, there is a risk of contamination in our manufacturing processes. Any contamination could materially adversely affect our ability to produce our Candidates on schedule and could cause reputational damage.

Some of the materials required in our manufacturing process are derived from biologic sources. Such materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of our Candidates could adversely impact or disrupt the manufacturing or the production of clinical material, which could materially and adversely affect our development timelines.

The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our Candidates, if approved, could limit our ability to market those products and decrease our ability to generate product revenue.

There is significant uncertainty related to third-party coverage and reimbursement of newly approved products. We expect the cost of a single administration of gene transfer products, such as those we are developing, to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our future products, if approved, will depend substantially, both domestically and abroad, on the extent to which the costs of such Candidates will be paid by health maintenance, managed care, pharmacy benefit and similar health care management organizations, or will be reimbursed by government authorities, private health coverage insurers and other third-party payors. Coverage and reimbursement by a third-party payor may depend upon several factors, including the third-party payor’s determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective;
- durable and a one-time treatment, as applicable; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement for a product from third-party payors is a time-consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost-effectiveness data. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our future products, if approved. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment.

To our knowledge, only a limited number of gene transfer products have been approved for coverage and reimbursement by CMS, the agency responsible for administering the Medicaid program. It is difficult to predict what the CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, as there is no body of established practices and precedents for these types of products either in the United States or the European Union. For example, several cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in

certain European Union member states and vice versa. It is difficult to predict what third-party payors will decide with respect to the coverage and reimbursement for our future products, if approved.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.

Outside the United States, international operations generally are subject to extensive government price controls and other market regulations, and increasing emphasis on cost-containment initiatives in the European Union, Canada and other countries may put pricing pressure on us. In general, the prices of therapeutics outside the United States are substantially lower than in the United States. Other countries may allow companies to fix their own prices for therapeutics, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulations could restrict the amount that we are able to charge for our Candidates. Accordingly, in markets outside the United States, the reimbursement for our Candidates may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenue.

Additionally, in countries where the pricing of gene therapy products is subject to governmental control, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our Candidate to other available therapies. Reimbursement of our products may be unavailable or limited in scope or amount, which would adversely affect our revenue, if any.

If we obtain approval to commercialize our future products outside of the United States, in particular in the European Union, a variety of risks associated with international operations could materially adversely affect our business.

We expect that we will be subject to additional risks in commercializing our future products, if approved, outside the United States, including:

- different regulatory requirements for approval of therapeutics in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing and insurance regimes;
- production shortages resulting from any events affecting material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism or natural disasters including earthquakes, typhoons, floods and fires.

The failure to comply with applicable foreign regulatory requirements may result in, among other things, fines, suspension, variation or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

If we engage in future acquisitions or strategic collaborations, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. Any potential acquisition or strategic collaboration may entail numerous risks, including:

- increased operating expenses and cash requirements;

- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing Candidates and initiatives in pursuing such acquisition or strategic collaboration;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or collaboration or even to offset transaction costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition or collaboration opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

Risks Related to our Business Operations

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

We are highly dependent on members of our executive team, the loss of whose services may adversely impact the achievement of our objectives. While we have entered into employment agreements with certain of our executive officers, any of them could leave our employment at any time. We currently do not have "key person" insurance on any of our employees. The loss of the services of one or more of our current key employees might impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining other qualified employees, consultants and advisors for our business, including scientific and technical personnel, also will be critical to our success. There currently is a shortage of skilled individuals with substantial gene therapy experience, which is likely to continue. As a result, competition for skilled personnel, including in gene therapy research and capsid manufacturing, is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies and academic institutions for individuals with similar skill sets. In addition, the failure to succeed in preclinical or clinical trials or applications for marketing approval may make it more challenging to recruit and retain qualified personnel. The inability to recruit, or loss of services of certain executives, key employees, consultants or advisors, may impede the progress of our research, development and commercialization objectives.

If we are unable to manage growth in the scale and complexity of our operations, our performance may suffer.

If we are successful in executing our business strategy, we will need to expand our managerial, operational, financial and other systems and resources to manage our operations, continue our research and development activities and, in the longer term, build a commercial infrastructure to support commercialization of our current and future Candidates and products that are approved for sale. Future growth would impose significant added responsibilities on members of management. It is likely that our management, finance, development personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and any future Candidates requires that we continue to develop more robust business processes and improve our systems and procedures in each of these areas and to attract and retain sufficient numbers of talented employees. We may be unable to successfully implement these tasks on a larger scale and, accordingly, may not achieve our research, development and growth goals.

Our employees may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk of employee fraud or other misconduct, including intentional failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, provide accurate information to the FDA or comparable foreign regulatory authorities, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign

regulatory authorities, report financial information or data accurately or disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. This could include violations of the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), other U.S. federal and state law, and requirements of non-U.S. jurisdictions, including the European Union Data Protection Directive. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards, regulations, guidance or codes of conduct. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our Candidates and may affect the prices we may set.

Our business and financial prospects could be affected by changes in health care spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to health care availability, the method of delivery or payment for health care products and services could negatively impact our business, operations and financial condition.

For example, in the United States there is significant interest in promoting health care reform, as evidenced by the enactment of the Patient Protection and Affordable Care Act and the companion Health Care and Education Reconciliation Act (the “Health Care Reform Law”). The Health Care Reform Law increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud and abuse, and to provide access to increased health coverage.

The Health Care Reform Law also imposed substantial changes to the U.S. system for paying for health care, including programs to extend medical benefits to millions of individuals who have lacked insurance coverage. Generally, implementation of the Health Care Reform Law has thus far included significant cost-saving, revenue and payment reduction measures with respect to, for example, several government health care programs that might cover our products in the United States, should they be commercialized, including Medicaid and Medicare. Additional downward pricing pressure associated with the Health Care Reform Law includes that the Health Care Reform Law established and provided significant funding for a Patient-Centered Outcomes Research Institute to coordinate and fund Comparative Effectiveness Research, as those terms are defined in the Health Care Reform Law. While the stated intent of Comparative Effectiveness Research is to develop information to guide providers to the most efficacious therapies, outcomes of Comparative Effectiveness Research could influence the reimbursement or coverage for therapies that are determined to be less cost-effective than others. Should any of our products be approved for sale, but then determined to be less cost-effective than alternative therapies, the levels of reimbursement for these products, or the willingness to reimburse at all, could be adversely impacted.

In addition to legislative changes resulting from the passage of the Health Care Reform Law, other legislative changes have been proposed and adopted since the Health Care Reform Law was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which will remain in effect through the first half of 2032. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester through 2031. These Medicare sequester reductions were suspended through June 2022, with the full 2% cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our Candidates for which we may obtain regulatory approval or the frequency with which any such Candidate is prescribed or used.

Since enactment of the Health Care Reform Law, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017 (“TCJA”), Congress repealed the “individual mandate.” The repeal of this provision of the Health Care Reform Law, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, on December 14, 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the Health Care Reform Law is an essential and inseparable feature of the Health Care Reform Law, and therefore because the mandate

was repealed as part of the TCJA, the remaining provisions of the Health Care Reform Law are invalid as well. The U.S. Supreme Court heard this case on November 10, 2020 and on June 17, 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the statute. It is unclear how such litigation and other efforts to repeal and replace the Health Care Reform Law will impact the Health Care Reform Law and our business. Litigation and legislation over the Health Care Reform Law are likely to continue, with unpredictable and uncertain results.

Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition.

Income, sales, use or other tax laws, statutes, rules, or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities, and cash tax obligations. For example, the Inflation Reduction Act (the “IRA”), was signed into law in August 2022, and the One Big Beautiful Bill Act (“OBBBA”), was signed into law in July 2025. The IRA introduced new tax provisions, including a 1% excise tax imposed on certain stock repurchases by publicly traded companies. The 1% excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to exceptions. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may significantly affect our business or financial condition. The recent changes under the OBBBA include tax rate extensions and changes to the business interest deduction limitation, the expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), the bonus depreciation deduction rules, and the international tax framework. Regulatory guidance under the IRA, the OBBBA, and other tax-related legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. In addition, it is uncertain if and to what extent various states will conform to changes to federal tax legislation.

Current and future legislative efforts may limit the prices for our products, if and when they are licensed for marketing and that could materially impact our ability to generate revenues.

The costs and prices of prescription pharmaceuticals have been the subject of considerable discussion in the United States. To date, there have been several U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. At the federal level, Congress and the current administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

In addition, in October 2020, the HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America (“PhRMA”), but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of drugs from Canada. Certain of these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. Florida now has authority to import certain products from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each product selected for importation, which must be approved by the FDA. Florida will also need to relabel the products and perform quality testing of the products to meet FDA standards. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit a draft proposal for pre-review and meet with the agency to obtain initial feedback from the FDA prior to formally submitting their section 804 importation program proposal. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the FDA and ultimately shortening the review timeline. Further, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law.

Further, on November 20, 2020, the HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Medicare Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which has been delayed until January 1, 2032, by the IRA.

The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. With passage of the OBBBA in July 2025, Congress extended this exemption to drugs and biologics with multiple orphan drug designations. The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023. On August 15, 2024, HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions, including diabetes, chronic kidney disease, and rheumatoid arthritis. The prices of these ten drugs will become effective January 1, 2026. In August 2024, HHS published the results of the first Medicare drug price negotiations for ten selected drugs that treat a range of conditions and the prices will become effective January 1, 2026. In January 2025, CMS announced the next 15 drug and biologic prices that will be subject to the IRA's price negotiation provisions. This second cycle of negotiations with participating drug companies will occur during 2025, and any negotiated prices for this second set of drugs will be effective starting January 1, 2027. CMS issued a public statement on January 2025, declaring that lowering the cost of prescription drugs is a top priority of the new administration and CMS is committed to considering opportunities to bring greater transparency in the negotiation program.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated \$2,000 a year beginning in 2025.

The IRA includes a provision exempting orphan drugs from Medicare price negotiation but this exclusion has been interpreted by CMS in final guidance issued in July 2023 to apply only to those orphan drugs with an approved indication (or indications) for a single rare disease or condition. The final guidance clarifies that CMS will consider only active designations/approvals when evaluating a drug for the exclusion, such that designations/indications withdrawn before the selected drug publication date will not be considered. CMS also clarified that, if a drug loses its orphan drug exclusion status, the agency will use the earliest date of approval/licensure to determine whether the product is a qualifying single source drug subject to price negotiations.

In June 2023, Merck filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including pharmaceutical companies, also filed lawsuits in various courts with similar constitutional claims against HHS and CMS. There have been various decisions by the courts considering these cases since they were filed. The HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing. Most of these cases are now on appeal. In October 2024, the U.S. Court of Appeals for the Third Circuit heard oral argument in three of these cases. In May 2025, the Third Circuit rejected a pharmaceutical company's challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the U.S. Constitution since there is no protected property interest in selling goods to Medicare beneficiaries at a price higher than what the government is willing to pay in reimbursement. We expect that litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

In April 2025, the President issued an executive order directing the HHS to take steps to reduce the prices of pharmaceutical products, repeating many of the proposals advanced during the first Trump Administration, including directing the FDA to streamline and improve its existing drug importation program so as to make it easier for states to obtain approval without sacrificing the safety or quality of drug products. Other provisions of the executive order relate to the 340B program. Specifically, one provision calls on the Secretary of HHS to determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments and to consider and propose any appropriate adjustments for Medicare payment. The other provision directs HHS to condition grant funding to certain health centers on those centers passing through the 340B discounts they receive on insulin and injectable epinephrine products to patients who meet certain requirements. With respect to the IRA's Medicare drug pricing program, the executive order, among other things, calls for alignment in "the treatment of small molecule prescription drugs with that of biological products, ending the distortion that undermines relative investment in small molecule prescription drugs, coupled with other reforms to prevent any increase in overall costs to Medicare and its beneficiaries."

On May 12, 2025, the President issued an additional executive order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The executive order directs the Secretary of HHS to communicate most-favored-nation ("MFN"), price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. The executive order further provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes MFN pricing in the United States. Subsequently, on May 20, 2025, HHS indicated that the proposed MFN pricing will apply only to brand products without generic or biosimilar competition and the referenced foreign countries will include only those in which the branded product similarly does not have generic or biosimilar competition. Second, HHS indicated that the MFN target price will be the lowest price in a country that is a member of the Organization for Economic Co-operation and Development ("OECD") with a gross domestic product ("GDP") per capita of at least 60% of the U.S. GDP per capita. Based on previous estimates, there are likely at least 22 OECD countries that would satisfy this criterion. The implications of these actions remain unclear and are likely to result in litigation if the administration pursues an MFN regulatory pricing requirement.

More recently, on July 31, 2025, the President issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025 executive order and demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, return increased revenues abroad to American patients and provide for direct purchasing at MFN pricing. The letters also urged these companies to stipulate that they will not offer other developed nations lower prices for new drugs than the prices offered for such products in the U.S. Virtually all of these pharmaceutical companies have entered into agreements with the administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, President Trump launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the administration's pricing agreements with pharmaceutical manufacturers.

In December 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as OECD countries with a GDP of \$400 billion and a per capita GDP that is at least 60% of the US per capita GDP (an initial list of 19 reference countries is included in the proposed rule). Comments are due on the proposed pilot program rules on or before February 23, 2026, and the pilot programs are proposed to go into effect beginning October 1, 2026.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states, for example, require drug manufacturers and other entities in the drug supply chain, including health carriers, pharmacy benefit managers, wholesale distributors, to disclose information about pricing of pharmaceuticals. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal

and state governments will pay for healthcare products and services, which could result in reduced demand for our Candidates or additional pricing pressures.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing health care legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other health care payors to contain or reduce costs of health care may adversely affect:

- the demand for any Candidates for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Finally, in the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our Candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our Candidates, restrict or regulate post-approval activities and affect our ability to commercialize our Candidates, if approved.

In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our Candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Our relationships with customers, physicians and third-party payors will be subject, directly or indirectly, to federal and state health care fraud and abuse laws, false claims laws, health information privacy and security laws, and other health care laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

If we obtain FDA approval for our current or future Candidates and begin commercializing one or more of those products in the United States, our operations will be directly or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Health Care Program Anti-Kickback Statute, the federal civil and criminal laws and the Physician Payment Sunshine Act and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Health Care Program Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal health care program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The Health Care Reform Law amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The Health Care Reform Law provides and recent government cases against pharmaceutical and medical device manufacturers support the view that Federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act;
- HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any health care benefit program, regardless of the payor (e.g., public or private);
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers;
- federal transparency laws, including the federal Physician Payment Sunshine Act, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to the CMS information related to: (i) payments or other “transfers of value” made to physicians, other healthcare professionals and teaching hospitals and (ii) ownership and investment interests held by physicians and their immediate family members;
- state and foreign law equivalents of each of the above federal laws, state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in government health care programs, such as Medicare and Medicaid, imprisonment and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management’s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that we may run afoul of one or more of the requirements.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, EU and UK. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of

goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

In 2018, California passed into law the California Consumer Privacy Act (“CCPA”) which took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA’s requirements are similar to those found in the General Data Protection Regulation (“GDPR”), including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt-out of “sales” of their personal information. The CCPA contains significant penalties for companies that violate its requirements. In November 2020, California voters passed a ballot initiative for the California Privacy Rights Act (“CPRA”), which went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR-like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility is to enforce the CPRA and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, several other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime over the next several years. Like the CCPA and CPRA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of “sensitive” data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering privacy laws that will go into effect over the next several years. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Plaintiffs’ lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits could create potential risk for our business.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area (“EEA”), and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners’ or service providers’ privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the EU to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020, the Court of Justice of the European Union (the “CJEU”) invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the U.S. The CJEU decision also drew into question the long-term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the U.S. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the U.S. generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Following the withdrawal of the UK from the EU, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the UK and the EU have determined, through separate “adequacy” decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. The UK and the U.S. have also agreed to a U.S.-UK “Data Bridge”, which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the UK to the United States. In addition to the UK, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the United States). Any changes or updates to these developments have the potential to impact our business.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Commission initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022 and the European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU to the U.S. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. There is currently one pending litigation against the EU-U.S. Data Privacy Framework before the CJEU. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business internationally.

Following Brexit, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the United Kingdom and the EU have determined, through separate “adequacy” decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. Any changes or updates to these adequacy decisions have the potential to impact our business.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, through increased compliance costs, costs associated with contracting and potential enforcement actions.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

We are subject to anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures and legal expenses, be precluded from developing manufacturing and selling certain products outside the United States or be required to develop and implement costly compliance programs, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010 (“Bribery Act”), the U.S. Foreign Corrupt Practices Act (“FCPA”), and other anti-corruption laws that apply in countries where we do business and may do business in the future. The Bribery Act, FCPA and these other laws generally prohibit us, our officers, and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. Compliance with the FCPA, in particular, is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry, because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

We may in the future operate in jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted. If we expand our operations outside of the United States, we will need to dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws. In addition, various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and Candidates outside of the United States, which could limit our growth potential and increase our development costs.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. The Securities and Exchange Commission also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA’s accounting provisions. Any investigation of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any Candidate that we may develop.

We face an inherent risk of product liability exposure related to the testing of SGT-003, SGT-212, SGT-501 and any of our current and future Candidates in preclinical studies and clinical trials and may face an even greater risk if we commercialize any Candidate that we may develop. If we cannot successfully defend ourselves against claims that our Candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any Candidate that we may develop;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- significant time and costs to defend the related litigation;
- withdrawal of clinical trial participants;

- the inability to commercialize any of our Candidates; and
- injury to our reputation and significant negative media attention.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we commence additional clinical trials and if we successfully commercialize any Candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and viruses and other biologic materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages. We also could incur significant costs associated with civil or criminal fines and penalties. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Although we maintain workers' compensation insurance for certain costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities.

Our internal computer systems, or those of our collaborators, contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development.

Despite the implementation of security measures, our internal computer systems and those of our current and any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such systems are also vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third-party vendors and/or business partners, or from cyber-attacks by malicious third parties. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient.

While we are not aware of any such material system failure, accident, cyber-attack or security breach to date, if such an event were to occur and cause interruptions in our or our collaborators', contractors' or consultants' operations, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our current and other future Candidates could be delayed.

Risks Related to our Intellectual Property

We heavily rely on certain in-licensed patents and other intellectual property rights in connection with our development of our Candidates and may be required to acquire or license additional patents or other intellectual property rights to continue to develop and commercialize our Candidates.

Our ability to develop and commercialize our Candidates is heavily dependent on licenses to patent rights and other intellectual property granted to us by third parties. In particular, we have licensed certain patents and patent applications from the University of Missouri, the University of Washington and others that are important or necessary to the development of SGT-003, our other Candidates and other elements of our gene transfer program. We have further licensed certain intellectual property from the University of Pennsylvania and others that are important or necessary to the development of SGT-212 and from ICS Maugeri that are important or necessary to the development of SGT-501. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, development and commercialization obligations, milestone payments, royalties and other obligations on us. If we fail to comply with our obligations under our agreements, we may be subject to damages, which may be significant, and the licensor may have the right to terminate the license, in which event we may not be able to develop or market Candidates or technologies covered by the license. In addition, certain of these license agreements are not assignable by us without the consent of the respective licensor, which may have an adverse effect on our ability to engage in certain transactions.

Under certain of our existing license agreements, we do not have, and under future license agreements we may not have, the right to control the preparation, filing and prosecution of patent applications, or the maintenance, enforcement and defense of the patents and patent applications that we license from third parties. For example, under our inbound license agreements with the University of Missouri and the University of Washington, each of the applicable licensors controls the prosecution of patent applications and the maintenance of patents and patent applications. Therefore, we cannot be certain that the licensed patents and applications will be prosecuted, maintained, enforced and defended in a manner consistent with the best interests of our business. If our licensors fail to maintain, enforce or defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any of our Candidates that are the subject of such licensed rights could be adversely affected. For more information, see Part I, Item 1, “Business—Strategic Partnerships and Collaborations/Licenses”.

Moreover, licenses to additional third-party intellectual property, technology and materials may be required for our development programs but may not be available in the future or may not be available on commercially reasonable terms. For example, third parties may claim that the constructs containing the gene or protein of interest and the AAV capsids we are developing for use in product candidates are covered by patents held by them. We believe that we would have valid defenses to any such claims; however, if any such claims were ultimately successful, we might require a license to continue to use and sell Candidates and such AAV capsids. Such licenses may not be available on commercially reasonable terms, or at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. Moreover, even if we are able to obtain such licenses, they may only be non-exclusive, which could permit competitors and other third parties to use the same intellectual property in competition with us.

We may collaborate with non-profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. These institutions may provide us with an option to negotiate a license to any of the institution’s licensable rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the required timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program.

If we are unable to successfully obtain rights, or successfully challenge such rights, to any third-party intellectual property rights that are required for the development and commercialization of our Candidates, and such third-party intellectual property rights are successfully asserted against us, we may be liable for damages, which may be significant, and we may be required to cease the development and commercialization of our Candidates.

If we are unable to obtain and maintain patent protection for our Candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our Candidates may be adversely affected.

Our success depends, in large part, on our and our licensors' ability to seek, obtain, maintain, enforce and defend patent rights in the United States and other countries with respect to our Candidates and our future innovation related to our manufacturing technology. Our licensors and we have sought, and we intend to continue to seek, to protect our proprietary position by filing patent applications in the United States and, in at least some cases, one or more countries outside the United States related to our Candidates that are important to our business. However, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents or whether the claims of any issued patents will provide us with a competitive advantage.

Moreover, although we have pending patent applications in the United States and abroad, we cannot predict whether or in which jurisdictions the pending applications will result in issuance of patents that effectively protect any of our Candidates or will effectively prevent others from commercializing competitive products. Further, each of the provisional patent applications is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of each provisional patent application. If we do not timely file a non-provisional patent application in respect of a provisional patent application, we may lose our priority date with respect to such provisional patent application and any patent protection on the inventions disclosed in such provisional patent application. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether such future patent applications will result in the issuance of patents that effectively protect any of our Candidates or will effectively prevent others from commercializing competitive products.

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted regarding non-patent exclusivity. For example, EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products, which may reduce the duration of regulatory data protection and exclusivity periods for orphan drugs, and revise the eligibility for expedited pathways in addition to other changes, was published on April 26, 2023. On April 10, 2024, the European Parliament adopted a position on the proposal requesting several amendments to the package. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may, however, have a significant impact on the pharmaceutical industry and our business in the long term.

We may not be able to file, prosecute, maintain, enforce, defend or license all patents that are necessary to our business.

The patent prosecution process is expensive, time-consuming and complex, and we and our licensors may not be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner.

It is also currently unknown what claims may, if ever, issue from pending applications included in our patent rights. Additionally, certain of our in-licensed U.S. patent rights lack corresponding foreign patents or patent applications, and therefore we will be unable to obtain patent protection for our Candidates in certain jurisdictions. We or our licensors may not be able to obtain or maintain patent protection with respect to our Candidates.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights, and more generally, could affect the value of our intellectual property rights or narrow the scope of our licensed patents or future owned patents.

It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Patent applications included in our current and future patent rights may not result in patents being issued that protect our Candidates, effectively prevent others from commercializing competitive products or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. Even assuming patents issue from patent applications in which we have rights, changes in either the

patent laws or interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patents or narrow the scope of our patent protection.

Other parties have developed products that may be related or competitive to our own and such parties may have filed or may file patent applications, or may have received or may receive patents, claiming inventions that may overlap or conflict with those claimed in our patent applications or issued patents. We may not be aware of all third-party intellectual property rights potentially relating to our Candidates. In addition, we cannot provide any assurances that any of the inventions disclosed in our patent applications will be found to be patentable, including over third-party or our own prior art patents, publications or other disclosures, or will issue as patents. Even if our patent applications issue as patents, we cannot provide any assurances that such patents will not be challenged or ultimately held to be invalid or unenforceable. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and in other jurisdictions are typically not published until 18 months after filing, or, in some cases, at all. Therefore, we cannot know with certainty whether the inventors of our licensed patents and applications were the first to make the inventions claimed in those patents or pending patent applications, or that they were the first to file for patent protection of such inventions. Similarly, should we own any issued patents or patent applications in the future, we may not be certain that we were the first to file for patent protection for the inventions claimed in such patents or patent applications. Furthermore, given the differences in patent laws in the United States, Europe and other foreign jurisdictions, for example, the availability of grace periods for filing patent applications and what can be considered as prior art, we cannot make any assurances that any claims in our pending and future patent applications in the United States or other jurisdictions will issue, or if they do issue, whether they will issue in a form that provides us with any meaningful competitive advantage. Similarly, we cannot make any assurances that if the patentability, validity, enforceability or scope of our pending or future patents and patent applications in the United States or foreign jurisdictions are challenged by any third party, that the claims of such pending or future patents and patent applications will survive any such challenge in a form that provides us with any meaningful competitive advantage. For example, we are aware of certain third-party patents and publications related to certain microdystrophin constructs. While we believe that our owned or in-licensed patents and patent applications claim novel and non-obvious features of microdystrophin constructs that are not described in such third-party patents or publications, such third-party patents and publications may have earlier priority or publication dates and may be asserted as prior art against our owned or in-licensed patents and applications. Any such challenge, if successful, could limit or eliminate patent protection for our products and Candidates or otherwise materially harm our business. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights cannot be predicted with any certainty.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or may own in the future do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents that we license or may own in the future may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether any of our Candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non-infringing manner.

The degree of patent protection we require to successfully compete in the marketplace may be unavailable. We cannot provide any assurances that any of the patents or patent applications included in our patent rights include or will include claims with a scope sufficient to protect our Candidates or otherwise provide any competitive advantage. In addition, the laws of foreign countries may not protect our proprietary rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Certain extensions may be available, however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new Candidates, patents protecting such Candidates might expire before or shortly after such Candidates are commercialized. As a result, our patent rights may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing products similar or identical to our Candidates, including biosimilar versions of such products.

Our licensed patents, and any patents we may own in the future, may be challenged, narrowed, invalidated or held unenforceable.

Even if we acquire patent protection that we expect should enable us to maintain some competitive advantage, third parties, including competitors, may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. In litigation, a competitor could claim that our in-licensed patents or any patents we may own in the future are not valid or enforceable for a number of reasons. If a court agrees, we would lose our rights to those challenged patents. Third parties also may raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such proceedings could result in the revocation or cancellation of or amendment to our licensed patents and any patents we may own in the future in such a way that they no longer cover our Candidates.

Even if issued, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our current and future patent rights may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third-party submission of prior art to the U.S. Patent and Trademark Office (“USPTO”) challenging the validity of one or more claims of patents included in our patent rights. Such submissions may also be made prior to a patent’s issuance, precluding the granting of a patent based on one of the pending patent applications included in our patent rights. We may become involved in opposition, derivation, revocation, reexamination, post-grant and *inter partes* review, or interference proceedings challenging one or more patents included in our patent rights. For example, competitors may claim that they invented the inventions claimed in patents or patent applications included in our patent rights, such as the microdystrophin we use in SGT-003, prior to the inventors of such patents or patent applications, or may have filed one or more patent applications before the filing of the patents or patent applications included in our patent rights. A competitor who can establish an earlier filing or invention date may also assert that we are infringing their patents and that we therefore cannot practice our technology related to our Candidates as claimed in the patents or patent applications included in our patent rights. Competitors may also contest patents or patent applications included in our patent rights by showing that the claimed subject matter was not patent-eligible, was not novel or was obvious or that the patent claims failed any other requirement for patentability or enforceability. In addition, we may in the future be subject to claims by our or our licensors’ current or former employees or consultants asserting an ownership right in the patents or patent applications included in our patent rights as an inventor or co-inventor, as a result of the work they performed.

An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar therapeutics, without payment to us, or could limit the duration of the patent protection covering our Candidates. Such challenges may also result in our inability to manufacture or commercialize our Candidates without infringing third-party patent rights, and we may be required to obtain a license from third parties, which may not be available on commercially reasonable terms or at all, or we may need to cease the development, manufacture and commercialization of one or more of our Candidates. In addition, if the breadth or strength of protection provided by the patents and patent applications included in our patent rights is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future Candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us.

Even if they are unchallenged, the patents and pending patent applications included in our patent rights may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patent rights by developing similar or alternative therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapeutic that provides benefits similar to one or more of our Candidates but that uses a capsid or an expression construct that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we license or pursue with respect to our Candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our Candidates could be negatively affected.

Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

We currently depend, and will continue to depend, on our license, collaboration and other similar agreements. Further development and commercialization of our Candidates and platform technologies may require us to enter into additional license, collaboration or other similar agreements. The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, impact our ability to sublicense the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected Candidates.

If any of our licenses or material relationships are terminated or breached, we may:

- lose our rights to develop and market our Candidates;
- lose patent protection for our Candidates;
- experience significant delays in the development or commercialization of our Candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or

- incur liability for damages.

These risks apply to any agreements that we may enter into in the future for our Candidates.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We have certain obligations under licensing agreements with third parties that include annual maintenance fees and payments that are contingent upon achieving various development, commercial and regulatory milestones. Pursuant to many of these license agreements, we are required to make milestone payments if certain development, regulatory and commercial sales milestones are achieved, and may have certain additional research funding obligations. Also, pursuant to the terms of many of these license agreements, when and if commercial sales of a licensed product commence, we must pay royalties to our licensors on net sales of the respective licensed products.

We have entered into, or plan to enter into, license agreements with third parties and may need to obtain additional licenses from one or more of these same third parties or from others to advance our research or allow our commercialization of our Candidates. It is possible that we may be unable to obtain such licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to redesign Candidates or the methods for manufacturing them or to develop or license replacement products, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our Candidates. We cannot provide any assurances that third-party patents or other intellectual property rights do not exist that might be enforced against our manufacturing methods, Candidates or any technologies we may develop, resulting in either an injunction prohibiting our manufacture or sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

The majority of our existing license agreements provide the licensor sole control of patent prosecution of the licensed technology, and we may be required to reimburse the licensor for their costs of patent prosecution. Future license agreements may require the same. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. Further, in certain of our license agreements our licensors have the first right to bring any actions against any third party for infringing on the patents we have licensed. Our license agreements also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing Candidates. Disputes may arise regarding intellectual property subject to our licensing agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our products or processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of licensed patented inventions.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize our Candidates. In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby resulting in disputes or litigation, which could cause us to incur substantial costs and distract management's time, and if we are unsuccessful, we could lose our ability to develop and commercialize products covered by these license agreements. If these licenses are ultimately terminated by the licensor, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of our future collaborators to develop, manufacture, market and sell our Candidates without infringing, misappropriating or otherwise violating the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and complex litigation regarding patents and other intellectual property rights. We or our licensors may in the future become party to, or be threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our Candidates, including interference proceedings, post grant review and *inter partes* review before the USPTO. Our competitors or other third parties may assert infringement claims against us, alleging that, among other things, our therapeutics, manufacturing methods, formulations or administration methods are covered by their patents.

Given the vast number of patents in our field of technology, we cannot be certain or guarantee that a court would hold that any of our Candidates do not infringe an existing patent or a patent that may be granted in the future. Many companies and institutions have filed, and continue to file, patent applications related to gene therapy and related manufacturing methods. Some of these patent applications have already been allowed or issued and others may issue in the future. Since this area is competitive and of strong interest to pharmaceutical and biotechnology companies, there will likely be additional patent applications filed and additional patents granted in the future, as well as additional research and development programs expected in the future. Furthermore, because patent applications can take many years to issue, may be confidential for 18 months or more after filing and can be revised before issuance, there may be applications now pending that may later result in issued patents that may be infringed by the manufacture, use, sale or importation of our Candidates and we may or may not be aware of such patents. If a patent holder believes the manufacture, use, sale or importation of one of our Candidates infringes its patent, the patent holder may sue us even if we have licensed other patent protection for our Candidates. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our licensed patent portfolio may therefore have no deterrent effect.

It is also possible that we have failed to identify relevant third-party patents or applications for which we may need a license to develop and commercialize our Candidates. For example, applications filed before November 29, 2000, and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third-party patent rights that may be relevant to our Candidates because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our Candidates. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future Candidate, or we may incorrectly conclude that a third-party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our Candidates.

Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent or other intellectual property rights against us. For example, third parties may claim that gene or protein of interest, such as microdystrophin, or the AAV capsids we are developing for use in our Candidates are covered by patents held by them. Even if we believe such claim, or other intellectual property claims alleged by third parties, are without merit, there is no assurance that we would be successful in defending such claims. A court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize our Candidates covered by the asserted third-party patents. In order to successfully challenge the validity of any such U.S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U.S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U.S. patent. Similarly, there is no assurance that a court of competent jurisdiction would find that our Candidates did not infringe a third-party patent.

Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk that we may be found, to infringe, misappropriate or otherwise violate a third party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required or may choose to obtain a license from such third party to continue developing, manufacturing and marketing our Candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the

infringing Candidate. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. A finding of infringement, misappropriation or other violation of intellectual property rights, or claims that we have done so, could prevent us from manufacturing and commercializing our Candidates or force us to cease some or all of our business operations.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time-consuming. Competitors may infringe patents that we may own in the future or the patents of our licensing partners or we may be required to defend against claims of infringement. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing or misappropriating or successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents and applications and any patents and patent applications we may own in the future. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable intellectual property law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could have a material adverse effect on our business.

Some intellectual property that we have in-licensed may have been discovered through government-funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements, and a preference for U.S. manufacturing. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of the intellectual property rights we have licensed, including such rights licensed from the University of Missouri, the University of Washington and the University of Florida, are stated to have been generated through the use of U.S. government funding and may therefore be subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in our current or future Candidates pursuant to the Bayh-Dole Act of 1980 ("Bayh-Dole Act"). These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right to require us to grant exclusive, partially exclusive or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention, (ii) government action is necessary to meet public health or safety needs or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). The U.S. government also has the right to take title to these inventions if we, or the applicable licensor, fail to disclose the invention to the government and fail

to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We may not be able to protect our intellectual property and proprietary rights throughout the world.

Filing, prosecuting, maintaining, enforcing and defending patents on Candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. Although our license agreements grant us worldwide rights, certain of our in-licensed U.S. patents lack corresponding foreign patents or patent applications. For example, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States even in jurisdictions where we and our licensors pursue patent protection. Consequently, we and our licensors may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we and our licensors pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our inventions in jurisdictions where we and our licensors have not pursued and obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as it is in the United States. These products may compete with our Candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property rights, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, if pursued and obtained, or the marketing of competing products in violation of our intellectual property and proprietary rights generally. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could (i) result in substantial costs and divert our efforts and attention from other aspects of our business, (ii) put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and (iii) provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of the discovery and development processes of our Candidates or technology platforms that involve proprietary know-how, information or technology that is not covered by patents. Aspects of our manufacturing process are protected by trade secrets. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

We seek to protect our proprietary know-how, trade secrets and processes, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our employees, consultants, scientific advisors, CROs, manufacturers and contractors. These agreements typically limit the rights of third parties to use or disclose our confidential information. However, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, despite the existence generally of confidentiality agreements and other contractual restrictions. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary processes. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary know-how and trade secrets will be effective. If any of our employees, collaborators, CROs, manufacturers, consultants, advisors and other third parties who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. Enforcing a claim that a party illegally disclosed or misappropriated a

trade secret is difficult, expensive, and time-consuming, and the outcome is unpredictable. As a result, we could lose our trade secrets. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these security measures, they may still be breached, and we may not have adequate remedies for any breach.

In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Competitors could purchase our Candidates, if approved, and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe, misappropriate or otherwise violate our intellectual property rights, design around our protected know-how and trade secrets, or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate such trade secrets, from using that technology or information to compete with us. If our trade secrets are not adequately protected so as to protect our market against competitors' products and technologies, our competitive position could be adversely affected.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors, as well as our academic partners. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. An inability to incorporate such technologies or features would have a material adverse effect on our business and may prevent us from successfully commercializing our Candidates. Moreover, any such litigation or the threat of such litigation may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our Candidates. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. Moreover, even when we obtain agreements assigning intellectual property to us, the assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Moreover, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our Candidates.

Changes in either the patent laws or the interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy-Smith America Invents Act (the "Leahy-Smith Act") was signed into law. The Leahy-Smith Act includes several significant changes to U.S. patent law. Prior to March 2013 in the United States, assuming that other requirements for patentability are met, the first to make the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent through various post-grant proceedings administered by the USPTO. The USPTO developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business as, among other reasons, the USPTO must still

implement various regulations. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

The patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Two cases involving diagnostic method claims and “gene patents” have been decided by the U.S. Supreme Court. On March 20, 2012, the U.S. Supreme Court issued a decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (“Prometheus”), a case involving patent claims directed to a process of measuring a metabolic product in a patient to optimize a drug dosage for the patient. According to the U.S. Supreme Court, the addition of well understood, routine or conventional activity such as “administering” or “determining” steps was not enough to transform an otherwise patent-ineligible natural phenomenon into patent-eligible subject matter. On July 3, 2012, the USPTO issued a guidance memo to patent examiners indicating that process claims directed to a law of nature, a natural phenomenon or a naturally occurring relation or correlation that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the patent claim amounts to significantly more than the natural principle itself should be rejected as directed to patent-ineligible subject matter. On June 13, 2013, the U.S. Supreme Court issued its decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.* (“Myriad”), a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that an isolated segment of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent-eligible subject matter, but that complementary DNA may be patent-eligible.

In 2014, the USPTO issued a guidance to its patent examiners for evaluating claims for patent subject matter eligibility under the relevant statute (35 U.S.C. § 101). This guidance was in response to a series of decisions from the U.S. Supreme Court on patent claims reciting judicial exceptions, including Abstract Ideas, Laws of Nature/Natural Principles, Natural Phenomena and/or Natural Products. Based on judicial decisions and public feedback, several supplements to this guidance and additional memoranda and materials have since been issued and are continually being issued, while the current eligibility guidance has been incorporated into the latest (10th) edition of the MPEP (Manual for Patent Examination Procedure), last revised in June 2020. The current subject matter eligibility guideline instructs USPTO examiners to follow a two-part test, set forth in the U.S. Supreme Court decisions *Alice/Mayo*, as the only test that should be used to evaluate the eligibility of claims under examination, including claims directed to natural products and principles including all naturally occurring nucleic acids. Certain claims of our licensed patents and patent applications contain, and any future patents we may obtain may contain, claims that relate to specific recombinant DNA sequences that are naturally occurring at least in part and, therefore, could be the subject of future challenges made by third parties. In addition, the current USPTO subject matter eligibility guidance and the constantly evolving case law, together with contemplated congressional action, could all impact our ability to pursue similar patent claims in patent applications we may prosecute in the future.

We cannot assure our stockholders that our efforts to seek patent protection for our Candidates will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact the U.S. Supreme Court’s decisions in *Prometheus* and *Myriad* may have on the ability of life science companies to obtain or enforce patents relating to their products in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have a material adverse effect on our existing patent rights and our ability to protect and enforce our intellectual property in the future.

Moreover, although the U.S. Supreme Court has held in *Myriad* that isolated segments of naturally occurring DNA are not patent-eligible subject matter, certain third parties could allege that activities that we may undertake infringe other gene-related patent claims, and we may deem it necessary to defend ourselves against these claims by asserting non-infringement and/or invalidity positions, or paying to obtain a license to these claims. In any of the foregoing or in other situations involving third-party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter.

If we do not obtain patent term extension for patents relating to our Candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of our Candidates, one or more U.S. patents that we license or may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Amendments”). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process based on the first regulatory approval for a particular drug or biologic. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to

expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may be able to enter the market sooner.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition and our business may be adversely affected.

We have registered trademarks with the USPTO for the marks “SOLID BIOSCIENCES”, and “SOLID BIOSCIENCES” logo and registered marks in foreign jurisdictions for “SOLID BIOSCIENCES”, “SOLID GT” and “SOLID BIOSCIENCES” logo. Once registered, our trademarks or trade names may be challenged, infringed, diluted, tarnished, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, dilution or tarnishment claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources.

Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make gene therapy products that are similar to our Candidates but that are not covered by the claims of the patents that we license or may own in the future;
- we, or our current or future license partners or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we license or may own in the future;
- we, or our current and future license partners or collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative products or duplicate any of our processes without infringing our owned or licensed intellectual property rights;
- others may circumvent our regulatory exclusivities, such as by pursuing approval of a competitive product candidate via the traditional approval pathway based on their own clinical data, rather than relying on the abbreviated pathway provided for biosimilar applicants;
- it is possible that our pending licensed patent applications or those that we may own in the future will not lead to issued patents;
- issued patents that we hold rights to now or in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;
- others may have access to the same intellectual property rights licensed to us;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;

- the patents or other intellectual property rights of others may have an adverse effect on our business; and
- we may choose not to file a patent for certain trade secrets or know how, and a third party may subsequently file a patent covering such intellectual property.

If approved, our Candidates that are licensed and regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009 (“BPCIA”) was enacted as part of the Health Care Reform Law to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as “interchangeable” based on its similarity to an approved biologic. Under the BPCIA, a reference biological product is granted 12 years of regulatory exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive approval of a competing biologic, so long as its BLA does not rely on the reference product, sponsor’s data or submit the application as a biosimilar application.

In December 2022, Congress clarified through FDORA, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination under the BPCIA.

We believe that any of the Candidates we develop as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject Candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. Nonetheless, the approval of a biosimilar to our Candidates would have a material adverse impact on our business due to increased competition and pricing pressure.

Risks Related to Ownership of our Common Stock

Our executive officers, directors and principal stockholders maintain the ability to control or significantly influence all matters submitted to our stockholders for approval.

Our executive officers and directors and principal stockholders, in the aggregate, beneficially own shares representing a significant percentage of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to control or significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of voting power may:

- delay, defer or prevent a change in control;
- entrench our management and our Board of Directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire.

A significant number of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is performing well.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Our outstanding shares of common stock may be freely sold in the public market at any time to the extent permitted by Rules 144 and 701 under the Securities Act of 1933, as amended (the “Securities Act”), or to the extent such shares have already been registered under the Securities Act and are held by non-affiliates of ours. Moreover, holders of a

substantial number of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders.

In October 2020, in connection with the execution of our collaboration and license agreement with Ultragenyx, we issued and sold 521,719 shares of our common stock to Ultragenyx. For the ten-year period after date of such sale, subject to specified conditions, we have agreed to file a registration statement in order to register all or a portion of the shares sold to Ultragenyx.

In December 2024, in connection with the execution of our collaboration, patent and know-how license agreement with Mayo Foundation for Medical Education and Research (“Mayo”), we issued 364,990 shares of our common stock to Mayo in a private placement. In February 2025, we made the first milestone payment of 975,496 shares of our common stock to FA212 following the FDA’s clearance of our IND for SGT-212 for the treatment of FA. In January 2026, we made the second milestone payment of 1,316,899 shares of our common stock to FA212 following the dosing of the first participant in the Phase 1b FALCON clinical trial of SGT-212. We have filed resale registration statements to register all of the shares issued to Mayo and FA212.

In July 2019, December 2020, January 2024 and March 2026 we completed private placements, and in February 2025 we completed a public offering, of shares of our common stock and pre-funded warrants to purchase shares of our common stock to several accredited investors. In December 2022, we also issued shares of our common stock in the Acquisition and in a related private placement to several accredited investors. We have filed registration statements covering the resale of these shares by the purchasers in these private placements, and the stock consideration issued in the Acquisition, and have agreed to keep such registration statements effective until the date the shares covered by the respective registration statement have been sold or can be resold without restriction under Rule 144 of the Securities Act.

In addition, we have filed registration statements registering all shares of common stock that we may issue under our equity compensation plans. These shares can be freely sold in the public market upon issuance, subject to black-out periods and volume limitations applicable to affiliates.

We currently have on file with the SEC universal shelf registration statements which allow us to offer and sell registered common stock, preferred stock, debt securities, depositary shares, warrants and/or units from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale.

The price of our common stock has been, and in the future is likely to be, volatile and fluctuate substantially, which could result in substantial losses for holders of our common stock.

Our stock price has been, and in the future is likely to be, volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their shares of common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- our ability to successfully implement our proposed business strategy;
- results of or developments in preclinical studies and clinical trials of our Candidates or those of our competitors;
- the success of competitive products or technologies;
- regulatory or legal developments in the United States, the European Union and other countries;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our Candidates, or our clinical development programs and our commercialization efforts;
- the results of our efforts to discover, develop, acquire or in-license additional Candidates;
- actual or anticipated changes in our development timelines;
- our ability to raise additional capital;
- our inability to obtain or delays in obtaining adequate product supply for any approved product or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our Candidates;

- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of health care payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions;
- the effect of public health emergencies or pandemics on both the healthcare system and the patient population;
- the liquidity for our stock and daily share volumes transacted;
- our ability to maintain our listing on the Nasdaq Global Select Market; and
- the other factors described in this “Risk Factors” section.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation often has been instituted against that company. We and certain of our executive officers and board members have previously been named as defendants in purported class action lawsuits. Any such litigation instituted against us could cause us to incur substantial costs to defend such claims and divert management’s attention and resources.

An active trading market for our common stock may not be sustained.

Although our common stock is listed on the Nasdaq Global Select Market, given the limited trading history of our common stock, there is a risk that an active trading market for our shares may not continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for our stockholders to sell shares without depressing the market price for the shares, if at all.

We are a “smaller reporting company” and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company, and we will remain a smaller reporting company so long as the market value of our common stock held by non-affiliates is less than \$250 million measured on the last business day of our second fiscal quarter, or our annual revenues are less than \$100 million during the most recently completed fiscal year and the market value of our common stock held by non-affiliates is less than \$700 million measured on the last business day of our second fiscal quarter. Smaller reporting companies are able to provide simplified executive compensation disclosure and have certain other reduced disclosure obligations, including, among other things, being permitted to provide only two years of audited financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations”.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in our filings with the SEC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses. Those expenses will increase if we do not remain a smaller reporting company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Pursuant to Section 404 of the Sarbanes-Oxley Act (“Section 404”), we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain a smaller reporting company with less than \$100 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude within the prescribed timeframe that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Provisions in our certificate of incorporation and our bylaws and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions also could limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our Board of Directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our Board of Directors. Among other things, these provisions:

- establish a classified Board of Directors such that not all members of our board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our Board of Directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our Board of Directors to issue preferred stock without stockholder approval, which could be used to institute a stockholder rights plan, or so-called “poison pill,” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our Board of Directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law (“DGCL”) which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, is the only sole source of gain for an investment in our common stock.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for an investor for the foreseeable future.

Our certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for such disputes with us or our directors, officers or employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our certificate of incorporation or our bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. We do not intend to have this choice of forum provision apply to, and this choice of forum provision will not apply to, actions arising under the Securities Act or the Exchange Act. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity

We have certain processes for assessing, identifying and managing cybersecurity risks, which are built into our information technology function and are designed to help protect our information assets and operations from internal and external cyber threats, as well as secure our networks, systems and data. Such processes include physical, procedural, and technical safeguards, employee training and incident simulations. We have the capacity to engage certain external parties, such as consultants, independent privacy assessors, computer security firms and risk management, peer companies, industry groups and governance experts, to enhance our cybersecurity oversight. We also consider the internal risk oversight programs of third-party service providers before engaging them to help protect us from any related vulnerabilities.

To help manage our material risks from cybersecurity threats and to help protect against, detect, and prepare to respond to cybersecurity incidents, we conduct periodic training for employees involved in our systems and processes that handle sensitive data. We also conduct onboarding cybersecurity awareness assessments, cybersecurity training for all employees, and regular phishing email simulations for all employees. In addition, we use technology-based tools to help mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

The Audit Committee of our Board of Directors provides oversight of our cybersecurity risk and provides regular updates to the Board of Directors regarding such oversight. The Audit Committee receives periodic updates from management regarding cybersecurity matters, and is notified between such updates regarding significant new cybersecurity threats or incidents.

Our Senior Director of Information Technology leads the operational oversight of company-wide cybersecurity strategy, policy, standards and processes and works across relevant departments to assess and help us prepare our employees to address cybersecurity risks. Our Senior Director of Information Technology has over eighteen years of experience in information technology, eleven years of experience in information technology for life sciences companies, and a relevant bachelor's degree in information technology. We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

Item 2. Properties.

We lease our corporate headquarters, which consists of approximately 49,869 square feet of office, laboratory, research and development and manufacturing space in Charlestown, Massachusetts. The lease for our corporate headquarters has an initial term of approximately ten years that expires in 2032 with an option to extend the lease for an additional five years. In addition, we lease smaller laboratory and office space in North Carolina.

Item 3. Legal Proceedings.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

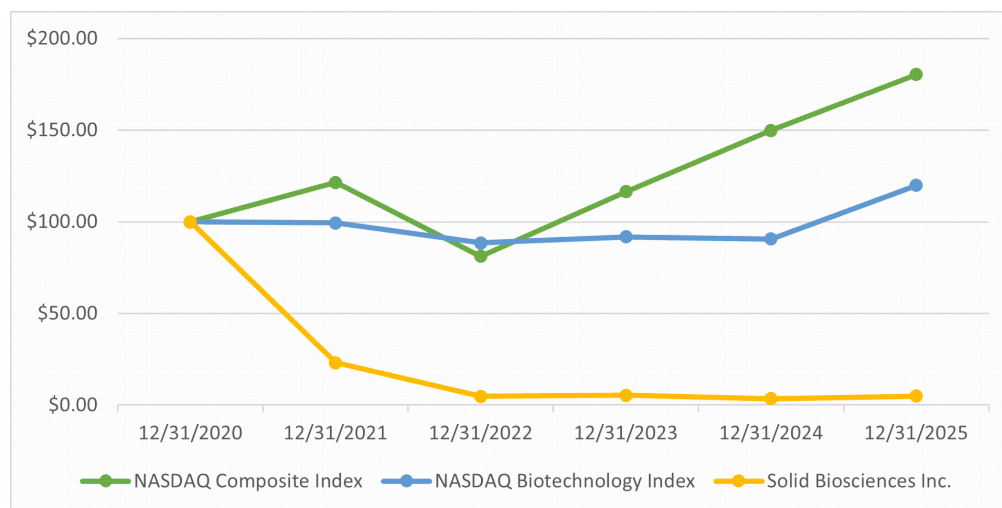
Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been publicly traded on the Nasdaq Global Select Market under the symbol "SLDB" since January 26, 2018 in connection with our initial public offering. Prior to that date, there was no established public trading market for our common stock.

The following graph compares the performance of our common stock to The Nasdaq Composite Index and to The Nasdaq Biotechnology Index from December 31, 2020 through December 31, 2025. The comparison assumes \$100 was invested after the market closed on December 31, 2020 in our common stock and in each of the foregoing indices, and it assumes reinvestment of dividends, if any. The stock price performance included in this graph is not necessarily indicative of future stock price performance.

COMPARISON OF CUMULATIVE TOTAL RETURN
Among The Nasdaq Composite Index, The Nasdaq Biotechnology Index and Solid Biosciences Inc.



The performance graph in this Item 5 is not deemed to be "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities under that Section, and shall not be deemed incorporated by reference into any of our filings under the Securities Act or the Exchange Act, except to the extent we specifically incorporate it by reference into such a filing.

Holders

As of March 16, 2026, we had approximately 44 holders of record of our common stock. This number does not include beneficial owners whose shares were held in street name. The actual number of holders of our common stock is greater than this number of record holders and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers or held by other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Purchase of Equity Securities

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

We did not sell any securities, during the year ended December 31, 2025 that were not registered under the Securities Act, and that have not otherwise been described in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by these forward-looking statements.

Overview

We are a life sciences company focused on advancing a portfolio of current and future gene therapy candidates, which we refer to collectively as our Candidates, including SGT-003 for the treatment of Duchenne muscular dystrophy ("Duchenne"), SGT-212 for the treatment of Friedreich's ataxia ("FA"), SGT-501 for the treatment of catecholaminergic polymorphic ventricular tachycardia ("CPVT"), SGT-601 for the treatment of TNNT2-mediated dilated cardiomyopathy ("TNNT2 DCM"), and additional assets for the treatment of genetic cardiac and neuromuscular diseases, at different stages of development, with varying levels of investment. We are advancing our diverse pipeline across rare neuromuscular and cardiac diseases, bringing together experts in science, technology, disease management and care. Patient-focused and founded by those directly impacted by Duchenne, our mission is to improve the daily lives of patients living with these devastating diseases.

Solid was purpose-built to advance the best science and accelerate the discovery and development of treatments that may benefit all patients with Duchenne. As we expand to bring meaningful treatments to patients living with other neuromuscular and cardiac diseases, the values and guiding principles that drive us continue. Our corporate vision is to build an innovation platform enabling the discovery and development of high-value genetic medicines for neuromuscular and cardiac diseases by integrating internal capabilities, including a vector core, use of validated animal models, optimized expression cassettes, novel capsids and regulatory expertise, and collaborations with leaders in related clinical and research fields. Our mission, which guides our operations, is to treat and change the course of neuromuscular and cardiac diseases at all stages. Underscoring this mission, our disease-focused business model is founded on the following fundamental principles:

- identify and develop meaningful therapies for underserved patients with sometimes fatal neuromuscular and cardiac diseases;
- build innovative libraries of delivery capsids and other enabling technologies with the potential to have broad impact on the gene therapy field at large;
- bring together the leading experts in neuromuscular and cardiac diseases, science, technology, disease management and care; and
- be guided by the needs of these patients.

We are continuing to advance our pipeline of Candidates. The U.S. Food and Drug Administration (the "FDA") has granted Fast Track, Orphan Drug, and Rare Pediatric Disease designations for SGT-003 for Duchenne and SGT-003 has also been awarded an Innovation Passport by the new UK Innovative Licensing and Access Pathway. The FDA has granted Fast Track, Orphan Drug and Rare Pediatric Disease designations to SGT-212 for the treatment of FA and SGT-501 for the treatment of CPVT.

As we continue to pursue opportunities in both the U.S. and international markets, we remain attentive to evolving global economic conditions, including uncertainties related to international trade policies, tariffs, and supply chain dynamics. Although these factors have not had a material impact on our operations to date, future changes in trade regulations, tariff structures, or logistical constraints could influence the cost, availability, or timing of materials and components used in our manufacturing processes. We continue to monitor these developments closely.

SGT-003

Participant dosing in the Phase 1/2 INSPIRE DUCHENNE trial of SGT-003 began in the second quarter of 2024. The INSPIRE DUCHENNE trial is a Phase 1/2 first-in-human, open-label, single-dose, multicenter trial designed to evaluate the safety, tolerability and efficacy of SGT-003 in pediatric patients with Duchenne at a dose of 1E14vg/kg. SGT-003 is administered as a one-time intravenous infusion. Since initiation of the INSPIRE DUCHENNE clinical trial, we amended the clinical trial protocol to increase the anticipated participant enrollment size, expand the participant cohort age groups, and extend the time points of certain secondary objective measurements. In connection with the expanded clinical trial, we have initiated work for additional Good Manufacturing Practices ("GMP") batches of SGT-003.

On March 11, 2026, we announced positive new interim data from the Phase 1/2 INSPIRE DUCHENNE clinical trial.

The interim clinical data reported is as of a February 23, 2026, data cutoff date. SGT-003 has been generally well tolerated in the 41 participants dosed as of March 18, 2026. The safety and tolerability profile observed in the INSPIRE DUCHENNE trial continued to be promising; SGT-003 is administered using a low-burden, steroid-only prophylactic immunomodulation regimen. As of March 18, 2026, there has been one treatment-related serious adverse event reported in the INSPIRE DUCHENNE trial. This serious adverse event was identified as a Grade 3 immune-mediated myositis which, importantly, was not associated with muscle pain or weakness, and occurred in a participant who had a large deletion in a region coded for by SGT-003's microdystrophin. The trial participant promptly responded to steroid treatment and the event has resolved. This serious adverse event was reviewed by the data and safety monitoring board (DSMB) with the recommendation to continue dosing without interruption.

For a full description of the initial results from the INSPIRE DUCHENNE trial, see Part I, Item I, "Business" appearing in this Annual Report on Form 10-K.

Enrollment and dosing in the INSPIRE DUCHENNE trial is ongoing and being conducted at 15 clinical sites across the United States, Canada, Italy and the United Kingdom. We believe we have aligned with the FDA on SGT-003's potency assay strategy and will continue commercial-readiness CMC activities, with our process performance qualification manufacturing batches to be completed in 2026.

In October 2025, we activated the first clinical trial site and began screening participants for IMPACT DUCHENNE, a Phase 3 randomized, double-blind, placebo-controlled trial evaluating SGT-003. In February 2026, we announced positive feedback from a Type C meeting with the FDA where we reached alignment on the IMPACT DUCHENNE trial design, including: the patient population of ambulant participants 7 to <12 years of age, the primary endpoint of change from baseline in Time to Rise (TTR) velocity from supine position evaluated at 18 months and other key secondary endpoints. The IMPACT DUCHENNE trial is currently planned to be conducted at sites in Australia, Canada, the European Union and the United Kingdom, and due to strong key opinion leader and community demand, we are also evaluating the potential to open clinical trial sites in the United States. Participant screening is underway and we anticipate dosing the first participant in the Phase 3 IMPACT DUCHENNE trial in April 2026.

In the first half of 2026, we plan to have additional meetings with the FDA to receive guidance on a potential accelerated approval pathway for SGT-003 and we expect to provide regulatory and clinical updates in mid-2026.

The FDA has granted Fast Track, Orphan Drug, and Rare Pediatric Disease designations for SGT-003 for the treatment of Duchenne. SGT-003 has been awarded an Innovation Passport by the new UK Innovative Licensing and Access Pathway, which aims to accelerate time to market and facilitate patient access to new medicines in the United Kingdom.

SGT-212

In January 2025, we announced that the FDA cleared our IND for SGT-212 for the treatment of FA. In October 2025, we activated the first clinical trial site and began screening participants for FALCON, an open-label, multi-center Phase 1b clinical trial of SGT-212, and in January 2026, we dosed the first participant in the trial. As of March 18, 2026, there have been no serious adverse events and no treatment-related adverse events reported in the FALCON trial. Intra-procedural MRI imaging demonstrated promising IDN targeting and coverage. The trial is expected to enroll approximately 10 non-ambulatory and ambulatory adult participants (aged 18-40) living with FA in up to three cohorts and is designed to evaluate the safety and tolerability of contemporaneous IDN and systemic IV infusion of SGT-212 with initial data anticipated in the second half of 2026, subject to participant enrollment. The FDA has granted Fast Track, Orphan Drug and Rare Pediatric Disease designations to SGT-212 for the treatment of FA.

SGT-501

In July 2025, we announced that the FDA cleared our IND and that Health Canada approved our clinical trial application for SGT-501 for the treatment of CPVT. In January 2026, we announced that clinical trial sites have been activated and participant screening is underway in the ARTEMIS clinical trial, an open-label, multi-center Phase 1b clinical trial evaluating SGT-501 in adult participants with CPVT. The ARTEMIS trial is designed to evaluate the safety and tolerability of a single IV infusion of SGT-501. We anticipate dosing our first participant in the second quarter of 2026 with initial safety data anticipated in the second half of 2026, subject to participant enrollment.

The FDA has granted Fast Track, Orphan Drug and Rare Pediatric Disease designations to SGT-501 for the treatment of CPVT.

Other Cardiac Programs

We are currently developing a preclinical product candidate, SGT-601, for the treatment of TNNT2 DCM. Efficacy studies in mice suggest that SGT-601 treatment resulted in a restoration of ejection fraction function and a stabilization in cardiac function over time.

Capsids

In March of 2026, we began using the mark POLARIS-101™ to represent our AAV-SLB101 capsid (“POLARIS-101™”). POLARIS-101™ is our rationally designed, proprietary capsid used in SGT-003 for Duchenne, which has been generally well tolerated as of March 18, 2026 (N=41) in the INSPIRE DUCHENNE clinical trial, and was also well tolerated in nonclinical NHP and mouse models. We aim to license POLARIS-101™ broadly to corporations, institutions and academic labs pursuing neuromuscular and cardiac rare disease research, with more than 50 agreements including licenses executed.

We are focused on developing transformative treatments to improve the lives of patients with rare neuromuscular and cardiac diseases. The majority of our current programs are designed to treat these diseases with gene transfer products. Gene transfer, a type of gene therapy, is designed to address diseases caused by mutated genes through the delivery of functional versions of genes, called transgenes. The transgenes are then utilized by the body to produce desired proteins that act therapeutically to treat the condition. In addition to a transgene, our gene transfer Candidates include a viral capsid or vector (a protein shell utilized as a vehicle to deliver a transgene to cells in the body) and a promoter (a specialized DNA sequence that directs cells to produce the protein in specific tissues). The capsid is modified to no longer self-replicate yet still retains its ability to introduce new genetic material directly into patients’ cells. Adeno-associated virus (“AAV”) capsids have been approved for use to deliver transgenes to patients, including via systemic delivery as well as stereotactic neurosurgical administration to the brain. The use of AAV capsids to deliver gene therapies has also been extensively studied by third parties in human clinical trials for multiple disease indications, and in certain of these trials AAV was delivered systemically to the participant.

We are building cardiac and neuromuscular next-generation capsid and promoter libraries with capsid selection from the first library anticipated in the second half of 2026.

Our Operations

Due to our significant research and development expenditure, licensing and patent investment, and general and administrative costs associated with our operations, we have generated substantial operating losses in each period since our inception. Our net losses were \$174.3 million and \$124.7 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of \$957.8 million. We expect to incur significant expenses and operating losses for the foreseeable future.

As we seek to develop and commercialize our Candidates, we anticipate that our expenses will increase significantly and that we will need substantial additional funding to support our continuing operations. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity financing, debt financings or other sources, which may include licensing agreements or strategic collaborations. We may be unable to raise additional funds or enter into such agreements or arrangements when needed on favorable terms, if at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of our Candidates.

Because of the numerous risks and uncertainties associated with product development, we are unable to predict the timing or amount of increased expenses or determine when or if we will be able to achieve or maintain profitability. Even if we are able to generate revenue from product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of December 31, 2025, we had cash, cash equivalents, and available-for-sale securities of \$187.9 million, excluding restricted cash of \$2.0 million. In March 2026, we issued and sold in a private placement (the “March 2026 Private Placement”), 14,973,257 shares of our common stock at a price per share of \$5.61, and, to certain investors in lieu of shares of common stock, pre-funded warrants to purchase 27,807,482 shares of our common stock at a price per warrant of \$5.609. We received net proceeds of approximately \$226.4 million, after deducting estimated offering costs. We believe that our cash, cash equivalents, and available-for-sale securities as of December 31, 2025, together with the net proceeds from the March 2026 Private Placement, will enable us to fund our operating expenses and capital expenditure requirements into the first half of 2028. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently anticipate.

Financial Operations Overview

Revenue

We have not generated any commercial product revenue to date and do not expect to do so for the foreseeable future, if ever. If our development efforts for our Candidates are successful and result in marketing approval, we may generate commercial product revenue in the future.

Operating Expenses

We classify our operating expenses into two categories: research and development and general and administrative expenses. Personnel costs, including salaries, benefits, bonuses, and equity-based compensation expense comprise a significant component of both expense categories. We allocate expenses associated with personnel costs based on the nature of work associated with these resources.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts, and clinical and preclinical development activities for our Candidates and include:

- expenses incurred under agreements with third parties, including contract research organizations (“CROs”) that conduct research, preclinical and clinical activities on our behalf, as well as contract development and manufacturing organizations (“CDMOs”) that manufacture SGT-003, SGT-212, SGT-501, and other Candidates for use in our preclinical studies and clinical trials;
- salaries, benefits and other related costs, including equity-based compensation expense, for personnel engaged in research and development functions;
- costs of outside consultants engaged to assist in our research and development activities, including their fees, equity-based compensation and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- costs incurred in seeking regulatory approval of our Candidates;
- expenses incurred under our intellectual property licenses; and
- facility-related research and development expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

Research and development activities are central to our business model. We are still in the early stages of development for most of our Candidates. Candidates in later stages of clinical development generally have higher development costs than those in preclinical development or in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect that our research and development expenses will continue to increase for the foreseeable future if and as we continue to conduct our INSPIRE DUCHENNE, IMPACT DUCHENNE, FALCON and ARTEMIS trials and continue to develop our pipeline and complete ongoing and planned preclinical studies and clinical trials of our Candidates.

We typically use our employee and infrastructure resources across our Candidates. We track outsourced development costs and milestone payments made under our licensing arrangements by Candidate, but we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to Candidates on a program-specific basis. These costs are included in unallocated research and development expenses in the table below.

The following table summarizes our research and development expenses by Candidate for the respective periods (in thousands):

	Year Ended December 31,	
	2025	2024
Allocated research and development expenses:		
SGT-003	\$ 58,959	\$ 15,197
SGT-501	9,641	17,223
SGT-212	5,468	5,874
SGT-601	7,819	2,773
Other development programs	5,027	11,055
Total allocated research and development expenses	86,914	52,122
Unallocated research and development expenses:		
Personnel related expenses	35,356	25,100
External expenses	18,055	19,209
Total unallocated research and development expenses	53,411	44,309
Total research and development expenses	\$ 140,325	\$ 96,431

We cannot determine with certainty the duration, costs, and timing of ongoing and planned clinical trials of SGT-003, SGT-212, SGT-501 or our other Candidates, or if, when, or to what extent we will generate revenue from the commercialization and sale of any of our Candidates for which we obtain marketing approval or our other research and development expenses. We may never succeed in obtaining marketing approval for any of our Candidates. The duration, costs, and timing of clinical trials and development of our Candidates will depend on a variety of factors, including:

- the scope, rate of progress, expense, and results of any clinical trials of our Candidates and other research and development activities that we may conduct;
- the imposition of regulatory restrictions on clinical trials, including full and partial clinical holds and the time and activities required to lift any such holds;
- uncertainties in clinical trial design and participant enrollment or drop out or discontinuation rates;
- significant and changing government regulation and regulatory guidance;
- potential additional studies or clinical trials requested by regulatory agencies;
- the timing and receipt of any marketing approvals; and
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including equity-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include legal fees relating to patent and corporate matters, professional fees for accounting, auditing, tax and consulting services, insurance costs, travel expenses, and facility-related expenses.

We expect that our general and administrative expenses will increase in the future as we support our research and development activities and activities related to our INSPIRE DUCHENNE trial, our IMPACT DUCHENNE trial, our FALCON trial, our ARTEMIS trial and any other planned or future clinical trials for and potential commercialization of our Candidates.

Other Income, Net

Other income, net consists primarily of interest income. Interest income consists of income earned on our cash and cash equivalents, available-for-sale securities, and restricted cash.

Income Taxes

We account for income taxes using an asset and liability approach, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial

statements but have not been reflected in taxable income. A valuation allowance is established to reduce deferred tax assets to their estimated realizable value.

We account for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more-likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Critical Accounting Policies and Use of Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ materially from these estimates.

While our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements and that involve a significant level of estimation uncertainty.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated costs incurred for the services when we have not yet been invoiced or otherwise notified of the actual costs. The majority of our service providers invoice us in arrears for services performed, on a pre-determined schedule or when contractual milestones are met; however, some require advanced payments. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. Examples of estimated accrued research and development expenses include fees paid to:

- CROs in connection with performing research activities, clinical trials and preclinical studies on our behalf;
- vendors in connection with preclinical development and clinical activities;
- vendors related to product manufacturing and development and distribution of clinical and preclinical supplies; and
- third parties under our intellectual property licenses.

We base our expenses related to preclinical studies and clinical trials on our estimates of the services rendered and efforts expended pursuant to quotes and contracts with multiple CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. In accruing fees, we estimate the time period over which services will be performed, and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or amount of prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period.

Equity-Based Compensation

We have equity plans under which we grant equity awards to employees, directors and non-employees. We measure all stock options and other stock-based awards granted to employees, directors and non-employees based on the fair value on the date

of the grant and recognize compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as a reduction of equity based compensation as they occur. We apply the straight-line method of expense recognition to all awards with only service-based vesting conditions. For performance-based restricted stock unit awards, which are subject to the achievement of performance milestones, the fair value is recognized as expense over the requisite service periods when the achievement of such performance milestones is determined to be probable. If a performance milestone is not determined to be probable or is not met, no equity-based compensation expense is recognized, and any previously recognized expense is reversed. For stock-based awards granted to non-employees, compensation expense is recognized over the period during which services are rendered by such non-employees until completed.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. We use the volatility of our own historical stock price. The expected term of stock options with service-based vesting conditions and options granted to non-employees has been determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We use a 0% expected dividend yield in our determination of fair value based on the fact that we have never paid cash dividends and do not expect to pay any cash dividends in the foreseeable future, if ever.

Derivative Liabilities

In connection with the asset purchase agreement with FA212 LLC (“FA212”), certain development milestone payments to FA212 are payable in either cash, equity, or a combination of both, at our discretion. Such contingent payments were determined to be derivative liabilities.

Derivative liabilities are recorded at fair value based on the probability weighted present value of the estimated cash flows pursuant to the contractual terms of each agreement. The derivative liabilities are remeasured quarterly with changes in fair value recorded in change in fair value of derivative liabilities in the consolidated statements of operations.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (in thousands, except percentages):

	Year Ended December 31,			
	2025	2024	\$ Change	% Change
Operating expenses:				
Research and development	\$ 140,325	\$ 96,431	\$ 43,894	45.5%
General and administrative	38,881	33,297	5,584	16.8%
Total operating expenses	179,206	129,728	49,478	38.1%
Loss from operations	(179,206)	(129,728)	(49,478)	38.1%
Other income, net:				
Interest income	9,904	9,469	435	4.6%
Interest expense	203	(340)	543	(159.7)%
Change in fair value of derivative liabilities	(6,050)	(4,750)	(1,300)	27.4%
Other income, net	824	652	172	26.4%
Total other income, net	4,881	5,031	(150)	(3.0)%
Net loss	\$ (174,325)	\$ (124,697)	\$ (49,628)	39.8%

Research and Development Expenses

The following table summarizes our research and development expenses by Candidate for the respective periods (in thousands, except percentages):

	Year Ended December 31,		\$ Change	% Change
	2025	2024		
Allocated research and development expenses:				
SGT-003	58,959	15,197	43,762	288.0%
SGT-501	9,641	17,223	(7,582)	(44.0)%
SGT-212	5,468	5,874	(406)	(6.9)%
SGT-601	7,819	2,773	5,046	182.0%
Other development programs	5,027	11,055	(6,028)	(54.5)%
Total allocated research and development expenses	86,914	52,122	34,792	66.8%
Unallocated research and development expenses:				
Personnel related expenses	35,356	25,100	10,256	40.9%
External expenses	18,055	19,209	(1,154)	(6.0)%
Total unallocated research and development expenses	53,411	44,309	9,102	20.5%
Total research and development expenses	<u>\$ 140,325</u>	<u>\$ 96,431</u>	<u>\$ 43,894</u>	<u>45.5%</u>

Research and development expenses for the year ended December 31, 2025 were \$140.3 million, compared to \$96.4 million for the year ended December 31, 2024. The increase of \$43.9 million in research and development expenses was primarily due to a \$43.8 million increase in costs for SGT-003 primarily related to manufacturing and clinical costs, a \$10.3 million increase in personnel related expenses, a \$5.0 million increase in costs for SGT-601 primarily related to manufacturing and research costs, partially offset by a net decrease of \$7.6 million in costs for SGT-501 related to lower manufacturing and study costs partially offset by an increase in clinical, regulatory and licensing fees, and a \$6.0 million decrease in costs for other development programs.

General and Administrative Expenses

General and administrative expenses were \$38.9 million for the year ended December 31, 2025, compared to \$33.3 million for the year ended December 31, 2024. The increase of \$5.6 million was primarily related to a \$6.1 million increase in personnel related costs and a \$0.6 million increase in information technology support and services, partially offset by a \$1.1 million decrease in general legal fees.

Other Income, Net

Other income, net was \$4.9 million and \$5.0 million for the years ended December 31, 2025 and 2024, respectively. The decrease of \$0.2 million was primarily related to the change in fair value of derivative liabilities offset by interest income.

Liquidity and Capital Resources

Sources of Liquidity

To date, we have financed our operations primarily through the sale of securities in private placements and follow-on offerings, the sale of common stock in our initial public offering, and sales of common stock under our “at-the-market offering” sales agreement with Jefferies LLC (“Jefferies”) (the “ATM Sales Agreement”). Through December 31, 2025, we raised an aggregate of \$144.6 million of gross proceeds from our sales of preferred units prior to the completion of our initial public offering, and an aggregate of \$863.7 million of net proceeds from the sale of our common stock through public offerings, including our IPO and follow-on public offerings, private placements, the ATM Sales Agreement, and pursuant to the stock purchase agreements.

On March 13, 2019, we entered into the ATM Sales Agreement, which was amended and restated in March 2024, under which we may offer and sell, from time to time, shares of our common stock through Jefferies as sales agent. Any such sales being made by any method that is deemed an “at-the-market offering” as defined in Rule 415 promulgated under the Securities Act. We will pay Jefferies a commission of up to 3% of the gross proceeds of any sales of common stock pursuant to the ATM Sales Agreement. During the years ended December 31, 2025 and 2024, we sold 1,189,572 and 2,212,937 shares of common stock, respectively, pursuant to the ATM Sales Agreement resulting in net proceeds of \$6.8 million and \$18.4 million, respectively. During the three months ended December 31, 2025, we sold 891,414 shares pursuant to the ATM Sales Agreement resulting in net proceeds of \$5.1 million.

On January 11, 2024, we issued and sold 16,973,103 shares of our common stock at a price per share of \$5.53 and, to one investor in lieu of shares of common stock, pre-funded warrants to purchase 2,712,478 shares of common stock at a price of \$5.529 per pre-funded warrant, in a private placement (the “January 2024 Private Placement”). We received \$103.7 million of net proceeds from the January 2024 Private Placement after deducting offering costs.

On February 19, 2025, we issued and sold in an underwritten offering (the “February 2025 Offering”), 35,739,810 shares of our common stock at a price of \$4.03 per share and, to certain investors in lieu of shares of common stock, pre-funded warrants to purchase 13,888,340 shares of common stock at a price of \$4.029 per pre-funded warrant. We received approximately \$188.0 million of net proceeds from the February 2025 Offering, after deducting underwriting discounts and commissions and offering costs.

On March 9, 2026, we issued and sold 14,973,257 shares of our common stock at a price of \$5.61 per share, and, to certain investors in lieu of shares of common stock, pre-funded warrants to purchase 27,807,482 shares of its common stock at a price of \$5.609 per pre-funded warrant, in the March 2026 Private Placement. We received approximately \$226.4 million of aggregate net proceeds from the March 2026 Private Placement, after deducting estimated offering costs.

As of December 31, 2025, we had cash, cash equivalents and available-for-sale securities of \$187.9 million, excluding restricted cash of \$2.0 million, and had no debt outstanding.

Summary of Cash Flows

The following table summarizes our sources and uses of cash for each of the periods presented (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	\$ (156,289)	\$ (100,012)
Net cash used in investing activities	(58,454)	(16,086)
Net cash provided by financing activities	194,446	122,437
Net increase in cash, cash equivalents and restricted cash	\$ (20,297)	\$ 6,339

Operating Activities

During the year ended December 31, 2025, operating activities used \$156.3 million of cash, primarily resulting from our net loss of \$174.3 million offset by non-cash charges of \$24.9 million due primarily to equity-based compensation of \$16.9 million, an increase in the fair value of the derivative liabilities of \$6.1 million, non-cash lease expense of \$2.4 million, and depreciation expense of \$1.6 million, partially offset by amortization of discount on available-for sale-securities of \$1.9 million. Net cash used by changes in our operating assets and liabilities was \$6.8 million which included an increase in prepaid expenses of \$8.0 million, a decrease in operating lease liability of \$1.8 million, and a decrease in accounts payable of \$1.1 million, partially offset by an increase of \$4.1 million in accrued expenses and other current and non-current liabilities.

During the year ended December 31, 2024, operating activities used \$100.0 million of cash, primarily resulting from our net loss of \$124.7 million offset by non-cash charges of \$21.8 million due primarily to equity-based compensation of \$10.5 million, an increase in the fair value of the derivative liabilities of \$4.8 million, non-cash acquired in-process research and development of \$3.4 million, depreciation expense of \$2.5 million, non-cash lease expense of \$2.4 million, and a non-cash upfront equity payment for a collaboration and license agreement of \$2.0 million, partially offset by amortization of discount on available-for sale-securities of \$3.6 million. Net cash provided by changes in our operating assets and liabilities was \$2.9 million which included an increase of \$4.8 million in accrued expenses and other current and non-current liabilities, and an increase in accounts payable of \$2.2 million, partially offset by an increase in prepaid expenses and other current and non-current assets of \$2.4 million and a decrease in operating lease liability of \$1.7 million.

Investing Activities

During the year ended December 31, 2025, investing activities used \$58.5 million of cash, resulting from the purchases of available-for sale securities of \$235.9 million and the purchases of property and equipment of \$1.2 million, partially offset by the sales and maturities of available-for sale securities of \$178.5 million.

During the year ended December 31, 2024, investing activities used \$16.1 million of cash, resulting from the purchases of available-for sale securities of \$204.3 million and the purchases of property and equipment of \$0.7 million, partially offset by the maturities of available-for sale securities of \$188.9 million.

Financing Activities

During the year ended December 31, 2025, financing activities provided \$194.4 million of cash, primarily resulting from the net proceeds from the issuance and sale of common stock and pre-funded warrants to purchase shares of common stock of \$194.7 million, and proceeds from the issuance of shares of \$0.4 million under our Amended and Restated 2021 Employee Stock Purchase Plan (“ESPP”), offset by payments of the principal portion of finance lease obligations of \$0.7 million.

During the year ended December 31, 2024, financing activities provided \$122.4 million of cash, primarily resulting from the net proceeds from the sale of common stock and pre-funded warrants to purchase shares of common stock in the January 2024 Private Placement of \$103.7 million and net proceeds from the sale of common stock under the ATM Sales Agreement of \$18.4 million, proceeds from the exercise of common stock options of \$0.5 million, and proceeds from the issuance of shares under the ESPP of \$0.3 million, partially offset by payments of the principal portion of finance lease obligations of \$0.5 million.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing development activities related to our Candidates. In addition, we have incurred and expect to continue to incur costs associated with operating as a public company. We expect that our expenses will increase substantially if and as we:

- enroll participants in our INSPIRE DUCHENNE, IMPACT DUCHENNE, FALCON and ARTEMIS trials and advance clinical development of SGT-003, SGT-212 and SGT-501;
- advance our other Candidates into clinical trials;
- continue research and preclinical development of our Candidates and adjacent technologies such as assays;
- seek to identify additional candidates;
- engage in regulatory interactions with the FDA and other regulatory authorities;
- submit regulatory filings relating to the development of our Candidates and seek marketing approvals for our Candidates that successfully complete clinical trials, if any;
- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- scale up our manufacturing processes and arrange manufacturing for larger quantities of our Candidates for preclinical and clinical development and potential commercialization;
- maintain, expand, protect and enforce our intellectual property portfolio;
- hire and retain additional clinical, quality control and scientific personnel;
- build out new facilities or expand existing facilities to support our activities;
- acquire or in-license other drugs, drug candidates, technologies and intellectual property; and
- add operational, financial and management information systems and personnel.

As of December 31, 2025, we had cash, cash equivalents and available-for-sale securities of \$187.9 million, excluding restricted cash of \$2.0 million. Based on our current operating plan, we believe that our cash, cash equivalents and available-for-sale securities as of December 31, 2025, together with the net proceeds from the March 2026 Private Placement, will be sufficient to fund our operating expenses and capital requirements into the first half of 2028. As a result, in order to continue to operate our business beyond that time, we will need to raise additional funds. However, there can be no assurance that we will be able to generate funds on terms acceptable to us, on a timely basis, or at all. In addition, we have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently anticipate.

Due to the numerous risks and uncertainties associated with the development of our Candidates and because the extent to which we may enter collaborations with third parties for development of our Candidates is unknown, we are unable to estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our Candidates. Our future capital requirements will depend on many factors, including:

- the progress, costs and results of the INSPIRE DUCHENNE, IMPACT DUCHENNE, FALCON and ARTEMIS trials and any future clinical trials of our Candidates;
- the costs, timing and outcome of regulatory review of our Candidates;

- the scope, progress, results and costs of discovery, laboratory testing, manufacturing, preclinical development and clinical trials for our Candidates;
- the costs associated with manufacturing and use of third-party manufacturers;
- the revenue, if any, received from commercial sale of our Candidates, should any of our Candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, maintaining, defending and enforcing our intellectual property rights and defending intellectual property-related claims;
- the outcome of any lawsuits filed against us;
- the terms of our current and any future license agreements and collaborations;
- our ability to establish and maintain additional strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- the payment or receipt of milestones, royalties and other collaboration-based revenues, if any;
- the extent to which we acquire or in-license other candidates, technologies and intellectual property; and
- if and as we need to adapt our business in response to public health emergencies or pandemics and collateral consequences related thereto.

We are supplying, and expect to continue to supply, our ongoing and future preclinical and clinical development programs with drug product produced at a current Good Manufacturing Practice compliant facility located at one of our CDMOs. We intend to establish the capability and capacity to supply Candidates at commercial scale from multiple sources.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval for any Candidates or generate revenue from the sale of any products for which we may obtain marketing approval. In addition, our Candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity securities, our existing stockholders' ownership interest may be diluted. Any debt or preferred equity financing, if available, may involve agreements that include restrictive covenants that may limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends, which could adversely impact our ability to conduct our business, and may require the issuance of warrants, which could potentially dilute existing stockholders' ownership interests.

If we raise additional funds through licensing agreements and strategic collaborations with third parties, we may have to relinquish valuable rights to our technology, future revenue streams, research programs, or Candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds, we may be required to delay, limit, reduce and/or terminate development of our Candidates or any future commercialization efforts or grant rights to develop and market Candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

We lease certain office space, lab space and lab equipment in Massachusetts and North Carolina. These leases are used for our continuing operations. For a description of our lease obligations, refer to Note 10 to our consolidated financial statements appearing in this Annual Report on Form 10-K.

Under various agreements with third-party licensors, we have agreed to pay annual maintenance fees and certain sublicensing fees and make milestone payments and pay royalties to third parties upon achievement of certain specified milestones. For a description of our license agreements, see Part I, Item 1, "Business—Strategic Partnerships and Collaborations/Licenses" and see Note 12 of our consolidated financial statements appearing in this Annual Report on Form 10-K.

We enter into contracts in the normal course of business with CROs and CDMOs for clinical trials, preclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts are generally cancelable by us upon prior notice of 30 days.

Recently Issued Accounting Pronouncements

We have reviewed all recently issued standards and have determined that, other than as disclosed in Note 2 to our consolidated financial statements appearing at the end of this Annual Report on Form 10-K, such standards will not have a material impact on our consolidated financial statements or do not otherwise apply to our operations.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of December 31, 2025, our cash equivalents consisted of money market accounts and treasury bills that have contractual maturities of less than 90 days from the date of acquisition. As of December 31, 2025, our investments consisted of treasury bills and government bonds that have contractual maturities of less than one year. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. However, because of the short-term nature of our portfolio, an immediate 10% change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

Inflation Risk

Inflation generally affects us by increasing our cost of labor and research, manufacturing and development costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations in the last two years. However, our operations may be adversely affected by the inflation in the future.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item 8 is included at the end of this Annual Report on Form 10-K beginning on page F-1.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer (our principal executive officer and principal financial and accounting officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), refers to controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to a company’s management, including its principal executive and principal financial and accounting officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

In designing and evaluating our disclosure controls and procedures, management recognizes that disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a control system, misstatements due to error or fraud may occur and not be detected.

Based on the evaluation of our disclosure controls and procedures, our chief executive officer and chief financial officer concluded that, as of December 31, 2025, our disclosure controls and procedures were designed and operating effectively.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the framework in *Internal Control-Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, management has concluded that the Company's internal control over financial reporting was effective as of December 31, 2025.

As a non-accelerated filer and a "smaller reporting company", as defined in Rule 12b-2 under the Exchange Act, our independent registered public accounting firm is not required to issue an attestation report on our internal control over financial reporting.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(b) Director and Officer Trading Arrangements

None of our directors or officers adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the fourth quarter of 2025.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Except to the extent provided below, the information required under this Item 10 is incorporated by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year ended December 31, 2025.

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that applies to our directors, executive officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Conduct is available on the Investor Relations portion of our website, www.solidbio.com. The nominating and corporate governance committee of our Board of Directors is responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. In addition, we intend to post on our website all disclosures that are required by law or the listing standards of Nasdaq concerning any amendments to, or waivers of, any provision of the Code of Conduct.

Item 11. Executive Compensation.

The information required under this Item 11 is incorporated by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year ended December 31, 2025.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required under this Item 12 is incorporated by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year ended December 31, 2025.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required under this Item 13 is incorporated by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year ended December 31, 2025.

Item 14. Principal Accountant Fees and Services.

The information required under this Item 14 is incorporated by reference to our definitive proxy statement for our 2026 Annual Meeting of Stockholders, which we intend to file with the Securities and Exchange Commission not later than 120 days after the end of the fiscal year ended December 31, 2025.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(1) Financial Statements:

Report of Independent Registered Public Accounting Firm (PCAOB ID 238)	Page F-1
Consolidated Balance Sheets at December 31, 2025 and 2024	F-3
Consolidated Statements of Operations for the Years Ended December 31, 2025 and 2024	F-4
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2025 and 2024	F-5
Consolidated Statements of Changes in Stockholders' Equity for the Years Ended December 31, 2025 and 2024	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2025 and 2024	F-7
Notes to Consolidated Financial Statements	F-9

(2) Financial Statement Schedules:

All financial statement schedules have been omitted because they are not applicable, not required or the information required is shown in the financial statements or the notes thereto.

(3) Exhibits. The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Description
2.1	<u>Agreement and Plan of Merger, dated as of September 29, 2022, by and among Solid Biosciences Inc., Greenland Merger Sub LLC, AavantiBio, Inc. and, solely in his capacity as the Equityholder Representative, Doug Swirsky (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on September 30, 2022).</u>
3.1	<u>Certificate of Incorporation of Solid Biosciences Inc., as amended (incorporated herein by reference to Exhibit 4.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-288022) filed on June 13, 2025).</u>
3.2	<u>Bylaws of Solid Biosciences Inc. (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-8 filed on January 29, 2018).</u>
4.1	<u>Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 filed on December 29, 2017).</u>
4.2*	<u>Description of the Company's Securities Registered under Section 12 of the Exchange Act</u>
10.1†	<u>Amended and Restated Registration Rights Agreement dated March 29, 2017 by and among Solid Biosciences, LLC and certain investors (incorporated by reference to Exhibit 10.17 to the Registration Statement on Form S-1 filed on December 29, 2017).</u>
10.2†	<u>Solid Biosciences, LLC Amended and Restated Equity Incentive Plan and form of unit restriction agreement (incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-K filed on March 29, 2018).</u>
10.3†	<u>Solid Biosciences Inc. 2018 Omnibus Incentive Plan (incorporated by reference to Exhibit 99.1 to the Registration Statement on Form S-8 filed on January 29, 2018).</u>
10.4†	<u>Form of Incentive Stock Option Agreement under 2018 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-K filed on March 13, 2019).</u>
10.5†	<u>Form of Nonqualified Stock Option Agreement under 2018 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.8 to the Annual Report on Form 10-K filed on March 13, 2019).</u>
10.6†	<u>Form of Restricted Stock Agreement under 2018 Omnibus Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 filed on December 29, 2017).</u>
10.7#	<u>Exclusive Patent License Agreement, dated as of October 16, 2015, by and between Solid GT, LLC and the University of Washington (incorporated by reference to Exhibit 10.7 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.8#	<u>License Agreement, dated as of October 15, 2015, by and between Solid GT, LLC and The Curators of the University of Missouri (incorporated by reference to Exhibit 10.8 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.9†	<u>Form of Indemnification Agreement for Directors and Officers (incorporated by reference to Exhibit 10.16 to the Registration Statement on Form S-1 filed on December 29, 2017).</u>
10.10†	<u>Summary of Non-Employee Director Compensation Program (incorporated by reference to Exhibit 10.10 to the Annual Report on Form 10-K filed on March 6, 2025).</u>
10.11	<u>Form of Pre-Funded Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on July 26, 2019).</u>
10.12	<u>Registration Rights Agreement, dated July 25, 2019, by and among the Company and the other parties thereto (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed on July 26, 2019).</u>
10.13†	<u>Consulting Agreement, dated as of November 19, 2020, by and between Solid Biosciences Inc. and Danforth Advisors, LLC (incorporated by reference to Exhibit 10.24 to the Annual Report on Form 10-K filed on March 15, 2021).</u>
10.14*†	<u>Executive Chair Agreement, effective January 1, 2022, by and between Solid Biosciences Inc. and Ian F. Smith, as amended by the First Amendment to Executive Chair Agreement, effective September 30, 2022, Second Amendment to the Executive Chair Agreement, effective January 1, 2024, Third Amendment to the Executive Chair Agreement, effective January 6, 2025 and Fourth Amendment to Executive Chair Agreement, effective January 1, 2026.</u>

10.15†	<u>Amended and Restated 2020 Equity Incentive Plan, as amended (incorporated herein by reference to Exhibit 99.1 to the Registrant's Registration Statement on Form S-8 (File No. 333-288022) filed on June 13, 2025).</u>
10.16†	<u>Form of Stock Option Agreement under the 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q filed on August 6, 2020).</u>
10.17†	<u>Form of Restricted Stock Unit Agreement under the 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.28 to the Annual Report on Form 10-K filed on March 14, 2022).</u>
10.18	<u>Stock Purchase Agreement, dated as of October 22, 2020, by and between the Company and Ultragenyx Pharmaceutical Inc. (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed on November 5, 2020).</u>
10.19#	<u>Investor Agreement, dated as of October 22, 2020, by and between the Company and Ultragenyx Pharmaceutical Inc. (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q filed on November 5, 2020).</u>
10.20#	<u>First Amendment, dated as of October 9, 2020, to the Exclusive Patent License by and between the Company and the University of Washington (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q filed on November 5, 2020).</u>
10.21	<u>Registration Rights Agreement, dated December 10, 2020, by and among the Company and the other parties thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on December 11, 2020).</u>
10.22#	<u>First Amendment, dated as of January 27, 2021, to the Exclusive Patent License by and between the Company and the Curators of the University of Missouri (incorporated by reference to Exhibit 10.36 to the Annual Report on Form 10-K filed on March 14, 2021).</u>
10.23	<u>Lease, dated June 15, 2021, between Solid Biosciences Inc. and Hood Park LLC (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on August 16, 2021).</u>
10.24†	<u>Amended and Restated 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.27 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.25†	<u>Form of Nonstatutory Inducement Stock Option Agreement (incorporated by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q filed on August 16, 2021).</u>
10.26†	<u>Form of Inducement Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 99.5 to the Registration Statement on Form S-8 filed on August 16, 2021).</u>
10.27	<u>Amended and Restated Sales Agreement, dated March 13, 2024, by and between the Company and Jefferies LLC (incorporated by reference to Exhibit 10.30 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.28	<u>Form of Parent Support Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 30, 2022).</u>
10.29	<u>Form of Support and Joinder Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on September 30, 2022).</u>
10.30	<u>Registration Rights Agreement, dated September 29, 2022, by and among Solid Biosciences Inc. and the persons party thereto (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed on September 30, 2022).</u>
10.31*†	<u>Employment Agreement, dated September 29, 2022, by and between Solid Biosciences Inc. and Alexander Cumbo, as amended.</u>
10.32†	<u>Executive Transition and Separation Agreement, dated September 29, 2022, by and between Solid Biosciences Inc. and Ilan Ganot (incorporated by reference to Exhibit 10.6 to the Current Report on Form 8-K filed on September 30, 2022).</u>
10.33*†	<u>Employment Agreement, dated September 29, 2022, by and between Solid Biosciences Inc. and David Tyrone Howton, as amended.</u>
10.34*†	<u>Employment Agreement, dated January 9, 2023, by and between Solid Biosciences Inc. and Kevin Tan, as amended.</u>
10.35*†	<u>Employment Agreement, dated October 2, 2023, by and between Solid Biosciences Inc. and Gabriel Brooks, as amended.</u>

10.36#	<u>Standard Exclusive License Agreement With Know-How (Agreement No. A19110), dated as of March 17, 2020, by and between AavantiBio, Inc. and University of Florida Research Foundation, Incorporated, as amended on August 23, 2022 (incorporated by reference to Exhibit 10.42 to the Annual Report on Form 10-K filed as on March 23, 2023).</u>
10.37#	<u>Standard Exclusive License Agreement With Know-How (Agreement No. A19111), dated as of March 17, 2020, by and between AavantiBio, Inc. and University of Florida Research Foundation, Incorporated, as amended on May 25, 2021 and August 23, 2022 (incorporated by reference to Exhibit 10.43 to the Annual Report on Form 10-K filed on March 23, 2023).</u>
10.38	<u>Form on Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on January 8, 2024).</u>
10.39	<u>Form of Registration Rights Agreement, dated January 8, 2024, by and among Solid Biosciences Inc. and the other parties thereto (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January 8, 2024).</u>
10.40†	<u>2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.49 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.41†	<u>Form of Non-Statutory Stock Option Agreement under the 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.42†	<u>Form of Restricted Stock Unit Agreement under the 2024 Inducement Stock Incentive Plan. Form of Restricted Stock Unit Agreement under the 2024 Inducement Stock Incentive Plan (incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.43†	<u>Form of Restricted Stock Unit Agreement under the 2020 Equity Incentive Plan (incorporated by reference to Exhibit 10.52 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.44##	<u>Patent License Agreement, dated as of March 10, 2016, by and between Solid GT, LLC and the Regents of the University of Michigan (incorporated by reference to Exhibit 10.53 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.45##	<u>Life Technologies Cell Line License Agreement, dated as of November 20, 2016, by and between Solid Biosciences, LLC and Life Technologies Corporation (incorporated by reference to Exhibit 10.54 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.46##	<u>License Agreement, dated as of June 23, 2016, by and between Solid GT, LLC and President and Fellows of Harvard College (incorporated by reference to Exhibit 10.55 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
10.47##	<u>License Agreement, dated as of August 3, 2017, by and between Solid Biosciences, LLC and President and Fellows of Harvard College (incorporated by reference to Exhibit 10.56 to the Annual Report 10-K filed March 13, 2024).</u>
10.48#	<u>Research, Collaboration & License Agreement, dated as of November 4, 2020, by and between the Trustees of the University of Pennsylvania and FA212 LLC, as amended (incorporated by reference to Exhibit 10.50 to the Annual Report on Form 10-K filed on March 6, 2025).</u>
10.49*#	<u>Asset Purchase Agreement, dated as of September 19, 2024, by and between Solid Biosciences Inc. and FA212 LLC, as amended.</u>
10.50	<u>Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on February 18, 2025).</u>
19.1	<u>Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Annual Report on Form 10-K filed on March 6, 2025).</u>
21.1*	<u>Subsidiaries of Solid Biosciences Inc.</u>
23.1*	<u>Consent of PricewaterhouseCoopers LLP, Independent Registered Public Accounting Firm.</u>
31.1*	<u>Certification of Chief Executive Officer of the Registrant Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Chief Financial Officer of the Registrant Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>

32.1**	<u>Certification of Chief Executive Officer of the Registrant Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
32.2**	<u>Certification of Chief Financial Officer of the Registrant Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
97.1	<u>Dodd-Frank Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K filed on March 13, 2024).</u>
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document With Embedded Linkbase Documents
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

† Indicates management contract or compensatory plan.

Certain portions of this exhibit have been omitted because they are not material and contain information that the Registrant customarily and actually treats as private or confidential.

Filed with this Annual Report on Form 10-K solely for the purpose of transitioning this previously-filed exhibit, which is the subject of expiring confidential treatment orders, to the rules governing the filing of redacted exhibits under Regulation S-K Item 601(b)(10)(iv) pursuant to the SEC's CF Disclosure Guidance: Topic 7. Portions of this exhibit have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

SOLID BIOSCIENCES INC.

Date: March 19, 2026

By: /s/ Alexander Cumbo
Alexander Cumbo
President, Chief Executive Officer and Director
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

<u>/s/ Alexander Cumbo</u> Alexander Cumbo	President, Chief Executive Officer and Director (Principal Executive Officer)	March 19, 2026
<u>/s/ Kevin Tan</u> Kevin Tan	Chief Financial Officer (Principal Financial and Accounting Officer)	March 19, 2026
<u>/s/ Ian F. Smith</u> Ian F. Smith	Executive Chairman of the Board	March 19, 2026
<u>/s/ Martin Freed</u> Martin Freed	Director	March 19, 2026
<u>/s/ Ilan Ganot</u> Ilan Ganot	Director	March 19, 2026
<u>/s/ Clare Kahn</u> Clare Kahn	Director	March 19, 2026
<u>/s/ Georgia Keresty</u> Georgia Keresty	Director	March 19, 2026
<u>/s/ Sukumar Nagendran</u> Sukumar Nagendran	Director	March 19, 2026
<u>/s/ Adam Stone</u> Adam Stone	Director	March 19, 2026
<u>/s/ Lynne Sullivan</u> Lynne Sullivan	Director	March 19, 2026

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Solid Biosciences Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Solid Biosciences Inc. and its subsidiaries (the “Company”) as of December 31, 2025 and 2024, and the related consolidated statements of operations, of comprehensive loss, of stockholders’ equity and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

External Research and Development Costs

As described in Note 2 to the consolidated financial statements, research and development costs are expensed as incurred. Research and development expenses include salaries, equity-based compensation and benefits of employees, third-party license fees and other operational costs related to the Company’s research and development activities, including allocated facility-related expenses and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials. The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancellable, and related payments are recorded as research and development expenses as incurred. Management records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, management analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. As disclosed by management, the majority of service providers invoice the Company in arrears for services performed, on a predetermined schedule or when contractual milestones are met; however, some require advanced payments.

The Company's research and development expense for the year ended December 31, 2025 was \$140.3 million, a majority of which relates to external research and development costs.

The principal consideration for our determination that performing procedures relating to external research and development costs is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's external research and development costs.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, testing external research and development costs on a sample basis by agreeing relevant information, including overall contract value, amounts incurred to date, and percentage of completion amounts to the (i) underlying agreements with outside vendors engaged to conduct preclinical studies and clinical trials, (ii) purchase orders, (iii) invoices received, (iv) underlying payments made for expenses incurred on the contracts, and (v) external confirmations or communications obtained by management from outside vendors.

/s/ PricewaterhouseCoopers LLP

Boston, Massachusetts

March 19, 2026

We have served as the Company's auditor since 2017.

SOLID BIOSCIENCES INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2025	2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,900	\$ 80,235
Available-for-sale securities	127,950	68,685
Prepaid expenses and other current assets	16,384	8,382
Restricted cash, current	1,222	—
Total current assets	205,456	157,302
Non-current assets:		
Operating lease, right-of-use assets	21,924	24,295
Property and equipment, net	4,169	4,747
Other non-current assets	223	366
Restricted cash, net of current portion	768	1,952
Total non-current assets	27,084	31,360
Total assets	\$ 232,540	\$ 188,662
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 3,224	\$ 4,237
Accrued expenses and other current liabilities	18,945	19,852
Operating lease liabilities, current	2,103	1,787
Finance lease liabilities	—	1,231
Derivative liabilities	9,200	3,150
Total current liabilities	33,472	30,257
Non-current liabilities:		
Operating lease liabilities, net of current portion	19,058	21,159
Total non-current liabilities	19,058	21,159
Total liabilities	52,530	51,416
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at December 31, 2025 and 2024; no shares issued and outstanding at December 31, 2025 and 2024	—	—
Common stock, \$0.001 par value; 240,000,000 and 120,000,000 shares authorized at December 31, 2025 and 2024, respectively; 78,967,888 and 40,468,141 shares issued and outstanding at December 31, 2025 and 2024, respectively	79	40
Additional paid-in capital	1,137,654	920,609
Accumulated other comprehensive income	52	47
Accumulated deficit	(957,775)	(783,450)
Total stockholders' equity	180,010	137,246
Total liabilities and stockholders' equity	\$ 232,540	\$ 188,662

The accompanying notes are an integral part of these consolidated financial statements.

SOLID BIOSCIENCES INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses:		
Research and development	\$ 140,325	\$ 96,431
General and administrative	38,881	33,297
Total operating expenses	179,206	129,728
Loss from operations	(179,206)	(129,728)
Other income, net:		
Interest income	9,904	9,469
Interest expense	203	(340)
Change in fair value of derivative liabilities	(6,050)	(4,750)
Other income, net	824	652
Total other income, net	4,881	5,031
Net loss	\$ (174,325)	\$ (124,697)
Net loss per share, basic and diluted	\$ (1.99)	\$ (3.06)
Weighted average shares of common stock outstanding used to compute basic and diluted net loss per share	87,504,631	40,816,694

The accompanying notes are an integral part of these consolidated financial statements.

SOLID BIOSCIENCES INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(in thousands)

	Year Ended December 31,	
	2025	2024
Net loss	\$ (174,325)	\$ (124,697)
Other comprehensive income:		
Unrealized gain on available-for-sale securities	5	32
Comprehensive loss	<u>\$ (174,320)</u>	<u>\$ (124,665)</u>

The accompanying notes are an integral part of these consolidated financial statements.

SOLID BIOSCIENCES INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2024	20,386,606	\$ 20	\$ 785,199	\$ 15	\$ (658,753)	\$ 126,481
Issuance of common stock in private placement, net of issuance costs of \$4,407	16,973,103	17	89,437	—	—	89,454
Issuance of pre-funded warrants in private placement, net of issuance costs of \$704	—	—	14,293	—	—	14,293
Issuance of common stock in at-the-market public offering, net of sales commissions of \$471	2,212,937	2	18,367	—	—	18,369
Issuance of common stock in private placement for upfront consideration	364,990	—	2,000	—	—	2,000
Vesting of restricted stock units	335,981	1	—	—	—	1
Issuance of common stock under employee stock purchase plan	122,962	—	337	—	—	337
Exercise of common stock options	71,562	—	457	—	—	457
Unrealized gain on available-for-sale securities	—	—	—	32	—	32
Equity-based compensation	—	—	10,519	—	—	10,519
Net loss	—	—	—	—	(124,697)	(124,697)
Balance at December 31, 2024	40,468,141	40	920,609	47	(783,450)	137,246
Issuance of common stock in public offering, net of issuance costs of \$8,665	35,739,810	36	135,331	—	—	135,367
Issuance of pre-funded warrants in public offering, net of issuance costs of \$3,366	—	—	52,590	—	—	52,590
Issuance of common stock in private placement for payment of developmental milestone consideration	975,496	1	4,999	—	—	5,000
Issuance of common stock in at-the-market public offering, net of sales commissions of \$164	1,189,572	1	6,781	—	—	6,782
Vesting of restricted stock units	434,314	1	(1)	—	—	—
Issuance of common stock under employee stock purchase plan	157,822	—	425	—	—	425
Exercise of common stock options	2,733	—	6	—	—	6
Unrealized gain on available-for-sale securities	—	—	—	5	—	5
Equity-based compensation	—	—	16,914	—	—	16,914
Net loss	—	—	—	—	(174,325)	(174,325)
Balance at December 31, 2025	78,967,888	\$ 79	\$ 1,137,654	\$ 52	\$ (957,775)	\$ 180,010

The accompanying notes are an integral part of these consolidated financial statements.

SOLID BIOSCIENCES INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (174,325)	\$ (124,697)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of discount on available-for-sale securities	(1,874)	(3,592)
Equity-based compensation expense	16,914	10,519
Depreciation and amortization expense	1,636	2,455
Non-cash lease expense	2,371	2,391
Non-cash acquired in-process research and development	—	3,400
Common stock issued as upfront payment for collaboration and license agreement	—	2,000
Change in fair value of derivative liabilities	6,050	4,750
Other	(239)	(88)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(7,993)	(2,445)
Accounts payable	(1,093)	2,205
Change in operating lease liability	(1,786)	(1,676)
Accrued expenses and other liabilities	4,050	4,766
Net cash used in operating activities	<u>(156,289)</u>	<u>(100,012)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(1,153)	(654)
Proceeds from sale of property and equipment	85	5
Proceeds from sales and maturities of available-for-sale securities	178,500	188,900
Purchases of available-for-sale securities	(235,886)	(204,337)
Net cash used in investing activities	<u>(58,454)</u>	<u>(16,086)</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants in public offering, net of underwriting discounts and commissions	189,637	—
Payments of common stock and pre-funded warrants issuance costs in public offering	(1,681)	—
Proceeds from issuance of common stock and pre-funded warrants in private placement	—	108,858
Payments of common stock and pre-funded warrants issuance costs in private placement	—	(5,111)
Proceeds from issuance of common stock in at-the-market public offering, net of sales commissions	6,782	18,369
Proceeds from exercises of common stock options	6	457
Employee stock purchase plan purchases	425	337
Payments of principal portion of finance lease obligations	(723)	(473)
Net cash provided by financing activities	<u>194,446</u>	<u>122,437</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(20,297)</u>	<u>6,339</u>
Cash, cash equivalents, and restricted cash at beginning of period	82,187	75,848
Cash, cash equivalents, and restricted cash at end of period	<u>\$ 61,890</u>	<u>\$ 82,187</u>

The accompanying notes are an integral part of these consolidated financial statements

SOLID BIOSCIENCES INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)
(in thousands)

	Year Ended December 31,	
	2025	2024
Supplemental disclosure of cash flow information:		
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows for operating leases	\$ 4,176	\$ 4,264
Operating cash flows for finance leases	\$ 91	\$ 469
Financing cash flows for finance leases	\$ 723	\$ 340
Supplemental disclosure of non-cash investing, financing, and operating activities:		
Common stock issued as payment for developmental milestone consideration	\$ 5,000	\$ —
Right-of-use assets obtained in exchange for operating lease liabilities	\$ —	\$ 407
Decrease in right-of-use asset and lease liability due to lease termination	\$ —	\$ (261)
Property and equipment purchases included in accounts payable and accruals	\$ 46	\$ —

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheets to the amounts reported in the consolidated statements of cash flows:

	December 31,	
	2025	2024
Cash and cash equivalents	\$ 59,900	\$ 80,235
Restricted cash, current	1,222	—
Restricted cash, net of current portion	768	1,952
Total cash, cash equivalents, and restricted cash, as reported in the consolidated statements of cash flows	\$ 61,890	\$ 82,187

The accompanying notes are an integral part of these consolidated financial statements.

SOLID BIOSCIENCES INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
(amounts in thousands, except share and per share data and where otherwise noted)

1. Nature of the Business

Overview

Solid Bioscience Inc. (the “Company”) is a life sciences company focused on advancing a portfolio of current and future gene therapy candidates (collectively “Candidates”), including SGT-003 for the treatment of Duchenne muscular dystrophy (“Duchenne”), SGT-212 for the treatment of Friedreich’s ataxia (“FA”), SGT-501 for the treatment of catecholaminergic polymorphic ventricular tachycardia, SGT-601 for the treatment of TNNT2-mediated dilated cardiomyopathy, and additional assets for the treatment of genetic cardiac and neuromuscular diseases, at different stages of development with varying levels of investment. The Company is advancing its diverse pipeline across rare neuromuscular and cardiac diseases, bringing together experts in science, technology, disease management and care. Patient-focused and founded by those directly impacted by Duchenne, the Company’s mission is to improve the daily lives of patients living with these devastating diseases.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on licenses, protection of proprietary technology, dependence on key personnel, compliance with government regulations, and the need to obtain additional financing to fund operations. Candidates currently under development will require significant additional research and development efforts, including extensive preclinical studies and clinical trials and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure, and extensive compliance and reporting capabilities.

The Company’s Candidates are in development. There can be no assurance that the Company’s research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval, or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from, among others, other pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, partners, and consultants.

Liquidity

The accompanying consolidated financial statements have been prepared on a basis that assumes the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the ordinary course of business. Through December 31, 2025, the Company has funded its operations primarily with the proceeds from the sale of common stock and pre-funded warrants to purchase shares of its common stock in private placements (including the January 2024 Private Placement (as defined below)), the sale of common stock in its initial public offering, follow-on public offerings in March 2021 and February 2025, and under its at-the-market sales agreement.

On January 11, 2024, the Company issued and sold in a private placement 16,973,103 shares of the Company’s common stock at a price per share of \$5.53 and, to one investor in lieu of shares of common stock, pre-funded warrants to purchase 2,712,478 shares of common stock at a price of \$5.529 per pre-funded warrant (the “January 2024 Private Placement”). The Company received \$103.7 million of net proceeds from the January 2024 Private Placement after deducting offering costs.

On February 19, 2025, the Company issued and sold 35,739,810 shares of its common stock at a price per share of \$4.03 and, to certain investors in lieu of shares of common stock, pre-funded warrants to purchase 13,888,340 shares of common stock at a price of \$4.029 per pre-funded warrant (the “February 2025 Offering”). The Company received approximately \$188.0 million of net proceeds from the February 2025 Offering after deducting underwriting discounts and commissions and estimated offering costs.

On March 9, 2026, the Company issued and sold 14,973,257 shares of its common stock at a price of \$5.61 per share, and, to certain investors in lieu of shares of common stock, pre-funded warrants to purchase 27,807,482 shares of its common stock at a price of \$5.609 per pre-funded warrant (the “March 2026 Private Placement”). The Company received approximately \$226.4 million of aggregate net proceeds from the March 2026 Private Placement after deducting estimated offering costs.

The Company determined the pre-funded warrants met the criteria for equity classification. No warrants were exercised during the years ended December 31, 2025 and 2024.

During the year ended December 31, 2025, the Company issued 1,189,572 shares of its common stock, pursuant to the Company's "at-the-market offering" sales agreement, between the Company and Jefferies LLC (the "ATM Sales Agreement") for net proceeds of \$6.8 million.

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. As of December 31, 2025, the Company had an accumulated deficit of \$957.8 million. During the years ended December 31, 2025 and 2024, the Company incurred net losses of \$174.3 million and \$124.7 million, respectively. The Company used \$156.3 million of cash in operations for the year ended December 31, 2025. The Company expects to continue to generate operating losses in the foreseeable future. Based upon its current operating plan, the Company expects that its cash, cash equivalents, and available-for-sale securities of \$187.9 million, excluding restricted cash of \$2.0 million, as of December 31, 2025, together with the net proceeds from the March 2026 Private Placement, will be sufficient to fund its operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of these financial statements. However, the Company has based this estimate on assumptions that may prove to be wrong, and its operating plan may change as a result of many factors currently unknown to it. As a result, the Company could deplete its capital resources sooner than it currently expects. The Company expects to finance its future cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances or licensing arrangements. If the Company is unable to obtain funding, the Company would be forced to delay, reduce or eliminate some or all of its research and development programs, preclinical and clinical testing or commercialization efforts, which could adversely affect its business prospects.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of Solid Biosciences, Inc. and its wholly-owned subsidiaries. The Company believes that the financial statements as presented reflect all normal recurring adjustments necessary for a fair statement of the information for all periods presented. All intercompany balances and transactions have been eliminated in consolidation.

Significant Judgments and Estimates

The preparation of the Company's consolidated financial statements in conformity with GAAP requires management to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these consolidated financial statements include, but are not limited to, estimates related to recognition of research and development expenses, equity-based compensation, and derivative liabilities. On an ongoing basis, the Company evaluates its judgments and estimates in light of changes in facts and circumstances. The Company bases its estimates on historical experience and on various other factors that the Company believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not apparent from other sources. Changes in estimates are recorded in the period in which they become known. Actual results could differ materially from the Company's estimates.

Cash Equivalents

The Company considers all short-term, highly liquid investments with original maturities of 90 days or less at acquisition date to be cash equivalents.

Available-for-Sale Securities

Available-for-sale securities consist of investments with original maturities greater than 90 days at acquisition date. The Company has classified its investments as short term based on their highly liquid nature and because such available-for-sale securities represent the investment of cash that is available for current operations.

The Company classifies all of its investments with maturities greater than 90 days at acquisition date as available-for-sale securities. The Company's investments are measured and reported at fair value using quoted prices in active markets for similar securities. Unrealized gains and losses on available-for-sale debt securities are reported as a separate component of

stockholders' equity. The cost of debt securities sold is determined on a specific identification basis, and realized gains and losses are included in other income, net within the consolidated statements of operations. Impairment of available-for-sale securities is assessed based on multiple factors, whose relative significance varies by circumstance. Factors considered include whether a decline in fair value below the amortized cost basis is due to credit-related factors or non-credit-related factors, the financial condition and near-term prospects of the issuer, and our intent and ability to hold the investment to allow for an anticipated recovery in fair value. A credit-related impairment is recognized as an allowance on the balance sheet with a corresponding adjustment to earnings. Any impairment that is not credit-related is recognized in other comprehensive income. No such adjustments were necessary during the periods presented.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, and available-for-sale securities. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company maintains each of its cash, cash equivalents, and available-for-sale securities balances with high-quality and accredited financial institutions, and accordingly, such funds are not exposed to significant credit risk. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply products for research and development activities of its programs, including clinical and preclinical testing. These programs could be adversely affected by a significant interruption in the supply of such drug substance products.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents and available-for-sale securities are carried at fair value, determined according to the fair value hierarchy described above. Derivative liabilities are recorded at fair value based on the probability weighted present value of the estimated cash flows pursuant to the contractual terms of each agreement. The derivative liabilities are remeasured quarterly with changes in fair value recorded in change in fair value of derivative liabilities in the consolidated statements of operations. See Note 4, *Fair Value Measurements*, for additional information.

Leases

At the inception of a contract, the Company determines if a contract meets the definition of a lease. A lease is a contract, or part of a contract, that conveys the right to control the use of identified property, plant, or equipment (an identified asset) for a period of time in exchange for consideration. The Company determines if the contract conveys the right to control the use of an identified asset for a period of time. The Company assesses throughout the period of use whether the Company has both of the following: (1) the right to obtain substantially all of the economic benefits from use of the identified asset and (2) the right to direct the use of the identified asset. This determination is reassessed if the terms of the contract are changed. Leases are classified as operating or finance leases based on the terms of the lease agreement and certain characteristics of the identified asset. Right-of-use assets and lease liabilities are recognized at the lease commencement date based on the present value of the minimum future lease payments. Adjustments to the right-of-use asset may be required for items such as lease prepayments or incentives received. The Company's policy is to not record leases with an original term of twelve months or less on the consolidated balance sheets. The Company recognizes lease expense for these short-term leases on a straight-line

basis over the lease term. Certain lease agreements include rental payments that are adjusted periodically for inflation or other variables. In addition to rent, the leases may require the Company to pay additional amounts for taxes, insurance, maintenance and other expenses, which are generally referred to as non-lease components. Such adjustments to rental payments and variable non-lease components are treated as variable lease payments and recognized in the period in which the obligation for these payments was incurred. Variable lease components and variable non-lease components are not measured as part of the right-of-use asset and liability. Only when lease components and their associated non-lease components are fixed are they accounted for as a single lease component and recognized as part of a right-of-use asset and liability. Total contract consideration is allocated to the combined fixed lease and non-lease components.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the useful life of the related asset as follows:

Asset Category	Estimated Useful Life
Laboratory equipment	5 years
Computer equipment	3 years
Computer software	2 years
Furniture and office equipment	5 years
Leasehold improvements	The shorter of the lease term or the estimated useful life of the related asset.

Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the net book value is written off and any resulting gain or loss is included in the consolidated statements of operations. Equipment under a finance lease is stated at fair value at the inception of the lease less accumulated depreciation and is depreciated over the remaining lease term or the estimated useful life of the equipment.

Impairment of Long-Lived Assets

Long-lived assets, comprised of property and equipment, to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

Revenue

Exclusive Licenses

If a license granted in an arrangement is determined to be distinct from the other promises or performance obligations identified in the arrangement, which generally include research and development services, the Company recognizes revenue from non-refundable, upfront fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. In assessing whether a license is distinct from the other promises, the Company considers relevant facts and circumstances of each arrangement, including the research and development capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from the license for its intended purpose without the receipt of the remaining promise, whether the value of the license is dependent on the unsatisfied promise, whether there are other vendors that could provide the remaining promise, and whether it is separately identifiable from the remaining promise. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the arrangement.

Research and Development Services

The promises under the Company's collaboration and license agreements generally include research and development services to be performed by the Company on behalf of the collaboration partner. For performance obligations that include research and development services, the Company generally recognizes revenue allocated to such performance obligations based on an appropriate measure of progress. The Company utilizes judgment to determine the appropriate method of measuring progress for purposes of recognizing revenue, which is generally an input measure, such as costs incurred.

Milestone Payments

At the inception of each arrangement that includes milestone payments based on certain events, the Company evaluates whether the milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the control of the Company, such as regulatory approvals, are not considered probable of being achieved until those approvals are received or the specified event occurs. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular milestone in making this assessment. There is considerable judgment involved in determining whether it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of all milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. If a milestone or other variable consideration relates specifically to the Company's efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Company generally allocates the milestone amount entirely to that performance obligation once it is probable that a significant reversal in the amount of cumulative revenue recognized would not occur.

Royalties

For arrangements that include sales-based royalties, including milestone payments based on a level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its licensing arrangements.

Collaboration Revenue

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 808 and those that are more reflective of a vendor-customer relationship and therefore within the scope of ASC 606, *Revenue from Contracts with Customers* ("ASC 606"). For elements of collaboration arrangements that are accounted for pursuant to ASC 808, an appropriate recognition method is determined and applied consistently, generally by analogy to ASC 606.

Costs Associated with License and Collaborative Arrangements

All costs associated with license and collaborative arrangements are expensed as incurred and recorded in research and development expense in the consolidated statements of operations.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expenses include salaries, equity-based compensation, employee benefits, third-party license fees and other operational costs related to the Company's research and development activities, including allocated facility-related expenses, regulatory costs, manufacturing costs, and external costs of outside vendors engaged to conduct both preclinical studies and clinical trials. Non-refundable pre-payments for goods or services that will be used or rendered for future research and development activities are deferred and capitalized. Such

amounts are recognized as expense as the goods or services are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

The Company may in-license the rights to develop and commercialize product candidates. For each in-license transaction the Company evaluates whether it has acquired processes or activities along with inputs that would be sufficient to constitute a “business” as defined under GAAP. A “business” as defined under GAAP consists of inputs and processes applied to those inputs that have the ability to create outputs. Although businesses usually have outputs, outputs are not required for an integrated set of activities to qualify as a business. When the Company determines that it has not acquired sufficient processes or activities to constitute a business, any upfront payments, as well as milestone payments, are immediately expensed as acquired research and development in the period in which they are incurred.

Research Contract Costs and Accruals

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable, and related payments are recorded as research and development expenses as incurred. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Estimates based on available information are made in determining the accrual balances at the end of any reporting period. Actual results could differ from the Company’s estimates; however, the Company’s historical accrual estimates have not been materially different from the actual costs.

Patent Costs

All patent-related costs incurred for filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Equity-Based Compensation

The Company measures all stock options and other stock-based awards granted to employees, directors and non-employees based on the fair value on the date of the grant and recognizes compensation expense of those awards, over the requisite service period, which is generally the vesting period of the respective award. Forfeitures are accounted for as a reduction of equity-based compensation as they occur. The Company applies the straight-line method of expense recognition to all awards with only service-based vesting conditions.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company calculates volatility utilizing its historical stock price. The expected term of stock options with service-based vesting conditions and options granted to non-employees has been determined utilizing the “simplified” method for awards that qualify as “plain-vanilla” options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company utilized a 0% expected dividend yield in its determination of grant fair value based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future, if ever.

The fair values of restricted stock units and performance-based restricted stock units are measured at the grant date based on the closing price of the Company’s common stock on the date of grant. For restricted stock units, the fair value of the award is recognized on a straight-line basis over the requisite service periods. For performance-based restricted stock unit awards, which are subject to the achievement of performance milestones, the fair value is recognized as expense over the requisite service periods when the achievement of such performance milestones is determined to be probable. If a performance milestone is not determined to be probable or is not met, no equity-based compensation expense is recognized, and any previously recognized expense is reversed.

The Company classifies stock-based compensation expense in its consolidated statements of operations in the same manner in which the award recipient’s payroll costs are classified or in which the award recipient’s service payments are classified.

The Company does not currently hold any treasury shares. Upon the exercise of stock options and the vesting of restricted stock units and performance stock units, the Company issues new shares of common stock and delivers them to the participant.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under the asset and liability method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in

income in the period that includes the enactment date. The Company records valuation allowances to reduce deferred income tax assets to the amount that is more likely than not to be realized. The Company determines whether it is more likely than not that a tax position will be sustained upon examination. If it is not more likely than not that a position will be sustained, no amount of benefit attributable to the position is recognized. The tax benefit to be recognized of any tax position that meets the more likely than not recognition threshold is calculated as the largest amount that is more than 50% likely of being realized upon resolution of the contingency.

Prior to January 25, 2018, the Company had not been subject to U.S. federal income taxes as the Company was organized as a limited liability company. As such, the taxable income or loss was passed through to and included in the tax returns of the members. Since January 25, 2018, the Company's income has since been subject to U.S. federal, state, local, and foreign income taxes and taxed at the prevailing corporate tax rates.

Segment Data

The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is on developing treatments through gene therapy and other means for patients with neuromuscular and cardiac diseases. All of the Company's tangible assets are held in the United States. Please refer to Note 15, *Segment Reporting* for further information.

Comprehensive Loss

Comprehensive loss includes net loss, as well as other changes in stockholders' equity that result from transactions and economic events other than those with members. The Company's only element of other comprehensive income in all periods presented was unrealized gains from available-for-sale securities.

Net Loss per Share

The Company follows the two-class method when computing net loss per share, as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and pre-funded warrants outstanding for the period. Diluted net loss is computed by adjusting net loss to reallocate undistributed earnings based on the potential impact of dilutive securities. Diluted net loss per share is computed by dividing the diluted net loss by the weighted average number of shares of common stock and pre-funded warrants outstanding for the period, including potential dilutive shares of common stock assuming the dilutive effect of common stock equivalents.

Any preferred stock that the Company may issue in the future could entitle the holders of such shares to participate in dividends and not require the holders of such shares to participate in losses of the Company. Accordingly, in periods in which the Company reports a net loss, such losses are not allocated to such participating securities. In periods in which the Company reports a net loss, diluted net loss per share is the same as basic net loss per share, since dilutive shares of common stock are not assumed to have been issued if their effect is anti-dilutive. As of December 31, 2025 and 2024, there was no preferred stock issued or outstanding with any contractual rights.

Contingencies

Loss contingency provisions are recorded if the potential loss from any claim, asserted or unasserted, or legal proceeding, is considered probable and the amount can be reasonably estimated, or a range of loss can be determined. These accruals represent the Company's best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. The Company reviews the status of each significant matter and assesses its potential financial exposure. Significant judgment is required in both the determination of probability and the determination as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, the Company reassesses the potential liability related to pending claims and may change its estimates. These changes in the estimates of the potential liabilities could have a material impact on the Company's consolidated results of operations and financial position.

Asset Acquisitions

Acquisitions of assets or a group of assets that do not meet the definition of a business are accounted for as asset acquisitions using the cost accumulation method, whereby the cost of the acquisition, including certain transaction costs, is allocated to the assets acquired on the basis of relative fair values. No goodwill is recognized in an asset acquisition. Intangible assets that are acquired in an asset acquisition for use in research and development activities which have an alternative future use are capitalized as in-process research and development (“IPR&D”). Acquired IPR&D which has no alternative future use is recognized as research and development expense at acquisition. Contingent milestone payments associated with asset acquisitions are recognized when probable and estimable. These amounts are expensed to research and development if there is no alternative future use associated with the asset or capitalized as an intangible asset if an alternative future use of the asset exists.

Recently Issued Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) No. 2024-03, “Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Sub-Topic 220-40): Disaggregation of Income Statement Expenses,” which requires additional disclosure of the nature of expenses included in the income statement. The standard requires disclosures about specific types of expenses included in the expense captions presented in the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. The requirements should be applied on a prospective basis while retrospective application is permitted. The Company is currently evaluating the impact of adopting this ASU on its consolidated financial statements and disclosures.

In December 2025, the FASB issued ASU No. 2025-11, “Interim Reporting (Topic 270): Narrow-Scope Improvements”. This ASU clarifies and improves existing interim reporting guidance by consolidating disclosure requirements within Topic 270 and introducing a disclosure principle requiring entities to disclose events and changes occurring after the most recent annual reporting period that are expected to have a material effect on the entity’s financial condition or results of operations. The ASU does not introduce significant changes to recognition or measurement guidance. The amendments in this ASU are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the effect of adopting this ASU on its consolidated financial statements and disclosures.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes (Topic 740): Improvements to Income Tax Disclosures.” This ASU updates income tax disclosure requirements primarily by requiring specific categories and greater disaggregation within the rate reconciliation and disaggregation of income taxes paid by jurisdiction. This ASU is effective for annual periods beginning after December 15, 2024 and is applicable to the Company’s fiscal year beginning January 1, 2025, with early application permitted. The Company adopted this standard on a retrospective basis beginning with this Annual Report on Form 10-K, with incremental income tax disclosures. See Note 14, *Income Taxes*, for additional information.

In September 2025, the FASB issued ASU No. 2025-07, “Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606): Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract”. This standard adds a new derivative scope exception for certain non-exchange-traded contracts with underlyings based on operations or activities specific to one party, and clarifies that share-based payments received from a customer in a revenue contract should be accounted for under ASC 606 until the entity's right to receive or retain them is unconditional. The Company adopted this standard beginning with this Annual Report on Form 10-K, noting that it did not have a material impact on its consolidated financial statements or related disclosures.

3. FA212 Asset Acquisition

On September 19, 2024, the Company entered into an asset purchase agreement with FA212 LLC (“FA212”) for the purchase of certain intellectual property, including patents and assigned licenses related to a preclinical drug candidate, which the Company now refers to as SGT-212, assigned manufacturing contracts as well as research and development materials such as manufactured materials and samples.

The Company paid FA212 an upfront payment of \$1.0 million in the third quarter of 2024. Additionally, the Company agreed to pay FA212 development milestone payments of up to \$34.0 million, cumulative sales milestone payments of up to \$21.0

million, and tiered royalties on net sales in the low-single-digits. The Company also assumed from FA212 contingent development milestone payments of up to \$4.2 million, regulatory milestone payments of up to \$13.0 million, cumulative sales milestone payments of up to \$27.5 million, and tiered royalties on worldwide net sales in the mid-single digits payable to the University of Pennsylvania.

Certain development milestone payments to FA212 are payable in either cash, equity, or a combination of both, at the Company's discretion. Such contingent payments were determined to be derivative liabilities and were initially recorded at their fair value of \$3.4 million.

The Company determined that the FA212 agreement represented an asset acquisition of IPR&D assets with no alternative future use and recognized the aggregate acquisition cost of \$5.1 million as research and development expense in the consolidated statement of operations for the year ended December 31, 2024, which included the upfront payment, initial recognition of the derivative liability, and \$0.7 million in transaction costs.

The Company submitted an investigational new drug application ("IND") for SGT-212 for the treatment of FA to the U.S. Food and Drug Administration ("FDA"), which was cleared in December 2024. Upon clearance of the IND, the first developmental milestone of \$5.0 million became payable to FA212. The \$5.0 million milestone liability payment is included in accrued expenses and other current liabilities in the accompanying consolidated balance sheet as of December 31, 2024. On February 28, 2025, the Company made the first development milestone payment in the form of 975,496 shares of its common stock. The derivative liabilities for the remaining contingent payments were recorded at a fair value of \$9.2 million and \$3.2 million at December 31, 2025 and 2024, respectively. See Note 4, *Fair Value Measurements*.

4. Fair Value Measurements

The following tables present information about the Company's financial assets and liabilities measured at fair value on a recurring basis:

December 31, 2025				
	Level 1	Level 2	Level 3	Total
Financial assets				
Cash equivalents:				
Money market funds	\$ —	\$ 51,333	\$ —	\$ 51,333
Total cash equivalents	—	51,333	—	51,333
Available-for-sale securities (Note 5):				
Treasury bills	—	72,932	—	72,932
Government bonds	—	55,018	—	55,018
Total available-for-sale securities	—	127,950	—	127,950
Total financial assets	\$ —	\$ 179,283	\$ —	\$ 179,283
Financial liabilities				
Derivative liabilities (Note 3):	\$ —	\$ —	\$ 9,200	\$ 9,200
Total financial liabilities	\$ —	\$ —	\$ 9,200	\$ 9,200

December 31, 2024				
	Level 1	Level 2	Level 3	Total
Financial assets				
Cash equivalents:				
Money market funds	\$ —	\$ 18,088	\$ —	\$ 18,088
Treasury bills	—	17,434	—	17,434
Total cash equivalents	—	35,522	—	35,522
Available-for-sale securities (Note 5):				
Treasury bills	—	27,895	—	27,895
Government bonds	—	40,790	—	40,790
Total available-for-sale securities	—	68,685	—	68,685
Total financial assets	\$ —	\$ 104,207	\$ —	\$ 104,207
Financial liabilities				
Derivative liabilities (Note 3):	\$ —	\$ —	\$ 3,150	\$ 3,150
Total financial liabilities	\$ —	\$ —	\$ 3,150	\$ 3,150

As of December 31, 2025 and 2024, the fair values of the Company's cash equivalents and available-for-sale securities were determined using Level 2 inputs.

The Company estimated the fair value of the derivative liabilities by using a Monte Carlo simulation forecasting the timing and likelihood of certain development milestone events being achieved and discounting the probability adjusted payments using an appropriate discount rate based on market interest rates. The main assumptions when determining the fair value of the derivative liabilities are the timing of and probability of achieving certain milestones, the estimated volatility of the Company's common stock, and the discount rate. The estimated fair value presented is not necessarily indicative of an amount that could be realized in a current market exchange. The use of alternative inputs and estimation methodologies could have a material effect on these estimates of fair value.

The significant unobservable inputs used in valuing the developmental milestone derivative liabilities at each measurement date are as follows:

Unobservable Input	December 31, 2025		December 31, 2024	
	Range	Average	Range	Average
Probability of achieving certain development milestones	40.0% - 100.0%	70.0%	28.0% - 70.0%	49.0%
Volatility	98.0%	98.0%	85.0%	85.0%
Discount rate	3.5% - 3.7%	3.6%	4.2% - 4.3%	4.3%
Timing of achieving certain development milestones	0.1 - 2.8 years	1.4 years	1.0 - 3.7 years	2.3 years

The following table presents a roll forward of activity associated with the Company's derivative liabilities measured using Level 3 inputs:

	Developmental Milestone Derivative Liabilities
Fair value of derivative liabilities as of January 1, 2025	\$ 3,150
Change in fair value of derivative liabilities	6,050
Fair value of derivative liabilities as of December 31, 2025	\$ 9,200

The Company recognized losses of \$6.1 million and \$4.8 million for the change in fair values of derivative liabilities during the years ended December 31, 2025 and 2024, respectively.

It is the Company's policy to recognize transfers between levels of the fair value hierarchy, if any, at the end of the reporting period. During the years ended December 31, 2025 and 2024, there were no transfers between Level 1, Level 2, and Level 3.

As of December 31, 2025 and 2024, the Company's accounts payable, accrued expenses, and other current liabilities approximated their estimated fair values due to the short-term nature of these financial instruments.

5. Available-for-Sale Securities

A summary of the Company's available-for-sale securities is presented below:

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Treasury bills maturing in one year or less	\$ 72,902	\$ 30	\$ —	\$ 72,932
Government bonds maturing in one year or less	54,996	22	—	55,018
Total available-for-sale securities	\$ 127,898	\$ 52	\$ —	\$ 127,950

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Treasury bills maturing in one year or less	\$ 27,879	\$ 16	\$ —	\$ 27,895
Government bonds maturing in one year or less	40,759	31	—	40,790
Total available-for sale securities	<u>\$ 68,638</u>	<u>\$ 47</u>	<u>\$ —</u>	<u>\$ 68,685</u>

The weighted average contractual maturity of the Company's available-for-sale securities was approximately 0.6 years and 0.5 years as of December 31, 2025 and 2024, respectively.

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2025	2024
Prepaid research and development expenses	\$ 13,969	\$ 6,731
Prepaid other and other current assets	2,415	1,651
Total	<u>\$ 16,384</u>	<u>\$ 8,382</u>

7. Property and Equipment

Property and equipment consisted of the following:

	December 31,	
	2025	2024
Laboratory equipment	\$ 15,626	\$ 14,404
Furniture and fixtures	1,038	936
Computer equipment	744	764
Leasehold improvements	483	470
Computer software	71	320
Construction in process	397	879
	<u>18,359</u>	<u>17,773</u>
Less: accumulated depreciation and amortization expense	(14,190)	(13,026)
Total	<u>\$ 4,169</u>	<u>\$ 4,747</u>

Depreciation and amortization expense was \$1.6 million and \$2.5 million for the years ended December 31, 2025 and 2024, respectively.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

	December 31,	
	2025	2024
Accrued research and development expense	\$ 8,651	\$ 7,268
Accrued compensation	8,815	6,221
Accrued milestone payment (Note 3)	—	5,000
Accrued other and other current liabilities	1,479	1,363
Total	<u>\$ 18,945</u>	<u>\$ 19,852</u>

9. Equity-Based Compensation

Equity-Based Compensation Expense

The Company classified equity-based compensation expense in its consolidated statements of operations as follows:

	Year Ended December 31,	
	2025	2024
Research and development	\$ 5,760	\$ 3,537
General and administrative	11,154	6,982
Total	<u>\$ 16,914</u>	<u>\$ 10,519</u>

Equity Incentive Plans

As of December 31, 2025, the Company's approved equity incentive plans include: the 2018 Omnibus Incentive Plan (the "2018 Plan"); Amended and Restated 2020 Equity Incentive Plan, as amended (the "2020 Plan"); the Amended and Restated 2021 Employee Stock Purchase Plan; and the 2024 Inducement Stock Incentive Plan (the "2024 Plan"). These plans are administered by the Board of Directors (the "Board") and permit the granting of stock options, stock appreciation rights, restricted stock, restricted stock units (the "RSUs"), performance awards, and other stock-based or cash-based awards. Upon the adoption of the 2020 Plan, the Company no longer grants new equity awards under its 2018 Plan. Service based awards to employees generally vest over a four-year period with 25% of such awards vesting following twelve months of continued employment or service. The remaining awards vest in either monthly or yearly installments over the following three years. Stock options granted under the Company's equity incentive plans expire ten years from the date of grant.

Amended and Restated 2020 Equity Incentive Plan

On June 12, 2025 and June 11, 2024, the Company's stockholders approved amendments to the 2020 Plan to increase the number of shares of common stock reserved for issuance under the plan by 9,000,000 shares and 2,000,000 shares, respectively. As of December 31, 2025, there were 3,519,002 stock options outstanding, 2,959,311 RSUs outstanding, 2,074,188 performance stock units outstanding, and 7,554,772 shares remained available for future issuance under the 2020 Plan.

2024 Inducement Stock Incentive Plan

In March 2024, the Board approved the 2024 Plan, which provides for the reservation of 1,000,000 shares of common stock for equity granted as an inducement material to the individuals entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). As of December 31, 2025, there were 100,000 stock options outstanding, 751,045 RSUs outstanding, and 73,947 shares remained available for future issuance under the 2024 Plan.

Amended and Restated 2021 Employee Stock Purchase Plan

The ESPP was adopted by the Company's Board of Directors on April 14, 2021, approved by the stockholders on June 16, 2021, and became effective on June 16, 2021. The first offering period under the ESPP commenced on September 1, 2021.

On June 6, 2023, the Company's stockholders approved an amendment and restatement of the ESPP to (i) increase the number of shares of common stock reserved for issuance under the ESPP from 73,525 to 473,525 and (ii) provide for an annual increase to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2024 and ending with the fiscal year ending December 31, 2033, equal to the least of (a) 293,597 shares of common stock, (b) one percent (1%) of the outstanding shares of common stock on such date and (c) the number of shares of common stock determined by the Board of Directors. The Company's Board of Directors amended and restated the ESPP on November 12, 2023 to provide for 24-month offering periods.

The number of shares of the Company's common stock reserved for issuance under the ESPP is 970,988 shares. At December 31, 2025, 614,225 shares remained available for future issuance under the ESPP.

Stock Options

The table below summarizes the activity with respect to stock options for the year ended December 31, 2025:

	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2025	2,927,937	\$ 18.22	8.01	\$ 193
Granted	1,752,148	\$ 5.58		
Exercised	(2,733)	\$ 2.35		
Expired	(194,390)	\$ 50.40		
Forfeitures	(104,817)	\$ 6.10		
Outstanding at December 31, 2025	4,378,145	\$ 12.04	8.23	\$ 1,077
Vested and expected to vest as of December 31, 2025	4,378,145	\$ 12.04	8.23	\$ 1,077
Exercisable at December 31, 2025	1,876,526	\$ 19.97	7.22	\$ 231

The assumptions used in the Black-Scholes option-pricing model for all stock options granted during each period presented are as follows:

	Year Ended December 31,	
	2025	2024
Common stock price	\$4.10-\$6.17	\$5.76-\$8.64
Expected volatility	111.7% - 114.2%	119.7% - 128.7%
Expected dividends	0%	0.0%
Expected term (in years)	5.31 - 6.38	5.31 - 6.25
Risk-free rate	4.0% - 4.4%	3.7% - 4.4%

The weighted average grant date fair values of stock options granted during the years ended December 31, 2025 and 2024 were \$4.77 and \$6.96, respectively.

The Company recognized \$5.9 million and \$5.1 million of equity-based compensation expense in connection with stock options during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, there was \$10.9 million of total unrecognized equity-based compensation cost related to unvested stock options. This cost is expected to be recognized over a weighted average period of 2.3 years. The intrinsic value of stock options exercised during the years ended December 31, 2025 and 2024 was \$0 and \$0.3 million, respectively.

Restricted Stock Units

The following table summarizes activity with respect to RSUs during the year ended December 31, 2025:

	Units	Weighted- Average Grant Date Fair Value
Nonvested RSUs at January 1, 2025	1,480,272	\$ 7.50
Granted	3,070,020	\$ 4.01
Vested	(434,314)	\$ 7.35
Forfeitures	(306,201)	\$ 4.69
Nonvested RSUs at December 31, 2025	3,809,777	\$ 4.93

The Company recognized \$4.9 million and \$3.0 million of equity-based compensation expense in connection with RSUs during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, there was \$15.0 million of total unrecognized equity-based compensation expense related to nonvested RSUs. This cost is expected to be recognized over a weighted average period of 3.0 years. The aggregate grant date fair value of RSUs vested during the years ended December 31, 2025 and 2024 was \$3.2 million and \$2.2 million, respectively.

Performance Stock Units

In June 2024, the Board approved a grant of performance-based restricted stock unit awards (“PSUs” or “Performance Awards”) to the Company’s executive team. Each PSU represents the contingent right to receive one share of the Company’s common stock. These Performance Awards provide for the vesting of 25% of the target number of underlying RSUs granted upon the achievement of each of four independent performance milestones predetermined by the Board (“Performance Milestones”), subject to the grantee’s continued service with the Company (the “Approval Conditions”).

The Performance Milestones are tied to the achievement of certain business objectives and are non-market and non-financial in nature. The Board will determine that all Approval Conditions have been satisfied and the number of units that will ultimately vest on the 2026 Evaluation Date, which will occur in the first quarter of 2026, and the 2027 Evaluation Date, which will occur in the first quarter of 2027. A maximum of 25% of the target number of RSUs may vest at the 2026 Evaluation Date and the percentage of the target number of RSUs allocable to any Performance Milestone that has not been achieved on or prior to the 2027 Evaluation Date shall be cancelled.

The following table summarizes activity with respect to PSUs during the year ended December 31, 2025:

	Units	Weighted-Average Grant Date Fair Value
Nonvested PSUs at January 1, 2025	2,165,325	\$ 7.51
Granted	—	\$ —
Vested	—	\$ —
Forfeitures	(91,137)	\$ 7.51
Nonvested PSUs at December 31, 2025	2,074,188	\$ 7.51

The Company recognized \$5.9 million and \$2.2 million of equity-based compensation expense in connection with PSUs during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, there was \$3.6 million of unrecognized equity-based compensation cost related to nonvested PSUs based on the achievement of all Performance Milestones. This cost is expected to be recognized over a weighted average period of 0.9 years.

10. Leases

The Company has operating leases for laboratory and office space in Massachusetts and North Carolina.

In June 2021, the Company entered into a lease with Hood Park LLC (“Landlord”), pursuant to which the Company leases approximately 49,869 square feet of office, laboratory, research and development and manufacturing space located in Charlestown, Massachusetts (“Premises”). The Company relocated its corporate headquarters to the Premises in June 2022. The initial term of the lease commenced in June 2022 when the construction of the lessor assets was substantially completed and continues for a ten-year period, unless earlier terminated. The lease provides the Company with an option to extend the lease for an additional five-year term. The Company and the Landlord were each obligated to undertake certain improvements prior to the commencement of the lease, and significant improvements were completed as of June 2022. The monthly lease payment is approximately \$0.3 million with annual escalation of approximately 3%. The lease includes a \$10.2 million construction allowance which is considered a lease incentive and included within the right-of-use asset. The Company was required to post a customary letter of credit in the amount of \$1.8 million, subject to decrease on a set schedule, as a security deposit pursuant to the lease.

On December 22, 2022, the Company entered into a sub-lease agreement (the “Sub-Lease”) with Arkea Bio Corp (“Arkea”). The Sub-Lease permits use by Arkea of a portion of the space leased by the Company at 500 Rutherford Avenue in Charlestown, Massachusetts. The Company subleased approximately 12,461 square feet of the 49,869 square foot building interior space. The Sub-Lease term originally ended on February 28, 2025. The Sub-Lease was subsequently amended by the Sub-Lease Amendment, by and between Arkea and the Company, dated May 10, 2024, to increase the subleased area to approximately 13,714 square feet and extend the term to February 29, 2028.

As of December 31, 2025, minimum future lease payments for operating leases were as follows:

	Operating Leases
2026	\$ 4,284
2027	4,280
2028	4,364
2029	4,493
Thereafter	12,625
Total	30,046
Less: Imputed Interest	8,885
Total Lease Liabilities	\$ 21,161

The following table shows the components of lease costs:

	Year Ended December 31,	
	2025	2024
Lease costs		
Operating lease costs	\$ 4,762	\$ 4,961
Interest on finance leases	(203)	340
Sub-lease income	(931)	(963)
Total lease costs	\$ 3,628	\$ 4,338

Short-term lease and variable lease costs were not material for the years ended December 31, 2025 and 2024.

The following table shows the weighted average remaining lease term and weighted average discount rates for the Company's leases as follows:

	Year Ended December 31,	
	2025	2024
Weighted average remaining lease term (in years)		
Operating leases	6.6	7.6
Finance leases	—	0.8
Weighted average discount rate		
Operating leases	10.8%	10.8%
Finance leases	—	22.8%

11. Commitments and Contingencies

Letter of Credit

The Company had an outstanding letter of credit in the amount of \$2.0 million at December 31, 2025 and 2024, which was required as a condition of the Company's office and laboratory leases.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters, including, but not limited to, losses arising out of breach of such agreements or from intellectual property infringement claims made by third parties. In addition, the Company has entered into indemnification agreements with its executive officers and members of its Board of Directors that require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as executive officers or directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnification arrangements.

The Company does not believe that the outcome of any claims under indemnification arrangements will have a material effect on its financial position, results of operations or cash flows, and it has not accrued any liabilities related to such obligations in its consolidated financial statements as of December 31, 2025 and 2024.

Legal Proceedings

The Company may periodically become subject to legal proceedings and claims arising in connection with ongoing business activities, including claims or disputes related to patents that have been issued or that are pending in the field of research on

which the Company is focused. The Company is not aware of any material legal proceedings or claims as of December 31, 2025.

12. License Agreements

In-License Agreements

University of Washington License Agreement

In 2015, the Company entered into a license agreement with the University of Washington, acting through UW CoMotion, under which the Company obtained an exclusive, royalty-bearing, sublicensable, worldwide license under a patent application owned by the University of Washington relating to novel micro-dystrophins and all patents claiming priority to such patent to develop, manufacture, and commercialize products for use in the treatment of Duchenne and related disease indications caused by a lack of functional dystrophin. The Company has the right to grant sublicenses to third parties contingent upon written approval by the University of Washington prior to executing such sublicense, which approval may not be unreasonably withheld.

In consideration for the rights granted by the agreement, the Company paid a one-time, non-refundable license fee, which was recorded as a research and development expense in 2015. The Company is required to reimburse the University of Washington for costs incurred in applying for, prosecuting and maintaining patents and pay up to an aggregate of approximately \$1.0 million upon the achievement of certain milestones. In October 2017, the first milestone was achieved under this agreement. The milestone payment was recorded as a research and development expense in the fourth quarter of 2017. In October 2020, the license agreement was amended such that the Company was required to pay the University of Washington \$0.4 million in connection with the execution of the Collaboration Agreement. This payment was recorded as a research and development expense in the fourth quarter of 2020. The license agreement was also amended such that the Company is required to pay an aggregate of approximately \$3.4 million upon the achievement of certain milestones. There were no milestones achieved during the years ended December 31, 2025 and 2024. The Company must also pay royalties of a low single digit percentage of future sales by the Company and its sublicensees of products developed under the licensed patent rights. In addition, the Company must pay an annual maintenance fee until certain milestones are achieved, at which time a minimum annual royalty requirement will replace such maintenance fee and will apply to the Company and its sublicensees.

The license agreement remains in effect until the expiration of the last-to-expire patent licensed under the agreement. The Company may terminate the agreement at any time upon providing sixty days' written notice to the University of Washington. The University of Washington may terminate the agreement upon the Company's uncured, material breach of the agreement or if the Company enters into an insolvency-related event.

The Company recorded research and development expense in the amount of \$0 and \$0.1 million for the years ended December 31, 2025 and 2024, respectively, under the agreement.

The University of Missouri License Agreement

In 2015, the Company entered into a license agreement with the Curators of the University of Missouri (the "University of Missouri"), a public corporation of Missouri, under which the Company obtained an exclusive, royalty-bearing, sublicensable, worldwide license under certain patent and patent applications owned by the University of Missouri relating to a novel synthetic microdystrophin gene to make, sell and distribute products for use in the treatment of Duchenne and related disease indications resulting from a lack of functional dystrophin.

In consideration for the rights granted by the agreement, the Company paid a one-time, non-refundable license fee, which was recorded as a research and development expense in 2015. The Company is required to reimburse the University of Missouri for costs incurred in applying for, prosecuting and maintaining the licensed patents and pay up to an aggregate of approximately \$1.0 million upon the achievement of certain milestones for each product developed based on the licensed patents. In October 2017, the first milestone was achieved under this agreement. The milestone payment was recorded as a research and development expense in the fourth quarter of 2017.

Under the agreement, in the event the Company grants a sublicense to another party, the Company is required to pay the University of Missouri a percentage of the consideration received. The license agreement was amended such that the Company was required to pay the University of Missouri \$0.8 million in 2021 and \$1.3 million in 2022. These amounts were recorded as research and development expense in the fourth quarter of 2020. The Company paid \$0.8 million in February 2021 and \$1.3 million in February 2022. The license agreement was also amended such that the Company is required to pay an aggregate of approximately \$1.9 million upon the achievement of certain milestones.

There were no material milestones achieved during the years ended December 31, 2025 and 2024. The Company must pay a royalty of a low single digit percentage of future sales or by its sublicensees of products developed using the licensed patents. In addition, the Company must pay an annual maintenance fee until certain milestones are achieved, after which time a minimum annual royalty will replace such maintenance fee.

Under the agreement, the Company granted the University of Missouri a non-exclusive, royalty-free, irrevocable, paid-up license, with the right to grant sublicenses to non-profit, academic, educational or governmental institutions, to practice and use improvements made by the Company using the licensed patent rights, solely for non-commercial research purposes.

The license agreement remains in effect until the expiration of the last-to-expire patent or the abandonment of the last to be abandoned patent application licensed under the agreement. The University of Missouri may terminate the agreement, or render the license granted thereunder non-exclusive, in individual countries if the Company's sublicensees fail to achieve certain milestones. The Company may terminate the license agreement at any time upon providing six months' written notice to the University of Missouri and paying a termination fee. Each of the University of Missouri and the Company may also terminate the agreement for an uncured default or breach of the agreement by the other party. The Company's ability to cure such breach only applies to the first two notices of such breach provided by the University of Missouri, and thereafter, the University of Missouri may terminate the agreement for the Company's default or breach of the agreement upon thirty days' written notice without an opportunity to cure such default or breach.

The Company recorded research and development expense in the amount of \$0.1 million and \$0.1 million for the years ended December 31, 2025 and 2024, respectively, under the agreement.

University of Florida License Agreements

In 2020, AavantiBio entered into license agreements, broadly relating to FA, with the University of Florida Research Foundation, Inc. ("UFRF"). The Company acquired the agreements in connection with the Acquisition. In 2023, the Company entered into an additional license agreement with UFRF. Under each agreement the Company obtained an exclusive, royalty-bearing, sublicensable, world-wide license to certain patents and patent applications and a royalty-bearing non-exclusive license under the know-how, to make, have made, use, see, have sold, import and export licensed products. UFRF retains the right to practice the patent rights and know-how for internal non-commercial research, including research sponsored by commercial entities, and educational purposes.

In consideration for the rights granted under each agreement, AavantiBio paid a one-time non-refundable license fee. In connection with each agreement, the Company is required to pay an annual license maintenance fee until the first commercial sale of a licensed product after which time a minimum annual royalty will replace such maintenance fees. Under each agreement, the Company is required to reimburse UFRF for costs incurred in applying for, prosecuting and maintaining patents, pay up to an aggregate of approximately \$2.9 million upon the achievement of certain intellectual property, clinical and regulatory milestones for each licensed product under the agreement, and pay a low, single digit royalty on annual net sales by us and our sublicensees of licensed products on a licensed-product-by-licensed product basis. For any licensed product covered by both of these agreements, the Company is only obligated to make one payment for each milestone achieved and royalty payment due. Prior to the Acquisition, AavantiBio paid a single milestone fee related to the agreements of \$0.1 million. Under each agreement, in the event the Company grants a sublicense to another party, the Company is required to pay UFRF a percentage of the consideration received.

Under each agreement, the Company has the right to grant sublicenses to third parties through multiple tiers, to the extent we are in compliance with our diligence obligations under the agreement and that sublicensee is subject to the terms of such agreement.

Under each agreement, the Company is obligated to use commercially reasonable efforts to develop and commercialize products covered by the licensed patent rights or know-how and to achieve certain regulatory and commercialization milestones within estimated time periods. Under the agreements entered in 2023 and 2024, the Company agreed to pay to UFRF cumulative sales milestones of up to \$8.5 million and \$27.0 million, respectively, upon achievement of specified commercial milestone events and tiered royalties on worldwide net sales in the low-to-mid-single digits.

Under each agreement, UFRF controls the prosecution and maintenance of the licensed patents in consultation with the Company and at the Company's expense. In countries in which the Company has not requested prosecution or maintenance of licensed patents in a particular country or jurisdiction, the license granted to such patent rights will terminate in such country or jurisdiction. The Company has the first right to enforce such licensed patents at our expense.

Each of the agreements terminates on a licensed product-by-licensed product basis on the later of: (i) expiration of the patent rights covering such licensed product or (ii) ten years from the first commercial sale of such licensed product. After five years, the Company may terminate an agreement for any reason giving advance written notice and reason for termination. UFRF may terminate an agreement for our uncured default or breach of the agreement. UFRF may immediately terminate an agreement if we bring or assist others in bringing a patent challenge against of the licensed patent rights. If UFRF sends the Company a written demand to terminate a sublicense agreement due to such sublicensee bringing or assisting a patent challenge, UFRF may terminate such agreement if we do not terminate the license with such sublicensee.

Maugeri License Agreement

On June 29, 2023, the Company entered into a license agreement (the “Maugeri License Agreement”), with ICS Maugeri S.p.A. SB (“Maugeri”), to focus on the development and commercialization of cardiac-related products by the Company based on Maugeri’s inventions. Pursuant to the Maugeri License Agreement, Maugeri granted us an exclusive worldwide sublicensable license in certain Maugeri patent rights, including existing patent rights, and those in any improvements or know-how made in performance of the Maugeri License Agreement, and a non-exclusive worldwide sublicensable license in certain Maugeri know-how, including existing know-how, and on any improvement thereto, in each case, subject to certain conditions, that is necessary or reasonably useful to develop the licensed products under the terms of the Maugeri License Agreement. The Company will conduct certain activities agreed to by the parties with respect to the research and development of licensed products. A condition precedent to the effectiveness of the Maugeri License Agreement was regulatory review in Italy, which was completed in the third quarter of 2023 and, upon the completion of the condition precedent, the Maugeri License Agreement became effective.

The Company paid Maugeri an upfront license fee of €1.5 million, which was recorded as research and development expense during the second quarter of 2023. Additionally, the Company agreed to cumulative developmental, regulatory, and commercial milestone payments of up to €15.0 million, cumulative sales milestone payments of up to €15.0 million, upon achievement of specified milestone events, and tiered royalties on worldwide net sales in the low-to-mid-single-digits. In connection with this agreement, the Company paid a €1.0 million milestone payment to Maugeri in the third quarter of 2025. There were no milestones achieved during the year ended December 31, 2024.

The Maugeri License Agreement continues until the latest expiry of (i) the last valid claim (as defined in the Maugeri License Agreement), (ii) regulatory exclusivity, and (iii) all payment obligations. Either party may terminate the Maugeri License Agreement for the other party’s uncured material breach. The Company may also terminate the Maugeri License Agreement in its sole discretion upon 60 days’ prior written notice to Maugeri and payment of a fee.

The Company recorded \$1.2 million in research and development expense for the year ended December 31, 2025 and no research and development expense for the year ended December 31, 2024, under this agreement.

Mayo Clinic Collaboration and License Agreement

In December 2024, the Company entered into a collaboration, patent and know-how license agreement with the Mayo Foundation for Medical Education and Research (the “Mayo”) to further advance the Company’s research and development efforts in the field of genetic therapies, particularly for rare and debilitating cardiac diseases.

As part of the collaboration, the Company will be providing manufactured viral materials and CMC know-how while the Mayo will be responsible for supporting all preclinical research through IND-enabling studies for six programs. The Company will then be responsible for the clinical development of programs chosen by it to develop. Under the terms of the collaboration, the Company and Mayo agreed to share intellectual property rights arising from the collaboration, with the Company retaining exclusive rights to commercialize any resulting therapies.

In connection with the agreement, the Company paid a one-time upfront payment of \$0.6 million in cash and \$2.0 million of shares of its common stock to Mayo, which were recorded to research and development expense in the fourth quarter of 2024 having no alternative future use. Additionally, Mayo is eligible for cumulative developmental milestones of \$5.0 million, cumulative regulatory milestones of \$2.0 million, and cumulative sales milestone payments of up to \$18.0 million, upon achievement of specified milestone events, and tiered royalties on worldwide net sales in the low-to-high-single-digits for certain licensed products developed by the Company. The Company also agreed to pay an annual \$0.6 million know-how access fee to Mayo. There were no milestones achieved during the years ended December 31, 2025 and December 31, 2024.

The agreement also includes provisions for the potential sublicensing of certain intellectual property rights. The Company will also be responsible for reimbursing Mayo for costs incurred in the prosecution and maintenance of any patents resulting from the collaboration.

The collaboration remains in effect for the duration of the intellectual property rights associated with any therapies developed under the agreement. Either party may terminate the agreement with proper notice should specific terms be breached or should an insolvency-related event occur.

The Company recorded \$0.6 million and \$3.2 million in research and development expense for the years ended December 31, 2025 and 2024, respectively, under this agreement.

Other Agreements

The Company has committed to make potential future milestone payments and pay legal fees to third parties as part of licensing and development programs. The agreements generally required an upfront license fee and, under each agreement, the Company may be required to pay annual maintenance fees, royalties, milestone payments and sublicensing fees. Each license agreement is generally cancelable by the Company, given appropriate prior written notice. At December 31, 2025, potential future milestone payments under these agreements totaled an aggregate of \$18.3 million. None of these milestones were assessed to be probable as of December 31, 2025.

Out-License Agreements

From time to time, the Company enters into non-exclusive license and collaboration agreements for the out-licensing of POLARIS-101™, its proprietary, rationally designed capsid technology used in SGT-003, to both companies and academic institutions pursuing treatments for rare diseases. These arrangements may entitle the Company to receive non-refundable upfront payments, contingent obligations for potential development, regulatory and commercial performance milestone payments, cost reimbursement arrangements, product supply and royalty payments as a percentage of worldwide license product sales. At December 31, 2025, potential future milestone payments the Company may be entitled to under these agreements totaled an aggregate of \$97.1 million. None of these milestones were assessed to be probable as of December 31, 2025.

13. Net Loss per Share

The following table sets forth the computation of the Company's basic and diluted net loss per share:

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	\$ (174,325)	\$ (124,697)
Denominator:		
Shares used to compute net loss per share, basic and diluted		
Weighted average shares of common stock outstanding	72,768,275	38,178,327
Weighted average pre-funded warrants to purchase shares of common stock	14,736,356	2,638,367
Weighted average shares of common stock used to compute basic and diluted net loss per share	87,504,631	40,816,694
Net loss per share, basic and diluted	\$ (1.99)	\$ (3.06)

Included within weighted average shares of common stock outstanding for the years ended December 31, 2025 and 2024 are 16,600,818 and 2,712,478 shares of common stock issuable upon the exercise of the pre-funded warrants, respectively. The pre-funded warrants are exercisable at any time for nominal consideration, and as such, the shares are considered outstanding for the purpose of calculating basic and diluted net loss per share.

The outstanding securities presented below were excluded from the calculation of net loss per share because the inclusion of such securities would have been anti-dilutive due to the Company's net loss per share during the periods presented.

	Year Ended December 31,	
	2025	2024
Options to purchase common stock	4,378,145	2,927,937
Nonvested restricted stock units	3,809,777	1,480,272
Nonvested performance stock units	2,074,188	2,165,325
Shares subject to employee stock purchase plan	275,602	281,640
Warrants	2,000	9,230
Total	10,539,712	6,864,404

14. Income Taxes

The Company recorded no tax benefit for the years ended December 31, 2025 and 2024 for the net operating losses incurred due to its uncertainty of realizing a benefit from those items.

	December 31,	
	2025	2024
Income from continuing operations before income tax		
United States	\$ (174,199)	\$ (124,583)
Foreign	—	—
Total worldwide income from continuing operations before income tax	<u>\$ (174,199)</u>	<u>\$ (124,583)</u>

A reconciliation of income taxes computed using the U.S. federal statutory rate to that reflected in operations is as follows:

	December 31,			
	2025		2024	
Income tax computed at U.S. federal statutory tax rate	\$ (36,582)	21.0%	\$ (26,162)	21.0%
Tax credits				
Federal R&D credit	(4,693)	2.7%	(3,314)	2.7%
Federal orphan drug credit	(10,035)	5.8%	(3,171)	2.5%
Change in valuation allowance	48,928	(28.1)%	32,518	(26.1)%
Nontaxable or nondeductible items	939	(0.5)%	137	(0.1)%
Other items	1,443	(0.9)%	(8)	—
Total	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>

The Company established deferred tax assets and liabilities on identified book to tax temporary differences as of the date of conversion to a C-corporation. Deferred income taxes reflect the net tax effects of these temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of the Company's net deferred tax assets are as follows:

	December 31,	
	2025	2024
Deferred tax assets:		
Tax loss carryforwards	\$ 71,602	\$ 37,183
Tax credit carryforwards	31,823	15,324
Deferred expenses	5,593	6,067
Accrued expenses	2,076	1,536
Stock compensation	11,171	9,986
Intangible assets	2,691	2,535
Capitalized R&D	68,304	63,087
Derivative liabilities	2,432	833
Other	52	53
Total deferred tax assets	<u>195,744</u>	<u>136,604</u>
Valuation allowance	(190,437)	(130,690)
Deferred tax liabilities:		
Right-of-use asset	(5,054)	(5,570)
Depreciation	(253)	(344)
Total deferred tax liabilities	<u>(5,307)</u>	<u>(5,914)</u>
Net deferred taxes	<u>\$ —</u>	<u>\$ —</u>

As of December 31, 2025, the Company had federal net operating loss carryforwards of \$262.7 million which may be available to offset future taxable income and do not expire but are limited in their usage to an annual deduction equal to 80% of annual taxable income. In addition, as of December 31, 2025, the Company had state net operating loss carryforwards of approximately \$261.4 million which may be available to offset future taxable income, of which \$257.6 million begins to expire in 2032 and \$3.8 million has unlimited carryforward. The Company also had federal and state tax credits of \$27.8 million and \$5.1 million, respectively, which may be used to offset future tax liability and each of which begin to expire in 2037.

The Company's ability to utilize these federal and state carryforwards may be limited in the future if the Company experiences an ownership change pursuant to Section 382 of the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"). Ownership changes, as defined in the Internal Revenue Code, including those resulting from the issuance of

common stock in connection with the Company's public offerings, may limit the amount of net operating loss and tax credit carryforwards that can be utilized to offset future taxable income or tax liability. The Company completed a study in 2023 to assess whether a change of control had occurred under Section 382, and it was determined that all net operating loss carryforwards and credits generated before December 2, 2022 are limited. As a result, the carryforwards before the ownership change date of December 2, 2022 are not available for utilization and have been written off. The carryforwards as of December 31, 2025 were generated after the ownership change of December 2, 2022.

A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has evaluated the positive and negative evidence bearing upon the realizability of the deferred tax assets. The Company concluded, in accordance with the applicable accounting standards, that it is more likely than not that the Company will be unable to realize the benefit of its deferred tax assets. Accordingly, the Company has recorded a full valuation allowance against its deferred tax assets.

The following table presents the changes in the balance of the Company's deferred income tax asset valuation allowance:

	December 31,	
	2025	2024
Valuation allowance at beginning of year	\$ 130,690	\$ 91,705
Increases recorded to income tax provision	59,747	38,985
Valuation allowance at end of year	<u>\$ 190,437</u>	<u>\$ 130,690</u>

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending income tax examinations. The Company's C-Corporation tax years beginning with the year ended December 31, 2021 are open under statute. Any tax credit or net operating loss carryforward can be adjusted in future periods after the respective year of generation's statute of limitation has closed.

As of December 31, 2025 and 2024, the Company did not have unrecognized tax benefits. The Company recognizes interest and penalties related to income taxes as a component of income tax expense. As of December 31, 2025 and 2024, no interest and penalties have been recorded.

15. Segment Reporting

The Company has one reportable and one operating segment and conducts its business activities primarily in North America and on a consolidated basis. The Company's singular focus is developing treatments through gene therapy and other means for patients with neuromuscular and cardiac diseases. All of the Company's tangible assets are held in the United States.

The accounting policies of the Company are the same as those described in the summary of significant accounting policies.

The Company's chief operating decision maker ("CODM") is its chief executive officer. The CODM assesses performance for the Company and decides how to allocate resources based on net loss as reported on the consolidated statements of operations. The annual budgeting process is the primary mechanism used to make these decisions. The financial information also helps in making performance assessments using budgeted versus actual results.

The following table presents segment expenses, other segment items, and segment net loss for the periods presented:

	Year Ended December 31,	
	2025	2024
Segment expenses:		
SGT-003	58,340	15,197
SGT-501	9,641	17,223
External R&D other	10,649	10,580
Internal R&D expense ⁽¹⁾	29,335	21,705
External G&A expense	19,469	20,122
Internal G&A expense ⁽¹⁾	13,956	12,223
Other segment items ⁽²⁾	37,816	32,678
Other income, net	(4,881)	(5,031)
Consolidated net loss	<u>(174,325)</u>	<u>(124,697)</u>

⁽¹⁾ Internal expenses consisted primarily of payroll and related costs, temporary services, and travel and entertainment.

⁽²⁾ Other segment items primarily included other program costs, equity-based compensation expense, and depreciation and amortization expense.

The measure of segment assets is reported on the balance sheet as total consolidated assets.

16. Subsequent Events

Following the dosing of the first participant in the Phase 1b FALCON clinical trial of SGT-212, a \$7.5 million development milestone became payable to FA212 LLC. On January 15, 2026, the Company made the second milestone payment in the form of 1,316,899 shares of its common stock.

On March 9, 2026, the Company issued and sold 14,973,257 shares of its common stock at a price of \$5.61 per share, and, to certain investors in lieu of shares of common stock, pre-funded warrants to purchase 27,807,482 shares of its common stock at a price of \$5.609 per pre-funded warrant, in the March 2026 Private Placement. The Company received approximately \$226.4 million of aggregate net proceeds from the March 2026 Private Placement, after deducting estimated offering costs.

DESCRIPTION OF SECURITIES REGISTERED UNDER SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

The following description of the securities of Solid Biosciences Inc. (“us,” “our,” “we” or the “Company”) registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), is intended as a summary only and therefore is not a complete description. This description is based upon, and is qualified by reference to, our certificate of incorporation (“charter”), our bylaws and applicable provisions of the Delaware General Corporation Law (the “DGCL”). You should read our charter and bylaws, which are incorporated by reference as Exhibit 3.1 and Exhibit 3.2, respectively, to the Annual Report on Form 10-K of which this Exhibit 4.2 is a part, for the provisions that are important to you.

Authorized Capital Stock

Our authorized capital stock consists of 120,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share, all of which preferred stock is undesignated. Our common stock is registered under Section 12(b) of the Exchange Act.

Common Stock

Voting Rights. Each holder of our common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors.

Dividends. Subject to preferences that may be applicable to any then-outstanding preferred stock, holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities and the satisfaction of any liquidation preference granted to the holders of any then-outstanding shares of preferred stock.

Other Rights. Holders of our common stock have no preemptive, conversion, subscription or other similar rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate in the future.

Preferred Stock

We are authorized to issue up to 10,000,000 shares of “blank check” preferred stock, which may be issued in one or more series upon authorization of our board of directors. Our board of directors is authorized to fix the designations, powers, preferences and the relative, participating, optional or other special rights and any qualifications, limitations and restrictions of the shares of each series of preferred stock. The authorized shares of our preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. If the approval of our stockholders is not required for the issuance of shares of our preferred stock, our board may determine not to seek stockholder approval. A series of our preferred stock could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt.

Provisions of Our Certificate of Incorporation and Bylaws and the DGCL That May Have Anti-Takeover Effects

Board of Directors Vacancies: Our charter and bylaws authorize only our board of directors to fill vacant directorships, including newly created seats. In addition, the number of directors constituting our board of directors may only be set by a resolution adopted by a majority vote of our entire board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by

filling the resulting vacancies with its own nominees. This makes it more difficult to change the composition of our board of directors but promotes continuity of management.

Classified Board: Our charter and bylaws provide that our board of directors will be classified into three classes of directors, each with staggered three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

Stockholder Action; Special Meetings of Stockholders: Our charter provides that our stockholders may not take action by written consent, but may only take action at annual or special meetings of our stockholders. As a result, a holder controlling a majority of our capital stock would not be able to amend our bylaws or remove directors without holding a meeting of our stockholders called in accordance with our bylaws. Further, our bylaws and charter will provide that special meetings of our stockholders may be called only by a majority of our board of directors, the Chairman of our board of directors or our Chief Executive Officer, thus prohibiting a stockholder from calling a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

Advance Notice Requirements for Stockholder Proposals and Director Nominations: Our bylaws provide advance notice procedures for stockholders seeking to bring matters before our annual meeting of stockholders or to nominate candidates for election as directors at our annual meeting of stockholders. Our bylaws also specify certain requirements regarding the form and content of a stockholder's notice. These provisions might preclude our stockholders from bringing matters before our annual meeting of stockholders or from making nominations for directors at our annual meeting of stockholders if the proper procedures are not followed. We expect that these provisions might also discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of our company.

Supermajority Voting: The DGCL provides, generally, that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an annual election of directors. In addition, the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in an election of directors is required to amend or repeal or to adopt certain provisions of our charter.

No Cumulative Voting: The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless a corporation's certificate of incorporation provides otherwise. Our charter does not provide for cumulative voting.

Removal of Directors Only for Cause: Our charter provides that stockholders may remove directors only for cause and only by the affirmative vote of the holders of at least two-thirds of our outstanding common stock.

Delaware Business Combination Statute. We are subject to the provisions of Section 203 of the DGCL, regulating corporate takeovers. In general, DGCL Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years following the date on which the person became an interested stockholder unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) at or subsequent to the date of the transaction, the business combination is approved by the board of directors of the corporation and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least two-thirds of the outstanding voting stock that is not owned by the interested stockholder.

Generally, a business combination includes a merger, asset or stock sale, or other transaction or series of transactions together resulting in a financial benefit to the interested stockholder. An interested stockholder is a person who, together with affiliates and associates, owns or, within three years prior to the determination of interested stockholder status, did own 15% or more of a corporation's outstanding voting stock. We expect the existence of this provision to have an anti-takeover effect with respect to transactions our board of directors does not approve in advance. We also anticipate that DGCL Section 203 may also discourage attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

Exclusive Forum Selection. Our charter provides that the Court of Chancery of the State of Delaware will be the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our charter or our bylaws; any action to interpret, apply, enforce or determine the validity of our charter or our bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. We do not intend to have this choice of forum provision apply to, and this choice of forum provision will not apply to, actions arising under the Securities Act of 1933, as amended, or the Exchange Act.

EXECUTIVE CHAIR AGREEMENT

This Executive Chair Agreement (together with Exhibit A, the “Agreement”), effective January 1, 2022 (the “Effective Date”), is by and between Ian F. Smith, an individual having an address at [**] (the “Executive Chair”), and Solid Biosciences Inc., a Delaware corporation (together with its affiliates, the “Company”), having an address at 141 Portland Street, Fifth Floor, Cambridge, MA 02139.

WHEREAS, Executive Chair is currently serving as a member and chairman of the Board of Directors of the Company (the “Board”);

WHEREAS, Executive Chair has also been providing advisory services to Company pursuant to a consulting agreement between the Parties entered into on January 4, 2021 (the “Prior Agreement”) and both parties acknowledge and agree that, as of the Effective Date of this Agreement, the agreed upon services under the Prior Agreement have been completed;

WHEREAS, from and after the close of business on the Effective Date, Executive Chair shall no longer serve under the Prior Agreement, but shall be retained as the Executive Chairman pursuant to the terms and conditions set forth herein; and

NOW THEREFORE, in consideration of the promises and mutual covenants herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Executive Chair and the Company agree as follows:

1. Services. Company retains Executive Chair, and Executive Chair agrees to provide, part-time advisory services to Company, consistent with his position as Executive Chairman of the Board, and as more fully set forth on Exhibit A attached hereto (the “Services”). It is understood and agreed that the Executive Chair will not be an executive officer of the Company and that Chief Executive Officer of the Company will continue to be the Company’s principal executive officer and will continue to report directly to the board of directors and to the Executive Chairman.

2. Compensation. As consideration for Services provided under this Agreement, the Company shall grant, subject to approval of Company’s Board, to Executive Chair an option to purchase 194,500 shares of the Company’s Common Stock (“Stock Options”) at an exercise price per share equal to the closing price of the Company’s Common Stock on January 3, 2021 (the “Grant Date”), and 97,250 restricted stock units (the “RSUs” and together with the RSUs, the “Awards”). The Awards will vest in equal quarterly installments with the first installment vesting three months from the Grant Date and the final installment vesting date on the date that is 12 months from the Grant Date, subject to continued services as a Director of the Company. Additionally, in the event of a change in control of the Company and on terms consistent with board of director equity award agreements, all unvested Awards will accelerate and vest in full.

3. Work-Made-for Hire.

(a) All right, title and interest in any and all writings, ideas, inventions, know-how, designs, improvements or other property created during Executive Chair's advisory relationship relating in any way to the assets, business or operations of the Company, constituting copyrights, patents, trademarks, service marks and related rights or other forms of proprietary rights or information (regardless of whether any such copyrights, patents, trademarks and service marks or other rights have or may be registered) that are created, adapted or improved by Executive Chair (whether alone or in conjunction with any other person or employee), and all material created during Executive Chair's advisory relationship that includes any of the foregoing (collectively, "Covered Material"), shall be owned by the Company and to the extent that it includes copyrightable subject matter, shall be deemed a work made for hire for the Company within the meaning of the United States Copyright Act of 1976 and for all other purposes. If any Covered Material is deemed not to be work made for hire, such Covered Material is hereby assigned by Executive Chair to the Company and Executive Chair shall not have or claim to have, under this Agreement or otherwise, any right, title or interest of any kind or nature whatsoever in such Covered Material.

(b) The Company shall have the right to apply for and obtain registrations in the United States Copyright Office and the United States Patent and Trademark Office, in its own or its designee's name, of its rights in any or all of the Covered Material. If for any reason the rights in any Covered Material are registered, or applied to be registered, in Executive Chair's name, Executive Chair shall assign in writing such application or registration to the Company and hereby authorizes and appoints the Company its agent for the purpose of recording such assignment.

(c) Upon request of Company, Executive Chair shall execute, acknowledge and deliver all applications, assignments or other instruments; make or cause to be made all rightful oaths; testify in all legal proceedings; communicate all known facts which relate to such works, copyrights, inventions, ideas, discoveries, designs and improvements; perform all lawful acts and otherwise render all such assistance as the Company may deem necessary to protect the Company's interest therein including any assistance which the Company shall deem necessary in connection with any proceeding or litigation involving the same. The Company shall reimburse Executive Chair for all reasonable out-of-pocket costs, incurred by Executive Chair in rendering any such assistance requested by the Company pursuant to this Section. In the event that Executive Chair should fail or refuse to execute such documents within a reasonable time, Executive Chair appoints Company as attorney to execute and deliver any such documents on Executive Chair's behalf.

4. Nondisclosure. Executive Chair agrees to (a) hold the Confidential Information (as defined below) in confidence; (b) not disclose any Confidential Information to any third party without the prior written consent of Company; (c) not use the Confidential Information for any purpose except solely as required to perform the Services; and (d) treat Confidential Information with no less than a reasonable degree of care. For purposes of this Agreement, the term "Confidential Information" means any and all information and derivative information, in whatever form or medium, including oral information, concerning or relating to the Company or information of any third party that the Company is under an obligation to keep confidential or that is maintained by the Company as confidential, including, without limitation, intellectual property of the

Company, such as, but not limited to, Covered Material, patent applications, copyrights, copyright applications, and trade secrets; information regarding or resulting from research and development activities performed by or on behalf of the Company and other projects (such as, but not limited to, preclinical and clinical data, design details and specifications, engineering information, and works in process); and business and financial information (such as, but not limited to, current, future, and proposed products and services, financial information and models, information relating to procurement requirements, purchasing, manufacturing, investors, customer lists, customers, suppliers, facilities, product plans, product ideas, business strategies, marketing or business plans, financial or personnel matters, investors, employees, business and contractual relationships, business forecasts, sales, strategies, operations, policies, procedures, commercialization capabilities, and information regarding third parties). Notwithstanding the foregoing, Confidential Information does not include information that Executive Chair can demonstrate: (a) is publicly known and generally available in the public domain other than in consequence of improper action by any person; or (b) was acquired by Executive Chair free and clear of any duty of confidentiality or restricted use and without improper action by the transferor of such information or any other person. Executive Chair shall keep confidential all matters entrusted to Executive Chair by or on behalf of the Company and shall not use or attempt to use any Confidential Information except as may be required in the ordinary course of performing Executive Chair's duties as an advisor to the Company, and Executive Chair shall not use any Confidential Information in any manner that may injure or cause loss or may be calculated to injure or cause loss to the Company, whether directly or indirectly. Nothing in this Agreement prohibits Executive Chair from reporting possible violations of federal or state law or regulations to any governmental agency or entity or self-regulatory institution, including but not limited to the Equal Employment Opportunity Commission, the National Labor Relations Board, the Department of Justice, the Securities and Exchange Commission, Congress, and any Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation. Prior authorization of the Company shall not be required to make any such reports or disclosures and Executive Chair is not required to notify the Company that Executive Chair has made such reports or disclosures.

5. Compliance with Laws. Executive Chair agrees to provide the Services to Company and its affiliates in accordance with all applicable laws and regulations and the highest professional standards. Executive Chair represents and warrants that Executive Chair has not been, and is not under consideration to be (a) debarred from providing services pursuant to Section 306 of the United States Federal Food Drug and Cosmetic Act, 21 U.S.C. § 335a; (b) excluded, debarred or suspended from, or otherwise ineligible to participate in, any federal or state health care program or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)); (c) disqualified by any government or regulatory agencies from performing specific services, and is not subject to a pending disqualification proceeding; or (d) convicted of a criminal offense related to the provision of health care items or services, or under investigation or subject to any such action that is pending.

6. Compliance with Obligations to Third Parties. Executive Chair represents and warrants to Company that the terms of this Agreement and Executive Chair's performance of Services do not and will not conflict with any of Executive Chair's obligations to any third parties. Executive Chair represents that Executive Chair has not brought and will not bring with Executive

Chair to Company or use in the performance of Services any equipment, funds, space, personnel, facilities, confidential information, trade secrets or other resources of any third party which are not generally available to the public, nor will Executive Chair take any other action that would result in a third-party asserting ownership of, or other rights in, any Covered Material. If Executive Chair is a faculty member at or employee of a university or hospital or another organization or company ("Institution"), Executive Chair represents and warrants that Executive Chair is not prohibited by any applicable policy of such Institution, including without limitation any policy addressing conflicts of interest or intellectual property, from performing external consulting services and assigning rights to intellectual property arising from such services to Company or a third party. To the extent Executive Chair is subject to any policy of his/her employer that requires approval of agreements governing external consulting services, Executive Chair represents that such approval has been given and covenants that such approval will be obtained prior to entering into any amendment to this Agreement requiring such approval.

7. Non-hire of Employees and Consultants. During the Term and for a one year period thereafter, Executive Chair will not (except on the Company's behalf), directly or indirectly, alone or as a consultant, partner, officer, director, employee, joint venturer, lender or stockholder of any entity, employ, hire, retain, attempt to employ, hire or retain, or knowingly permit any company or business organization by which Executive Chair is employed or which is directly or indirectly controlled by Executive Chair to employ, hire or retain, any Company employee or consultant, or any such person whose employment or consultancy with the Company has terminated within six months prior to or after Executive Chair's departure from the Company.

8. Nonsolicitation of Employees and Consultants. During the Term and for a one year period thereafter, Executive Chair will not (except on the Company's behalf), directly or indirectly, alone or as a consultant, partner, officer, director, employee, joint venturer, lender or stockholder of any entity, in any manner seek to solicit or induce any Company employee or consultant, or any such person whose employment or consultancy with the Company has terminated within six months prior to or after Executive Chair's departure from the Company, to leave his or her employment or consultancy with the Company, or assist in the recruitment or hiring of any such person.

9. Nondisparagement. Executive Chair shall not at any time, whether during or after the Term, regardless of the reason for such termination, make to any person or entity disparaging, critical or otherwise detrimental comments of a business or personal nature relating to the Company or its personnel.

10. Use of Name. Executive Chair will not use the name, logo, trade name, service mark, or trademark, or any simulation, abbreviation, or adaptation of same, or the name of Company or any of its affiliates for publicity, promotion, or other uses without Company's prior written consent.

11. Company Property. Executive Chair shall not make, use or permit to be used any Company Property otherwise than for the benefit of the Company. The term "Company Property" shall include all Confidential Information; the Company's records, files and data; all Company computers, cellular telephones, personal digital assistants, credit and/or calling cards, keys, access

cards and the like; and all other documentation or materials of any nature and in any form, whether written, printed, electronic or in digital format or otherwise, relating to any matter within the scope of the business of the Company or concerning any of its dealings or affairs and any other Company property in Executive Chair's possession, custody or control. Executive Chair further agrees that upon expiration or termination of this Agreement, Executive Chair shall immediately return all Company Property to Company. Executive Chair acknowledges and agree that all Company Property shall be and remain the sole and exclusive property of the Company. Immediately upon the expiration or termination of this Agreement, Executive Chair shall deliver all Company Property in Executive Chair's possession, and all copies thereof, to the Company.

12.Term & Termination. The term of this Agreement will commence on the Effective Date and will expire on December 31, 2022, unless extended by mutual written agreement of the parties or earlier terminated in accordance with this Section 12 (the "Term"). Notwithstanding anything to the contrary herein, the Company may terminate this Agreement, for any or no reason, on written notice to Executive Chair and Executive Chair may terminate this agreement, for any reason or no reason, on fifteen (15) days prior written notice to the Company.

13.Notices. All notices required or permitted under this Agreement must be in writing and must be given by directing the notice to the address for the receiving party set forth in this Agreement or at such other address as the receiving party may specify in writing under this procedure. Notices to Company will be marked "Attention: Chief Legal Officer." All notices must be given (i) by personal delivery, with receipt acknowledged, (ii) by prepaid certified or registered mail, return receipt requested, or (iii) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or at a later date stated in the notice.

14.Remedies. Executive Chair agrees that (i) Company may be irreparably injured by a breach of this Agreement by Executive Chair; (ii) money damages would not be an adequate remedy for any such breach; (iii) as a remedy for any such breach Company will be entitled to seek equitable relief, including injunctive relief and specific performance, without being required by Executive Chair to post a bond; and (iv) such remedy will not be the exclusive remedy for any breach of this Agreement.

15.Independent Contractor. Executive Chair is an independent contractor and not an employee of the Company. Executive Chair shall be responsible for all taxes arising from compensation and other amounts paid under this Agreement. Neither federal, state or local income tax, nor payroll tax of any kind, shall be withheld or paid by the Company on Executive Chair's behalf. Executive Chair will not be eligible for, and shall not participate in, any employee pension, health, welfare, or other fringe benefit plan of the Company.

16.Waiver; Amendments. Any waiver by the Company of a breach of any provision of this Agreement shall not operate or be construed as a waiver of any subsequent breach of such provision or any other provision hereof. In addition, any amendment to or modification of this Agreement or any waiver of any provision hereof must be agreed to in writing by both parties.

17.Severability. Executive Chair agrees that each provision and the subparts of each provision herein shall be treated as separate and independent clauses, and the unenforceability of

any one clause shall in no way impair the enforceability of any of the other clauses of the Agreement. Moreover, if one or more of the provisions contained in this Agreement shall for any reason be held to be excessively broad as to scope, activity, subject or otherwise so as to be unenforceable at law, such provision or provisions shall be construed by the appropriate judicial body by limiting or reducing it or them, so as to be enforceable to the maximum extent compatible with the applicable law as it shall then appear. Executive Chair hereby further agrees that the language of all parts of this Agreement shall in all cases be construed as a whole according to its fair meaning and not strictly for or against either of the parties.

18.Survival. Executive Chair's obligations under Section 3 through 22 of this Agreement shall survive the expiration or termination of this Agreement and shall be binding upon Executive Chair's successors, heirs, executors, administrators and legal representatives.

19.Assignment. The Company shall have the right to assign this Agreement to its successors and assigns, and all covenants and agreements hereunder shall inure to the benefit of and be enforceable by said successors or assigns. Executive Chair may not assign this Agreement. In no event will Executive Chair assign or delegate responsibility for actual performance of the Services to any third party.

20.Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of laws of such state. The parties agree to submit to the exclusive jurisdiction of the state and federal courts located in Commonwealth of Massachusetts and waive any defense of inconvenient forum to the maintenance of any action or proceeding in such courts.

21.Entire Agreement. This Agreement sets forth the complete, sole and entire agreement between the parties with respect to the subject matter herein and supersedes any and all other agreements, negotiations, discussions, proposals, or understandings, whether oral or written, previously entered into, discussed or considered by the parties.

22.Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument. A facsimile or portable document format (".pdf") copy of this Agreement, including the signature pages, will be deemed an original.

IN WITNESS HEREOF, Executive Chair has executed this Agreement as of the last date written below.

SOLID BIOSCIENCES INC.

IAN F. SMITH

By: /s/ Ilan Ganot
Name: Ilan Ganot
Title: President & Chief Executive Officer

/s/ Ian Smith

EXHIBIT A

Executive Chairman Services

The Company requires, in addition to the traditional duties as Chairman of the Board, that the Executive Chair, as Executive Chairman, will be available to perform the duties customarily related to this function, including:

- Provide mentorship and guidance to the Company's Chief Executive Officer (who will remain the Company's principal executive officer) and senior leadership team on operational and strategic matters; Chief Executive Officer will continue to report to the Board, as well as to the Executive Chair
 - Act as a liaison between the Company's senior management and the Board;
 - Participate in regular meetings with the Chief Executive Officer and Chief Operating Officer to further advance the Company's strategic initiatives;
 - Make himself available as reasonably requested by the Board or Executive Chair officers of the Company to fulfill such other duties as may be reasonably requested, consistent with his status as the Executive Chair Chairman; and
 - Devote between thirty-five to fifty (35-50) hours per month, including one (1) full day per week, on a schedule and at a location(s) mutually agreed between Executive Chair and the Company's Chief Executive Officer, to include flexible availability to the Company's Chief Executive Officer and Chief Operating Officer
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FIRST AMENDMENT TO
EXECUTIVE CHAIR AGREEMENT

THIS FIRST AMENDMENT TO EXECUTIVE CHAIR AGREEMENT is effective September 30, 2022 (the “First Amendment Date”), is by and between Ian F. Smith, an individual having an address at [**] (the “Executive Chair”), and Solid Biosciences Inc., a Delaware corporation (together with its affiliates, the “Company”), having an address at 500 Rutherford Ave., Charlestown, MA 02129.

WHEREAS, Executive Chair and the Company are parties to that certain Executive Chair Agreement (“Agreement”), effective as of January 1, 2022 (the “Effective Date”), and

WHEREAS, the parties desire to amend the Agreement in manner set forth below.

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Compensation. Section 2 of the Agreement is amended by inserting a new Section 2A as follows: and restated in its entirety as follows:

“2A. Compensation – 2023. As consideration for Services provided under this Agreement from and after January 1, 2023, the Company shall, subject to approval of Company’s Board, grant to Executive Chair equity awards (the “2023 Awards”) with an aggregate total Black Scholes value of \$700,000, consisting of (i) 50% stock options (the “2023 Stock Options”) at an exercise price per share equal to the closing price of the Company’s Common Stock on January 2, 2023 (the “2023 Grant Date”) and (ii) 50% restricted stock units (“2023 RSUs”), in each case adjusted, as applicable and appropriate, to reflect fully the effect of any reclassification, stock split, reverse split, stock dividend, reorganization, recapitalization or other like change with respect to Company Common Stock occurring (or for which a record date is established) after the date of this Amendment and prior to the 2023 Grant Date. The 2023 Awards will vest in equal quarterly installments with the first installment vesting three months from the 2023 Grant Date and the final installment vesting date on the date that is 12 months from the 2023 Grant Date, subject to continued services as a Director of the Company. Additionally, in the event of (i) the early termination of this Agreement prior to the expiration of the Term and/or (ii) a change in control of the Company and on terms consistent with board of director equity award agreements, all unvested 2023 Awards will accelerate and vest in full.”

2. Term. Section 12 of the Agreement is amended and restated in its entirety as follows:

“Term & Termination. The term of this Agreement will commence on the Effective Date and will expire on December 31, 2023, unless extended by mutual written agreement of the parties or earlier terminated in accordance with this Section 12 (the “Term”). Notwithstanding anything to the contrary herein, the Company may terminate this Agreement, for any or no reason, on written notice to Executive Chair and Executive Chair may terminate this agreement, for any reason or no

reason, on fifteen (15) days prior written notice to the Company. The Board shall periodically review the ongoing benefit of the Executive Chair position to the Company and may elect to terminate the Agreement in accordance with the preceding sentence following any such review.”

3. Governing Law. This First Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of laws of such state. The parties agree to submit to the exclusive jurisdiction of the state and federal courts located in Commonwealth of Massachusetts and waive any defense of inconvenient forum to the maintenance of any action or proceeding in such courts.

4. Entire Agreement. Except as amended hereby, the Agreement shall remain in full force and effect as originally written..

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this First Amendment to Executive Chair Agreement as of the date first above written.

SOLID BIOSCIENCES INC.

By: /s/ Ilan Ganot

Name: Ilan Ganot

Title: Chief Executive Officer

IAN F. SMITH

/s/ Ian F. Smith

SECOND AMENDMENT TO
EXECUTIVE CHAIR AGREEMENT

THIS SECOND AMENDMENT TO EXECUTIVE CHAIR AGREEMENT (“Amendment”) is effective January 1, 2024 (the “Second Amendment Date”), is by and between Ian F. Smith, an individual having an address at [**] (the “Executive Chair”), and Solid Biosciences Inc., a Delaware corporation (together with its affiliates, the “Company”), having an address at 500 Rutherford Ave., Charlestown, MA 02129.

WHEREAS, Executive Chair and the Company are parties to that certain Executive Chair Agreement (“Agreement”), effective as of January 1, 2022 (the “Effective Date”), and

WHEREAS, the parties desire to amend the Agreement in manner set forth below.

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Definitions. Each capitalized term used but not defined herein shall have the meaning ascribed to such term in the Agreement.

2. Compensation. Section 2 of the Agreement is amended by inserting a new Section 2B as follows:

“2A. Compensation – 2023. As consideration for Services provided under this Agreement from and after January 1, 2024, the Company shall, subject to approval of Company’s Board, grant to Executive Chair equity awards (the “2024 Awards”) with an aggregate total Black Scholes value of \$150,000, consisting of (i) 50% stock options (the “2024 Stock Options”) at an exercise price per share equal to the closing price of the Company’s Common Stock on 2024 Grant Date and (ii) 50% restricted stock units (“2024 RSUs”), in each case adjusted, as applicable and appropriate, to reflect fully the effect of any reclassification, stock split, reverse split, stock dividend, reorganization, recapitalization or other like change with respect to Company Common Stock occurring (or for which a record date is established) after the date of this Amendment and prior to the Grant Date. The 2024 Awards will vest in equal quarterly installments with the first installment vesting three months from the 2024 Grant Date and the final installment vesting date on the date that is 12 months from the 2024 Grant Date, subject to continued services as a Director of the Company. Additionally, in the event of (i) the early termination of this Agreement prior to the expiration of the Term and/or (ii) a change in control of the Company and on terms consistent with Board of Director equity award agreements, all unvested 2024 Awards will accelerate and vest in full. The Company’s external compensation consultants evaluated the cash rate and found the rates to be appropriate. The consultants were present for the official recommendation to the Compensation Committee.”

3. Term. Section 12 of the Agreement is amended and restated Second in its entirety as follows:

“Term & Termination. The term of this Agreement will commence on the Effective Date and will expire on December 31, 2024, unless extended by mutual written agreement of the parties or earlier terminated in accordance with this Section 12 (the “Term”). Notwithstanding anything to the contrary herein, the Company may terminate this Agreement, for any or no reason, on written notice to Executive Chair, and Executive Chair may terminate this agreement, for any reason or no reason, on fifteen (15) days prior written notice to the Company. The Board shall, on or about June 1, 2024, and periodically thereafter, review the ongoing benefit of the Executive Chair position to the Company and may elect to terminate the Agreement in accordance with the preceding sentence following any such review in accordance with the preceding sentence.

4. Remaining Provisions of the Agreement. Except as provided herein, each of the other provisions of the Agreement shall remain in full force and effect.

5. References. Upon the effectiveness of this Amendment, on and after the date hereof, each reference in the Agreement to “this Agreement,” “hereunder,” “hereof,” “herein,” or words of like import shall mean and be reference to the Agreement, as amended hereby.

6. Governing Law. This Second Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of laws of such state. The parties agree to submit to the exclusive jurisdiction of the state and federal courts located in Commonwealth of Massachusetts and waive any defense of inconvenient forum to the maintenance of any action or proceeding in such courts.

7. Counterparts. This Amendment may be executed in one or more counterparts, including by electronic (PDF) transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

8. Entire Agreement. This Agreement, as supplemented and modified by this Amendment contains the Parties’ entire agreement, and there are no promises or conditions in any other agreement between the Parties, whether oral or written, concerning the subject matter hereof. As supplemented and modified by this Amendment, the agreement supersedes any prior written or oral agreements between the Parties concerning the subject matter hereof.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment No. 2 to Executive Chair Agreement as of the date first above written.

SOLID BIOSCIENCES INC.

By: /s/ Bo Cumbo

Name: Bo Cumbo

Title: President and CEO

Date: 12/31/2023

IAN F. SMITH

/s/ Ian F. Smith

Date: 01/01/2024

THIRD AMENDMENT TO
EXECUTIVE CHAIR AGREEMENT

THIS THIRD AMENDMENT TO EXECUTIVE CHAIR AGREEMENT (“Amendment”) is effective January 1, 2025 (the “Third Amendment Date”), is by and between Ian F. Smith, an individual having an address at [**] (the “Executive Chair”), and Solid Biosciences Inc., a Delaware corporation (together with its affiliates, the “Company”), having an address at 500 Rutherford Ave., 3rd Floor, Charlestown, MA 02129.

WHEREAS, the Executive Chair and the Company are parties to that certain Executive Chair Agreement (“Agreement”), effective as of January 1, 2022 and amended to date by that certain Third Amendment to Executive Chair Agreement (the “Effective Date”), and

WHEREAS, the parties desire to further amend the Agreement in the manner set forth below.

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Definitions. Each capitalized term used but not defined herein shall have the meaning ascribed to such term in the Agreement.

2. Compensation. Section 2 of the Agreement is amended by inserting a new Section 2B as follows:

“2B. Compensation – 2025. As consideration for Services provided under this Agreement from and after January 1, 2025, the Company shall, subject to approval of Company’s Board, grant to Executive Chair equity awards (the “2025 Awards”) with an aggregate total Black Scholes value of \$150,000.00 consisting of (i) 50% stock options (the “2025 Stock Options”) at an exercise price per share equal to the closing price of the Company’s Common Stock on the 2025 Grant Date and (ii) 50% restricted stock units (“2025 RSUs”), in each case adjusted, as applicable and appropriate, to reflect fully the effect of any reclassification, stock split, reverse split, stock dividend, reorganization, recapitalization or other like change with respect to Company Common Stock occurring (or for which a record date is established) after the date of this Amendment and prior to the Grant Date. The 2025 Awards will vest in equal quarterly installments with the first installment vesting three months from the 2025 Grant Date and the final installment vesting date on the date that is 12 months from the 2025 Grant Date, subject to continued services as a Director of the Company. Additionally, in the event of (i) the early termination of this Agreement prior to the expiration of the Term and/or (ii) a change in control of the Company and on terms consistent with Board of Director equity award agreements, all unvested 2025 Awards will accelerate and vest in full. The Company’s external compensation consultants evaluated the cash rate and the conversion rate and found the rates to be appropriate. The consultants were present for the official compensation recommendation to the Compensation Committee.”

3. Term. Section 12 of the Agreement is amended and restated Third in its entirety as follows:

“Term & Termination. The term of this Agreement will commence on the Effective Date. It will expire on December 31, 2025, unless extended by mutual written agreement of the parties or earlier terminated in accordance with this Section 12 (the “Term”). Notwithstanding anything to the contrary herein, the Company may terminate this Agreement, for any or no reason, on written notice to the Executive Chair, and the Executive Chair may terminate this Agreement, for any reason or no reason, on fifteen (15) days’ prior written notice to the Company. The Board shall, on or about June 1, 2025, and periodically thereafter, review the ongoing benefit of the Executive Chair position to the Company and may elect to terminate the Agreement following any such review in accordance with the preceding sentence.

4. Remaining Provisions of the Agreement. Except as provided herein, each of the other provisions of the Agreement shall remain in full force and effect.

5. References. Upon the effectiveness of this Amendment, on and after the date hereof, each reference in the Agreement to “this Agreement,” “hereunder,” “hereof,” “herein,” or words of like import shall mean and be a reference to the Agreement, as amended hereby.

6. Governing Law. This Third Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of laws of such state. The parties agree to submit to the exclusive jurisdiction of the state and federal courts located in the Commonwealth of Massachusetts and waive any defense of inconvenient forum to the maintenance of any action or proceeding in such courts.

7. Counterparts. This Amendment may be executed in one or more counterparts, including by electronic (PDF) transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

8. Entire Agreement. The Agreement, as supplemented and modified by this Amendment, contains the Parties' entire agreement, and there are no promises or conditions in any other agreement between the Parties, whether oral or written, concerning the subject matter hereof. As supplemented and modified by this Amendment, the Agreement supersedes any prior written or oral agreements between the Parties concerning the subject matter hereof.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment No. 2 to the Agreement below.

SOLID BIOSCIENCES INC.

By:/s/ Bo Cumbo
Name: Bo Cumbo
Title: President and CEO
Date: 01/06/2025

By: /s/ Ian F. Smith
Name: Ian F. Smith
Date:01/06/2025

**FOURTH AMENDMENT TO
EXECUTIVE CHAIR AGREEMENT**

THIS FOURTH AMENDMENT TO EXECUTIVE CHAIR AGREEMENT (“Amendment”) is effective January 1, 2026 (the “Fourth Amendment Date”), is by and between Ian F. Smith, an individual having an address at [**] (the “Executive Chair”), and Solid Biosciences Inc., a Delaware corporation (together with its affiliates, the “Company”), having an address at 500 Rutherford Ave., 3rd Floor, Charlestown, MA 02129.

WHEREAS, the Executive Chair and the Company are parties to that certain Executive Chair Agreement (“Agreement”), effective as of January 1, 2022, and amended to date by that certain Second Amendment and Third Amendment to Executive Chair Agreement (the “Effective Date”), and

WHEREAS, the parties desire to further amend the Agreement in the manner set forth below.

NOW, THEREFORE, in consideration of the premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Definitions. Each capitalized term used but not defined herein shall have the meaning ascribed to such term in the Agreement.

2. Compensation. Section 2 of the Agreement is amended by inserting a new Section 2B as follows:

“2B. Compensation - 2026. As consideration for Services provided under this Agreement from and after January 1, 2026, the Company shall, subject to approval of Company’s Board, grant to Executive Chair equity awards (the “2026 Awards”) with an aggregate total Black Scholes value of \$150,000.00 consisting of (i) 50% stock options (the “2026 Stock Options”) at an exercise price per share equal to the closing price of the Company’s Common Stock on the 2026 Grant Date and (ii) 50% restricted stock units (“2026 RSUs”), in each case adjusted, as applicable and appropriate, to reflect fully the effect of any reclassification, stock split, reverse split, stock dividend, reorganization, recapitalization or other like change with respect to Company Common Stock occurring (or for which a record date is established) after the date of this Amendment and prior to the Grant Date. The 2026 Awards will vest in equal quarterly installments with the first installment vesting three months from the 2026 Grant Date and the final installment vesting date on the date that is 12 months from the 2026 Grant Date, subject to continued services as a Director of the Company. Additionally, in the event of (i) the early termination of this Agreement prior to the expiration of the Term and/or (ii) a change in control of the Company and on terms consistent with Board of Director equity award agreements, all unvested 2026 Awards will accelerate and vest in full. The Company’s external compensation consultants evaluated

the cash rate and the conversion rate and found the rates to be appropriate. The consultants were present for the official compensation recommendation to the Compensation Committee.”

3. Term. Section 12 of the Agreement is amended and restated Second in its entirety as follows:

“Term & Termination. The term of this Agreement will commence on the Effective Date. It will expire on December 31, 2026, unless extended by mutual written agreement of the parties or earlier terminated in accordance with this Section 12 (the “Term”). Notwithstanding anything to the contrary herein, the Company may terminate this Agreement, for any or no reason, on written notice to the Executive Chair, and the Executive Chair may terminate this Agreement, for any reason or no reason, on fifteen (15) days’ prior written notice to the Company. The Board shall, on or about June 1, 2026, and periodically thereafter, review the ongoing benefit of the Executive Chair position to the Company and may elect to terminate the Agreement following any such review in accordance with the preceding sentence.

4. Remaining Provisions of the Agreement. Except as provided herein, each of the other provisions of the Agreement shall remain in full force and effect.

5. References. Upon the effectiveness of this Amendment, on and after the date hereof, each reference in the Agreement to “this Agreement,” “hereunder,” “hereof,” “herein,” or words of like import shall mean and be a reference to the Agreement, as amended hereby.

6. Governing Law. This Amendment shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, without giving effect to the principles of conflicts of laws of such state. The parties agree to submit to the exclusive jurisdiction of the state and federal courts located in the Commonwealth of Massachusetts and waive any defense of inconvenient forum to the maintenance of any action or proceeding in such courts.

7. Counterparts. This Amendment may be executed in one or more counterparts, including by electronic (PDF) transmission, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

8. Entire Agreement. The Agreement, as supplemented and modified by this Amendment, contains the parties’ entire agreement, and there are no promises or conditions in any other agreement between the parties, whether oral or written, concerning the subject matter hereof. As supplemented and modified by this Amendment, the Agreement supersedes any prior written or oral agreements between the parties concerning the subject matter hereof.

[Signature page follows]

IN WITNESS WHEREOF, the parties have executed this Amendment to the Agreement below.

SOLID BIOSCIENCES INC.

By: /s/ Bo Cumbo
Name: Bo Cumbo
Title: President and CEO
Date: 01-Jan-2026

IAN F. SMITH

By: /s/ Ian Smith
Ian F. Smith
Date: 30-Dec-2025

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the “Agreement”) is made as of September 29, 2022 by and between Solid Biosciences Inc. (the “Company”) and Bo Cumbo (the “Executive”) (together, the “Parties”).

RECITALS

WHEREAS, the Executive is currently employed by AavantiBio, Inc. (“AavantiBio”) pursuant to that certain Employment Agreement, dated as of July 31, 2020, by and between AavantiBio and the Executive (as amended from time to time, the “Prior Employment Agreement”);

WHEREAS, the Company has entered into an Agreement and Plan of Merger (the “Merger Agreement”) dated as of September 29, 2022, by and among the Company, Greenland Merger Sub LLC, AavantiBio, and Doug Swirsky, solely in his capacity as the equityholder representative, pursuant to which AavantiBio will continue as a wholly owned subsidiary of the Company (such transaction, the “Transaction”);

WHEREAS, the Parties desire to enter into an agreement whereby the Executive will be employed as an employee of the Company on the terms contained in this Agreement, subject to, and contingent and effective upon, the closing of the Transaction (the “Closing”);

WHEREAS, this Agreement shall terminate and be of no force or effect upon termination of the Merger Agreement in accordance with the terms thereof, and upon the termination of this Agreement as a result of the termination of the Merger Agreement, no party shall have any further obligations or liability under this Agreement; and

WHEREAS, the Executive has agreed to accept such employment with the Company upon the Closing on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements of the Parties herein contained, the Parties hereto agree to the following terms, which shall govern the Executive’s employment upon the Closing (the “Effective Date”):

1. *Agreement.* This Agreement shall be effective as of the Effective Date. The Executive’s employment on the terms contained in this Agreement shall commence on the Effective Date and shall continue until such employment relationship is terminated in accordance with Section 6 hereof (the “Term of Employment”).
2. *Position.* During the Term of Employment, the Executive shall serve as the Chief Executive Officer of the Company, working out of the Company’s office in Charlestown, Massachusetts, and travelling as reasonably required by the Executive’s job duties.
3. *Scope of Employment.* During the Term of Employment, the Executive shall be responsible for the performance of those duties consistent with the Executive’s position as Chief Executive Officer. The Executive shall report to the Company’s board of directors (the “Board”) and shall perform and discharge faithfully, diligently, and to the best of the Executive’s ability, the Executive’s duties and responsibilities hereunder. The Executive shall devote substantially all of the Executive’s business time, loyalty, attention and efforts to the business and affairs of the Company and its affiliates. Membership on boards of directors of any other companies will be permitted only with the express approval of the Board, and membership on boards of directors of community, charitable or industry organizations will be permitted provided that such activities do not create a conflict of interest or otherwise interfere with the Executive’s performance of the Executive’s duties hereunder, as determined by the Board in the Board’s sole discretion. The Executive agrees to abide by the rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

4. *Compensation.* As full compensation for all services rendered by the Executive to the Company and any affiliate thereof, during the Term of Employment, the Company will provide to the Executive the following:

(a) *Base Salary.* The Executive shall receive a base salary at the annualized rate of \$585,000 (the “Base Salary”). The Executive’s Base Salary shall be paid in equal installments in accordance with the Company’s regularly established payroll procedures. The Executive’s Base Salary will be reviewed from time to time by the Board and is subject to change in the discretion of the Board.

(b) *Annual Discretionary Bonus.* Beginning on January 1, 2023, the Executive will be eligible to earn an annual performance bonus of up to 55% of the Executive’s Base Salary (the “Target Bonus”), based upon the Board’s assessment of the Executive’s performance and the Company’s attainment of targeted goals as set by the Board in its sole discretion. The Board may determine to provide the bonus in the form of cash, equity award(s), or a combination of cash and equity. Following the close of each calendar year, the Board will determine whether the Executive has earned a performance bonus, and the amount of any performance bonus, based on the set criteria. No amount of the annual bonus is guaranteed, and the Executive must be an employee in good standing on the date of payment in order to be eligible for any annual bonus, as such bonus also serves as an incentive for the Executive to remain employed by the Company, except as specifically set forth below; provided that if the Executive is terminated by the Company without Cause after January 1 but prior to the payment of any annual bonus that would have been paid under this Section 4(b) for the year prior to the year in which the Executive’s employment is terminated, the Executive shall be entitled to receive, on the payment date, the amount of the annual bonus that the Executive would have received for the year prior to termination had the Executive remained employed on the payment date, less all applicable taxes and withholdings. The Executive’s bonus eligibility will be reviewed from time to time by the Board and is subject to change in the discretion of the Board.

(c) *Equity Award.* Subject to approval by the compensation committee of the Board or a majority of the Company’s Independent Directors as defined in Nasdaq Listing Rule 5605(a)(2), and as a material inducement to the Executive entering into employment with the Company, the Company will grant to the Executive:

(i) a non-qualified stock option (the “Option”) to purchase 3,433,500 shares of the Company’s common stock, such Option to (1) have an exercise price per share equal to the fair market value of the Company’s common stock on the date of grant, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date, at a rate of 25% of the total shares underlying the Option on the first anniversary of the grant date and, following that, as to an additional 1/48th of the total shares underlying the Option upon the Executive’s completion of each additional month of service over the 36-month period measured from the first anniversary of the grant date, (3) have a term of up to 10 years and (4) have such other terms as are set forth in the applicable Option agreement; and

(ii) 1,716,749 restricted stock units (the “RSUs” and, together with the Option, the “Equity Awards”), which RSUs shall (1) entitle the Executive to receive one share of the Company’s common stock for each RSU that vests, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date, at a rate of 25% of the total shares underlying the RSUs on each anniversary of the grant date and (3) have such other terms as are set forth in the applicable RSU agreement.

(iii) The Equity Awards will be granted outside of the Company’s equity incentive plans as “inducement grants” within the meaning of Nasdaq Listing Rule 5635(c)(4). The Equity Awards are subject to adjustment for stock splits, combinations or other changes in capitalization. For the avoidance of doubt, subject to the grant of the Equity Awards, the Executive will not be eligible to receive any equity awards in the Company’s regular 2023 annual equity grant cycle, but will otherwise be eligible to receive additional equity awards, if any, at such times and on such terms and conditions as the Board shall, in its sole discretion, determine.

(d) *Paid Time Off.* The Executive shall receive paid vacation time plus sick time, consistent with the Company’s policies as in effect from time to time. In addition, the Executive shall receive paid time off for Company holidays which are set annually and in accordance with Company policy.

(e) *Benefits.* Subject to eligibility requirements and the Company’s policies, the Executive shall have the right, on the same basis as other employees of the Company, to participate in, and to receive benefits under, any medical,

vision and dental insurance policy maintained by the Company and the Company shall pay a portion of the cost of the premiums for such medical, vision and dental insurance that is consistent with the Company's then current employee benefit policy if the Executive elects to participate in such plans. Benefits are subject to change at any time in the Company's sole discretion.

(f) *Withholdings*. All compensation payable to the Executive shall be subject to applicable taxes and withholdings.

5. *Expenses*. The Executive will be reimbursed for the Executive's actual, necessary and reasonable business expense pursuant to Company policy, subject to the provisions of Section 3 of Exhibit A attached hereto.

6. *Employment Termination*. This Agreement and the employment of the Executive shall terminate upon the occurrence of any of the following:

(a) Upon the death of the Executive or at the election of the Company due to the Executive's "Disability". As used in this Agreement, the term "Disability" shall mean a physical or mental illness or disability that prevents the Executive from performing the duties of the Executive's position for a period of more than any three consecutive months or for periods aggregating more than twenty-six weeks during any twelve-month period. The Company shall determine in good faith and in its sole discretion whether the Executive is unable to perform the services provided for herein.

(b) At the election of the Company, with or without "Cause" (as defined below), immediately upon written notice by the Company to the Executive. As used in this Agreement, "Cause" shall mean a finding by the Board that the Executive:

- (i) performed the Executive's duties, in the good faith opinion of the Board, in a grossly negligent or reckless manner or with willful malfeasance;
- (ii) exhibited habitual drunkenness or engaged in substance abuse;
- (iii) committed any material violation of any state or federal law relating to the workplace environment (including, without limitation, laws relating to sexual harassment or age, sex or other prohibited discrimination) or any material violation of any material Company policy;
- (iv) willfully failed or refused to perform in the usual manner at the usual time those duties which the Executive regularly and routinely performed in connection with the business of the Company or such other duties reasonably related to the capacity in which the Executive is employed hereunder which may be assigned to the Executive by the Board, which failure or refusal continues for a period of more than seven (7) days after written notice thereof has been provided to the Executive by the Board, such notice to set forth in reasonable detail the nature of such failure or refusal;
- (v) performed any material action when specifically and reasonably instructed not to do so by the Board;
- (vi) committed any fraud or used or appropriated for the Executive's personal use or benefit any funds, properties or opportunities of the Company not authorized by the Board to be so used or appropriated; or
- (vii) was convicted of, or pled guilty or "no contest" to, any felony or any other crime related to the Executive's employment or involving moral turpitude.

(c) At the election of the Executive, with or without "Good Reason" (as defined below), immediately upon written notice by the Executive to the Company (subject, if it is with Good Reason, to the timing provisions set forth in the definition of Good Reason). As used in this Agreement, "Good Reason" shall mean (without the Executive's consent):

- (i) a material diminution in the nature or scope of Executive's duties, responsibilities, or authority;
 - (ii) a material diminution of the Executive's base compensation;
-

- (iii) the Company's requiring Executive to relocate Executive's primary office more than fifty (50) miles from the Executive's then-current primary office; or
- (iv) any material breach of this Agreement by the Company not otherwise covered by this paragraph;

provided, however, that in each case, the Company shall have a period of not less than thirty (30) days to cure any act constituting Good Reason following Executive's delivery to the Company of written notice within sixty (60) days of the action or omission constituting Good Reason and that the Executive actually terminates employment within thirty (30) days following the expiration of the Company's cure period.

7. Effect of Termination.

(a) *All Terminations Other Than by the Company Without Cause or by the Executive With Good Reason.* If the Executive's employment is terminated under any circumstances other than a Qualifying Termination (as defined below) (including a voluntary termination by the Executive without Good Reason pursuant to Section 6(c), a termination by the Company for Cause pursuant to Section 6(b) or due to the Executive's death or Disability pursuant to Section 6(a)), the Company's obligations under this Agreement shall immediately cease and the Executive shall only be entitled to receive (i) the Base Salary that has accrued and to which the Executive is entitled as of the effective date of such termination and to the extent consistent with general Company policy, accrued but unused paid time off through and including the effective date of such termination, to be paid in accordance with the Company's established payroll procedure and applicable law but no later than the next regularly scheduled pay period, (ii) unreimbursed business expenses for which expenses the Executive has timely submitted appropriate documentation in accordance with Section 5 hereof, and (iii) any amounts or benefits to which the Executive is then entitled under the terms of the benefit plans then-sponsored by the Company in accordance with their terms (and not accelerated to the extent acceleration does not satisfy Section 409A of the Internal Revenue Code of 1986, as amended, (the "Code")) (the payments described in this sentence, the "Accrued Obligations").

(b) *Termination by the Company Without Cause or by the Executive With Good Reason Prior to or More Than Twelve Months Following a Change in Control.* If the Executive's employment is terminated by the Company without Cause pursuant to Section 6(b) or by the Executive with Good Reason pursuant to Section 6(c) (in either case, a "Qualifying Termination") prior to or more than twelve (12) months following a Change in Control (as defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of twelve (12) months, and (ii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no event longer than twelve (12) months following the Executive's termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply (collectively, the "Severance Benefits").

(c) *Termination by the Company Without Cause or by the Executive With Good Reason Within Twelve Months Following a Change in Control.* If a Qualifying Termination occurs within twelve (12) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of eighteen (18) months; (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 150% of the Executive's Target Bonus for the year in which termination occurs or the Executive's Target Bonus immediately prior to the Change in Control, if higher, (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no event longer than eighteen (18) months following the Executive's termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, and (iv) provide that the vesting of the Executive's then-unvested equity awards that vest based solely on the passage of time shall be accelerated, such that all then unvested

time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the termination date (collectively, the “Change in Control Severance Benefits”).

(d) *Severance and Release of Claims Agreement.* As a condition of the Executive’s receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the “Severance Agreement”) (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of the Executive’s continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following the Executive’s separation from employment), which Severance Agreement must become irrevocable within 60 days following the date of the Executive’s termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive’s employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the “Payment Date”).

(e) *Change in Control Definition.* For purposes of this Agreement, “Change in Control” shall mean the occurrence of any of the following events, provided that such event or occurrence constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the assets of the Company, as defined in Treasury Regulation §§ 1.409A-3(i)(5)(v), (vi) and (vii): (i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934 (the “Exchange Act”)) (a “Person”) of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) fifty percent (50%) or more of either (x) the then-outstanding shares of common stock of the Company (the “Outstanding Company Common Stock”) or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the “Outstanding Company Voting Securities”); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (1) any acquisition directly from the Company or (2) any acquisition by any entity pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or (ii) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term “Continuing Director” means at any date a member of the Board (x) who was a member of the Board on the Effective Date or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or (iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a “Business Combination”), unless, immediately following such Business Combination, each of the following two (2) conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company’s assets either directly or through one (1) or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the “Acquiring Corporation”) in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or

sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, fifty percent (50%) or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or (iv) the liquidation or dissolution of the Company.

8. *Modified Section 280G Cutback.* Notwithstanding any other provision of this Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a “Change in Ownership or Control” (as defined below), the following provisions shall apply:

(a) The Company shall not be obligated to provide to the Executive any portion of any “Contingent Compensation Payments” (as defined below) that the Executive would otherwise be entitled to receive to the extent necessary to eliminate any “excess parachute payments” (as defined in Section 280G(b)(1) of the Code) for the Executive. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Payments” and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Amount.”

(b) Notwithstanding the provisions of Section 8(a), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by the Executive if the Eliminated Payments (determined without regard to this sentence) were paid to the Executive (including state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of the Executive’s “base amount” (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a “Section 8(b) Override.” For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(c) For purposes of this Section 8 the following terms shall have the following respective meanings:

(i) “Change in Ownership or Control” shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(ii) “Contingent Compensation Payment” shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to or for the benefit of a “disqualified individual” (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(d) Any payments or other benefits otherwise due to the Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the “Potential Payments”) shall not be made until the dates provided for in this Section 8(d). Within thirty (30) days after each date on which the Executive first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment

relating to such Change in Ownership or Control, the Company shall determine and notify the Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 8(b) Override is applicable. Within thirty (30) days after delivery of such notice to the Executive, the Executive shall deliver a response to the Company (the “Executive Response”) stating either (A) that the Executive agrees with the Company’s determination pursuant to the preceding sentence or (B) that the Executive disagrees with such determination, in which case the Executive shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y) the Eliminated Amount, and (z) whether the Section 8(b) Override is applicable. In the event that the Executive fails to

deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If the Executive states in the Executive Response that the Executive agrees with the Company's determination, the Company shall make the Potential Payments to the Executive within three (3) business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If the Executive states in the Executive Response that the Executive disagrees with the Company's determination, then, for a period of sixty (60) days following delivery of the Executive Response, the Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in Charlestown, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three (3) business days following delivery to the Company of the Executive Response, make to the Executive those Potential Payments as to which there is no dispute between the Company and the Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three (3) business days following the resolution of such dispute.

(e) The Contingent Compensation Payments to be treated as Eliminated Payments shall be determined by the Company by determining the "Contingent Compensation Payment Ratio" (as defined below) for each Contingent Compensation Payment and then reducing the Contingent Compensation Payments in order beginning with the Contingent Compensation Payment with the highest Contingent Compensation Payment Ratio. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio, such Contingent Compensation Payment shall be reduced based on the time of payment of such Contingent Compensation Payments with amounts having later payment dates being reduced first. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio and the same time of payment, such Contingent Compensation Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Contingent Compensation Payment with a lower Contingent Compensation Payment Ratio. The term "Contingent Compensation Payment Ratio" shall mean a fraction the numerator of which is the value of the applicable Contingent Compensation Payment that must be taken into account by the Executive for purposes of Section 4999(a) of the Code, and the denominator of which is the actual amount to be received by the Executive in respect of the applicable Contingent Compensation Payment. For example, in the case of an equity grant that is treated as contingent on the Change in Ownership or Control because the time at which the payment is made or the payment vests is accelerated, the denominator shall be determined by reference to the fair market value of the equity at the acceleration date, and not in accordance with the methodology for determining the value of accelerated payments set forth in Treasury Regulation Section 1.280G-1 Q/A-24(b) or (c)).

(f) The provisions of this Section 8 are intended to apply to any and all payments or benefits available to the Executive under this Agreement or any other agreement or plan under which the Executive receives Contingent Compensation Payments.

9. *Restrictive Covenants Agreements.* As a condition of the Executive's employment pursuant to the terms set forth in this Agreement, the Executive shall execute and comply with the terms of (a) the Invention, Nondisclosure and Nonsolicitation Agreement and (b) the Noncompetition Agreement attached hereto as Exhibit B and Exhibit C, respectively.

10. *Absence of Restrictions.* The Executive represents and warrants that the Executive is not bound by any employment contracts, restrictive covenants or other restrictions that prevent the Executive from entering into employment with, or carrying out the Executive's responsibilities for, the Company, or which are in any way inconsistent with any of the terms of this Agreement.

11. *Notice.* Any notice delivered under this Agreement shall be deemed duly delivered three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent for next-business day delivery via a reputable nationwide overnight courier service, or immediately upon hand delivery, in each case to the address of the recipient set forth below.

To Executive:

At the address set forth in the Executive's personnel file

To Company:

Solid Biosciences Inc.
500 Rutherford Avenue
Third Floor
Charlestown, MA 02129

Either Party may change the address to which notices are to be delivered by giving notice of such change to the other Party in the manner set forth in this Section 11.

12. *Applicable Law; Jury Trial Waiver.* This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the State of Delaware (or, if appropriate, a federal court located within the State of Delaware), and the Company and the Executive each consents to the jurisdiction of such a court. The Company and the Executive each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

13. *Successors and Assigns.* This Agreement shall be binding upon and inure to the benefit of both Parties and their respective successors and assigns, including any corporation with which or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Executive are personal and shall not be assigned by the Executive.

14. *At-Will Employment.* During the Term of Employment, the Executive will continue to be an at-will employee of the Company, which means that, notwithstanding any other provision set forth herein, the employment relationship can be terminated by either Party for any reason, at any time, with or without prior notice and with or without Cause.

15. *Acknowledgment.* The Executive states and represents that the Executive has had an opportunity to fully discuss and review the terms of this Agreement with an attorney. The Executive further states and represents that the Executive has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs the Executive's name of the Executive's own free act.

16. *No Oral Modification, Waiver, Cancellation or Discharge.* This Agreement may be amended or modified only by a written instrument executed by both the Company and the Executive. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

17. *Captions and Pronouns.* The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

18. *Interpretation.* The Parties agree that this Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the drafting Party. References in this Agreement to "include" or "including" should be read as though they said "without limitation" or equivalent forms. References in this Agreement to the "Board" shall include any authorized committee thereof.

19. *Severability.* Each provision of this Agreement must be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement. Moreover, if a court of competent jurisdiction determines any of the provisions contained in this Agreement to be unenforceable because the provision

is excessively broad in scope, whether as to duration, activity, geographic application, subject or otherwise, it will be construed, by limiting or reducing it to the extent legally permitted, so as to be enforceable to the extent compatible with then applicable law to achieve the intent of the Parties.

20. *Entire Agreement.* Except as expressly provided in the Merger Agreement and any other agreements to which the Executive is or will be a party in connection with the Transaction, this Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement, including, but not limited to, the Prior Employment Agreement.

[Signatures on Page Following]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the day and year set forth above.

SOLID BIOSCIENCES INC.

By: /s/ Ian Smith
Name: Ian Smith
Title: Chairman of the Board

EXECUTIVE:

/s/ Bo Cumbo
Bo Cumbo

EXHIBIT A

Payments Subject to Section 409A

1. Subject to this Exhibit A, any severance payments that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments provided under the Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code ("Section 409A"). Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the letter agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

- (i) Each installment of the severance payments due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Agreement; and
- (ii) Each installment of the severance payments due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not

provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of Section 2 of this Exhibit A, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in the Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before

the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

4. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit A) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

5. The Agreement is intended to comply with, or be exempt from, Section 409A and shall be interpreted accordingly.

[Remainder of page intentionally left blank.]

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to the Employment Agreement (“First Amendment”) effective as of August 14, 2025 (“Effective Date”) is made and entered by and between Solid Biosciences Inc. (the “Company”) and Bo Cumbo (the “Executive”) (together, the “Parties”).

WHEREAS, the Parties wish to amend that certain Employment Agreement by and between Company and Executive effective September 29, 2022 (“Agreement”).

NOW THEREFORE, in consideration of the mutual promises set forth herein, the Parties agree as follows:

1. Section 7(b) of the Agreement shall be deleted in its entirety and replaced with the following:

(b) Termination by the Company Without Cause or by the Executive With Good Reason More than Three (3) Months Prior to or More Than Twelve (12) Months Following a Change in Control. If the Executive’s employment is terminated by the Company without Cause pursuant to Section 6(b) or by the Executive with Good Reason pursuant to Section 6(c) (in either case, a “Qualifying Termination”) more than three (3) months prior to or more than twelve (12) months following a Change in Control (as defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedures, the Executive’s Base Salary for a period of twelve (12) months, (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 100% of the Executive’s Target Bonus pro-rated for the year in which such Qualifying Termination occurs based on the number of full weeks the Executive has work for the Company in such year through the date of such termination; and (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than twelve (12) months following the Executive’s termination date) the share of the premium for health coverage that the Company pays for active and similarly situated employees who receive the same type of coverage unless the Company’s provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply (collectively, the “Severance Benefits”).

2. Section 7(c) of the Agreement shall be deleted in its entirety and replaced with the following:

(c) Termination by the Company Without Cause or by the Executive With Good Reason Within Three (3) Months Prior to or Within Twelve Months Following a Change in Control. If a Qualifying Termination occurs within three (3) months prior to or within twelve (12) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedures, the Executive’s Base Salary for a period of eighteen (18) months; (ii) pay to the Executive, in a single lump sum on the Payment Date an amount equal to 150% of the Executive’s Target Bonus for the year in which such Qualifying Termination occurs or the Executive’s Target Bonus immediately prior to the Change in Control, if higher, (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than eighteen (18) months following the Executive’s termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company’s provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, (iv) provide that the vesting of the Executive’s then-unvested equity awards that vest based solely on the passage of time shall be accelerated, such that all then unvested time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the later of the termination date and the closing of the Change in Control[, provided, however, that if Executive’s Company equity awards that vest

based solely on the passage of time are not continued, assumed or substituted in connection with the Change in Control, it is understood that such awards shall vest and become fully exercisable or non-forfeitable immediately prior to the closing of such Change in Control] (collectively, the “Change in Control Severance Benefits”).

3. Section 7(d) of the Agreement shall be deleted in its entirety and replaced with the following:

(d) *Severance and Release of Claims Agreement.* As a condition of the Executive’s receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the “Severance Agreement”) (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of the Executive’s continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following the Executive’s separation from employment), which Severance Agreement must become irrevocable within 60 days following the date of the Executive’s termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive’s employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the “Payment Date”). For the avoidance of doubt, if the Executive experiences a Qualifying Termination prior to a Change in Control, (i) any then-outstanding and unvested equity awards that vest based solely on the passage of time held by the Executive shall remain outstanding (but any vesting shall be suspended) for up to (but no longer than) three (3) months following the date of termination so that, if it is later determined that such termination occurred during the three (3)-month period prior to the closing of a Change in Control and that the Executive is entitled to Change in Control acceleration and/or Change in Control Severance Benefits rather than Severance Benefits, the vesting of such awards may be accelerated, in accordance with Section 7(c) hereof, immediately prior to the closing of the Change in Control and (ii) any Change in Control Severance Benefits shall be reduced by any Severance Benefits previously paid to you, if it is later determined that the termination occurred during the three (3)-month period prior to the closing of a Change in Control and that you are entitled to Change in Control Severance Benefits rather than Severance Benefits.

4. All capitalized terms used but not defined herein shall have the respective meanings given to them in the Agreement.
5. Except as amended herein, all provisions of the Agreement shall remain in full force and effect.
6. This First Amendment may be executed in two counterparts, both of which shall constitute one and the same legal instrument, and delivery of an executed copy of this First Amendment by a Party via pdf or other electronic transmission shall be as effective as delivery of a manually executed copy of this First Amendment by such Party.

IN WITNESS WHEREOF, the Parties have entered into this First Amendment.

Solid Biosciences Inc.

Executive

By: /s/ Ty Howton

Name: Ty Howton

Title: Chief Operating Officer

Date: 10/30/2025

By: /s/ Bo Cumbo

Name: Bo Cumbo

Title: President & CEO

Date: 10/28/2025

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the “Agreement”) is made as of September 29, 2022 by and between Solid Biosciences Inc. (the “Company”) and Ty Howton (the “Executive”) (together, the “Parties”).

RECITALS

WHEREAS, the Executive is currently employed by AavantiBio, Inc. (“AavantiBio”) pursuant to that certain Employment Agreement, dated as of March 4, 2021, by and between AavantiBio and the Executive (as amended from time to time, the “Prior Employment Agreement”);

WHEREAS, the Company has entered into an Agreement and Plan of Merger (the “Merger Agreement”) dated as of September 29, 2022, by and among the Company, Greenland Merger Sub LLC, AavantiBio, and Doug Swirsky, solely in his capacity as the equityholder representative, pursuant to which AavantiBio will continue as a wholly owned subsidiary of the Company (such transaction, the “Transaction”);

WHEREAS, the Parties desire to enter into an agreement whereby the Executive will be employed as an employee of the Company on the terms contained in this Agreement, subject to, and contingent and effective upon, the closing of the Transaction (the “Closing”);

WHEREAS, this Agreement shall terminate and be of no force or effect upon termination of the Merger Agreement in accordance with the terms thereof, and upon the termination of this Agreement as a result of the termination of the Merger Agreement, no party shall have any further obligations or liability under this Agreement; and

WHEREAS, the Executive has agreed to accept such employment with the Company upon the Closing on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements of the Parties herein contained, the Parties hereto agree to the following terms, which shall govern the Executive’s employment upon the Closing (the “Effective Date”):

1. *Agreement.* This Agreement shall be effective as of the Effective Date. The Executive’s employment on the terms contained in this Agreement shall commence on the Effective Date and shall continue until such employment relationship is terminated in accordance with Section 6 hereof (the “Term of Employment”).
 2. *Position.* During the Term of Employment, the Executive shall serve as the Chief Administrative Officer & Corporate Secretary of the Company, working out of the Company’s office in Charlestown, Massachusetts, and travelling as reasonably required by the Executive’s job duties.
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3. *Scope of Employment.* During the Term of Employment, the Executive shall be responsible for the performance of those duties consistent with the Executive's position as Chief Administrative Officer & Corporate Secretary. The Executive shall report to the Chief Executive Officer of the Company and/or the Company's board of directors (the "Board") and shall perform and discharge faithfully, diligently, and to the best of the Executive's ability, the Executive's duties and responsibilities hereunder. The Executive shall devote substantially all of the Executive's business time, loyalty, attention and efforts to the business and affairs of the Company and its affiliates. Membership on boards of directors of up to two other companies will be permitted only with the express approval of the Chief Executive Officer, and membership on boards of directors of community, charitable or industry organizations will be permitted only provided that such activities do not create a conflict of interest or otherwise interfere with the Executive's performance of the Executive's duties hereunder, as determined by the Chief Executive Officer in the Chief Executive Officer's sole discretion. The Executive agrees to abide by the rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

4. *Compensation.* As full compensation for all services rendered by the Executive to the Company and any affiliate thereof, during the Term of Employment, the Company will provide to the Executive the following:

(a) *Base Salary.* The Executive shall receive a base salary at the annualized rate of \$455,000 (the "Base Salary"). The Executive's Base Salary shall be paid in equal installments in accordance with the Company's regularly established payroll procedures. The Executive's Base Salary will be reviewed from time to time by the Board and is subject to change in the discretion of the Board.

(b) *Annual Discretionary Bonus.* Beginning on January 1, 2023, the Executive will be eligible to earn an annual performance bonus of up to 40% of the Executive's Base Salary (the "Target Bonus"), based upon the Board's assessment of the Executive's performance and the Company's attainment of targeted goals as set by the Board in its sole discretion. The Board may determine to provide the bonus in the form of cash, equity award(s), or a combination of cash and equity. Following the close of each calendar year, the Board will determine whether the Executive has earned a performance bonus, and the amount of any performance bonus, based on the set criteria. No amount of the annual bonus is guaranteed, and the Executive must be an employee in good standing on the date of payment in order to be eligible for any annual bonus, as such bonus also serves as an incentive for the Executive to remain employed by the Company, except as specifically set forth below; provided that if the Executive is terminated by the Company without Cause after January 1 but prior to the payment of any annual bonus that would have been paid under this Section 4(b) for the year prior to the year in which the Executive's employment is terminated, the Executive shall be entitled to receive, on the payment date, the amount of the annual bonus that the Executive would have received for the year prior to termination had the Executive remained employed on the payment date, less all applicable taxes and withholdings. The Executive's bonus eligibility will be reviewed from time to time by the Board and is subject to change in the discretion of the Board.

(c) *Equity Award.* Subject to approval by the compensation committee of the Board or a majority of the Company's Independent Directors as defined in Nasdaq Listing Rule 5605(a)(2), and as a material inducement to the Executive entering into employment with the Company, the Company will grant to the Executive:

(i) a non-qualified stock option (the “Option”) to purchase 1,566,152 shares of the Company’s common stock, such Option to (1) have an exercise price per share equal to the fair market value of the Company’s common stock on the date of grant, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date, at a rate of 25% of the total shares underlying the Option on the first anniversary of the grant date and, following that, as to an additional 1/48th of the total shares underlying the Option upon the Executive’s completion of each additional month of service over the 36-month period measured from the first anniversary of the grant date, (3) have a term of up to 10 years and (4) have such other terms as are set forth in the applicable Option agreement; and

(ii) 783,076 restricted stock units (the “RSUs” and, together with the Option, the “Equity Awards”), which RSUs shall (1) entitle the Executive to receive one share of the Company’s common stock for each RSU that vests, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date, at a rate of 25% of the total shares underlying the RSUs on each anniversary of the grant date and (3) have such other terms as are set forth in the applicable RSU agreement.

(iii) The Equity Awards will be granted outside of the Company’s equity incentive plans as “inducement grants” within the meaning of Nasdaq Listing Rule 5635(c)(4). The Equity Awards are subject to adjustment for stock splits, combinations or other changes in capitalization. For the avoidance of doubt, subject to the grant of the Equity Awards, the Executive will not be eligible to receive any equity awards in the Company’s regular 2023 annual equity grant cycle, but will otherwise be eligible to receive additional equity awards, if any, at such times and on such terms and conditions as the Board shall, in its sole discretion, determine.

(d) *Paid Time Off*. The Executive shall receive paid vacation time plus sick time, consistent with the Company’s policies as in effect from time to time. In addition, the Executive shall receive paid time off for Company holidays which are set annually and in accordance with Company policy.

(e) *Benefits*. Subject to eligibility requirements and the Company’s policies, the Executive shall have the right, on the same basis as other employees of the Company, to participate in, and to receive benefits under, any medical, vision and dental insurance policy maintained by the Company and the Company shall pay a portion of the cost of the premiums for such medical, vision and dental insurance that is consistent with the Company’s then current employee benefit policy if the Executive elects to participate in such plans. Benefits are subject to change at any time in the Company’s sole discretion.

(f) *Withholdings*. All compensation payable to the Executive shall be subject to applicable taxes and withholdings.

5. *Expenses*. The Executive will be reimbursed for the Executive’s actual, necessary and reasonable business expense pursuant to Company policy, subject to the provisions of Section 3 of Exhibit A attached hereto.

6. *Employment Termination.* This Agreement and the employment of the Executive shall terminate upon the occurrence of any of the following:

(a) Upon the death of the Executive or at the election of the Company due to the Executive's "Disability". As used in this Agreement, the term "Disability" shall mean a physical or mental illness or disability that prevents the Executive from performing the duties of the Executive's position for a period of more than any three consecutive months or for periods aggregating more than twenty-six weeks during any twelve-month period. The Company shall determine in good faith and in its sole discretion whether the Executive is unable to perform the services provided for herein.

(b) At the election of the Company, with or without "Cause" (as defined below), immediately upon written notice by the Company to the Executive. As used in this Agreement, "Cause" shall mean a finding by the Company's Chief Executive Officer or the Board that the Executive:

- (i) performed the Executive's duties, in the good faith opinion of the Company's Chief Executive Officer or the Board, in a grossly negligent or reckless manner or with willful malfeasance;
 - (ii) exhibited habitual drunkenness or engaged in substance abuse;
 - (iii) committed any material violation of any state or federal law relating to the workplace environment (including, without limitation, laws relating to sexual harassment or age, sex or other prohibited discrimination) or any material violation of any material Company policy;
 - (iv) willfully failed or refused to perform in the usual manner at the usual time those duties which the Executive regularly and routinely performed in connection with the business of the Company or such other duties reasonably related to the capacity in which the Executive is employed hereunder which may be assigned to the Executive by the Company's Chief Executive Officer or the Board, which failure or refusal continues for a period of more than seven (7) days after written notice thereof has been provided to the Executive by the Company's Chief Executive Officer or the Board, such notice to set forth in reasonable detail the nature of such failure or refusal;
 - (v) performed any material action when specifically and reasonably instructed not to do so by the Company's Chief Executive Officer or the Board;
 - (vi) committed any fraud or used or appropriated for the Executive's personal use or benefit any funds, properties or opportunities of the Company not authorized by the Company's Chief Executive Officer or the Board to be so used or appropriated; or
 - (vii) was convicted of, or pled guilty or "no contest" to, any felony or any other crime related to the Executive's employment or involving moral turpitude.
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(c) At the election of the Executive, with or without “Good Reason” (as defined below), immediately upon written notice by the Executive to the Company (subject, if it is with Good Reason, to the timing provisions set forth in the definition of Good Reason). As used in this Agreement, “Good Reason” shall mean (without the Executive’s consent):

- (i) a material diminution in the nature or scope of Executive’s duties, responsibilities, or authority;
- (ii) a material diminution of the Executive’s base compensation;
- (iii) the Company’s requiring Executive to relocate Executive’s primary office more than fifty (50) miles from the Executive’s then-current primary office; or
- (iv) any material breach of this Agreement by the Company not otherwise covered by this paragraph;

provided, however, that in each case, the Company shall have a period of not less than thirty (30) days to cure any act constituting Good Reason following Executive’s delivery to the Company of written notice within sixty (60) days of the action or omission constituting Good Reason and that the Executive actually terminates employment within thirty (30) days following the expiration of the Company’s cure period.

7. Effect of Termination.

(a) *All Terminations Other Than by the Company Without Cause or by the Executive With Good Reason.* If the Executive’s employment is terminated under any circumstances other than a Qualifying Termination (as defined below) (including a voluntary termination by the Executive without Good Reason pursuant to Section 6(c), a termination by the Company for Cause pursuant to Section 6(b) or due to the Executive’s death or Disability pursuant to Section 6(a)), the Company’s obligations under this Agreement shall immediately cease and the Executive shall only be entitled to receive (i) the Base Salary that has accrued and to which the Executive is entitled as of the effective date of such termination and to the extent consistent with general Company policy, accrued but unused paid time off through and including the effective date of such termination, to be paid in accordance with the Company’s established payroll procedure and applicable law but no later than the next regularly scheduled pay period, (ii) unreimbursed business expenses for which expenses the Executive has timely submitted appropriate documentation in accordance with Section 5 hereof, and (iii) any amounts or benefits to which the Executive is then entitled under the terms of the benefit plans then-sponsored by the Company in accordance with their terms (and not accelerated to the extent acceleration does not satisfy Section 409A of the Internal Revenue Code of 1986, as amended, (the “Code”) (the payments described in this sentence, the “Accrued Obligations”).

(b) *Termination by the Company Without Cause or by the Executive With Good Reason Prior to or More Than Twelve Months Following a Change in Control.* If the Executive's employment is terminated by the Company without Cause pursuant to Section 6(b) or by the Executive with Good Reason pursuant to Section 6(c) (in either case, a "Qualifying Termination") prior to or more than twelve (12) months following a Change in Control (as defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of twelve (12) months, and (ii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no event longer than twelve (12) months following the Executive's termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply (collectively, the "Severance Benefits").

(c) *Termination by the Company Without Cause or by the Executive With Good Reason Within Twelve Months Following a Change in Control.* If a Qualifying Termination occurs within twelve (12) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of twelve (12) months; (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 100% of the Executive's Target Bonus for the year in which termination occurs or the Executive's Target Bonus immediately prior to the Change in Control, if higher, (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no event longer than twelve (12) months following the Executive's termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, and (iv) provide that the vesting of the Executive's then-unvested equity awards that vest based solely on the passage of time shall be accelerated, such that all then unvested time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the termination date (collectively, the "Change in Control Severance Benefits").

(d) *Severance and Release of Claims Agreement.* As a condition of the Executive's receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the "Severance Agreement") (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of the Executive's continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following the Executive's separation from employment), which Severance Agreement must become irrevocable within 60 days following the date of the Executive's termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive's employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the "Payment Date").

(e) *Change in Control Definition.* For purposes of this Agreement, “Change in Control” shall mean the occurrence of any of the following events, provided that such event or occurrence constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the assets of the Company, as defined in Treasury Regulation §§ 1.409A-3(i)(5)(v), (vi) and (vii): (i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934 (the “Exchange Act”)) (a “Person”) of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) fifty percent (50%) or more of either (x) the then-outstanding shares of common stock of the Company (the “Outstanding Company Common Stock”) or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the “Outstanding Company Voting Securities”); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (1) any acquisition directly from the Company or (2) any acquisition by any entity pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or (ii) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term “Continuing Director” means at any date a member of the Board (x) who was a member of the Board on the Effective Date or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or (iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a “Business Combination”), unless, immediately following such Business Combination, each of the following two (2) conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company’s assets either directly or through one (1) or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the “Acquiring Corporation”) in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, fifty percent (50%) or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or (iv) the liquidation or dissolution of the Company.

8. *Modified Section 280G Cutback.* Notwithstanding any other provision of this Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a “Change in Ownership or Control” (as defined below), the following provisions shall apply:

(a) The Company shall not be obligated to provide to the Executive any portion of any “Contingent Compensation Payments” (as defined below) that the Executive would otherwise be entitled to receive to the extent necessary to eliminate any “excess parachute payments” (as defined in Section 280G(b)(1) of the Code) for the Executive. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Payments” and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Amount.”

(b) Notwithstanding the provisions of Section 8(a), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by the Executive if the Eliminated Payments (determined without regard to this sentence) were paid to the Executive (including state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of the Executive’s “base amount” (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a “Section 8(b) Override.” For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(c) For purposes of this Section 8 the following terms shall have the following respective meanings:

(i) “Change in Ownership or Control” shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(ii) “Contingent Compensation Payment” shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to or for the benefit of a “disqualified individual” (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(d) Any payments or other benefits otherwise due to the Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the “Potential Payments”) shall not be made until the dates provided for in this Section 8(d). Within thirty (30) days after each date on which the Executive first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify the Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 8(b) Override is applicable. Within thirty (30) days after delivery of such notice to the Executive, the Executive shall deliver a response to the Company (the “Executive Response”) stating either (A) that the Executive agrees with the Company’s determination pursuant to the preceding sentence or (B) that the Executive disagrees with such determination, in which case the Executive shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y) the Eliminated Amount, and (z) whether the Section 8(b) Override is applicable. In the event that the Executive fails to deliver an Executive Response on or before the required date, the Company’s initial determination shall be final. If the Executive states in the Executive Response that the Executive agrees with the Company’s determination, the Company shall make the Potential Payments to the Executive within three (3) business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If the Executive states in the Executive Response that the Executive disagree with the Company’s determination, then, for a period of sixty (60) days following delivery of the Executive Response, the Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in Charlestown, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator’s award in any court having jurisdiction. The Company shall, within three (3) business days following delivery to the Company of the Executive Response, make to the Executive those Potential Payments as to which there is no dispute between the Company and the Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three (3) business days following the resolution of such dispute.

(e) The Contingent Compensation Payments to be treated as Eliminated Payments shall be determined by the Company by determining the “Contingent Compensation Payment Ratio” (as defined below) for each Contingent Compensation Payment and then reducing the Contingent Compensation Payments in order beginning with the Contingent Compensation Payment with the highest Contingent Compensation Payment Ratio. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio, such Contingent Compensation Payment shall be reduced based on the time of payment of such Contingent Compensation Payments with amounts having later payment dates being reduced first. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio and the same time of payment, such Contingent Compensation Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Contingent Compensation Payment with a lower Contingent Compensation Payment Ratio. The term “Contingent Compensation Payment Ratio”

shall mean a fraction the numerator of which is the value of the applicable Contingent Compensation Payment that must be taken into account by the Executive for purposes of Section 4999(a) of the Code, and the denominator of which is the actual amount to be received by the Executive in respect of the applicable Contingent Compensation Payment. For example, in the case of an equity grant that is treated as contingent on the Change in Ownership or Control because the time at which the payment is made or the payment vests is accelerated, the denominator shall be determined by reference to the fair market value of the equity at the acceleration date, and not in accordance with the methodology for determining the value of accelerated payments set forth in Treasury Regulation Section 1.280G-1 Q/A-24(b) or (c)).

(f) The provisions of this Section 8 are intended to apply to any and all payments or benefits available to the Executive under this Agreement or any other agreement or plan under which the Executive receives Contingent Compensation Payments.

9. *Restrictive Covenants Agreements.* As a condition of the Executive's employment pursuant to the terms set forth in this Agreement, the Executive shall execute and comply with the terms of

(a) the Invention, Nondisclosure and Nonsolicitation Agreement and (b) the Noncompetition Agreement attached hereto as Exhibit B and Exhibit C, respectively.

10. *Absence of Restrictions.* The Executive represents and warrants that the Executive is not bound by any employment contracts, restrictive covenants or other restrictions that prevent the Executive from entering into employment with, or carrying out the Executive's responsibilities for, the Company, or which are in any way inconsistent with any of the terms of this Agreement.

11. *Notice.* Any notice delivered under this Agreement shall be deemed duly delivered three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent for next-business day delivery via a reputable nationwide overnight courier service, or immediately upon hand delivery, in each case to the address of the recipient set forth below.

To Executive:

At the address set forth in the Executive's personnel file To
Company:
Solid Biosciences Inc. 500
Rutherford Avenue Third
Floor Charlestown, MA
02129

Either Party may change the address to which notices are to be delivered by giving notice of such change to the other Party in the manner set forth in this Section 11.

12. *Applicable Law; Jury Trial Waiver.* This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware (without reference to the conflict of laws

provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the State of Delaware (or, if appropriate, a federal court located within the State of Delaware), and the Company and the Executive each consents to the jurisdiction of such a court. The Company and the Executive each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

13.*Successors and Assigns.* This Agreement shall be binding upon and inure to the benefit of both Parties and their respective successors and assigns, including any corporation with which or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Executive are personal and shall not be assigned by the Executive.

14.*At-Will Employment.* During the Term of Employment, the Executive will continue to be an at-will employee of the Company, which means that, notwithstanding any other provision set forth herein, the employment relationship can be terminated by either Party for any reason, at any time, with or without prior notice and with or without Cause.

15.*Acknowledgment.* The Executive states and represents that the Executive has had an opportunity to fully discuss and review the terms of this Agreement with an attorney. The Executive further states and represents that the Executive has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs the Executive's name of the Executive's own free act.

16.*No Oral Modification, Waiver, Cancellation or Discharge.* This Agreement may be amended or modified only by a written instrument executed by both the Company and the Executive. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

17. *Captions and Pronouns.* The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

18. *Interpretation.* The Parties agree that this Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the drafting Party. References in this Agreement to “include” or “including” should be read as though they said “without limitation” or equivalent forms. References in this Agreement to the “Board” shall include any authorized committee thereof.

19. *Severability.* Each provision of this Agreement must be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement. Moreover, if a court of competent jurisdiction determines any of the provisions contained in this Agreement to be unenforceable because the

provision is excessively broad in scope, whether as to duration, activity, geographic application, subject or otherwise, it will be construed, by limiting or reducing it to the extent legally permitted, so as to be enforceable to the extent compatible with then applicable law to achieve the intent of the Parties.

20. *Entire Agreement.* Except as expressly provided in the Merger Agreement and any other agreements to which the Executive is or will be a party in connection with the Transaction, this Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement, including, but not limited to, the Prior Employment Agreement.

[Signatures on Page Following]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the day and year set forth above.

SOLID BIOSCIENCES INC.

By: /s/ Ian Smith

Name Ian Smith

Title: Chairman of the Board

EXECUTIVE:

/s/ Ty Howton
Ty Howton

EXHIBIT A

Payments Subject to Section 409A

1. Subject to this Exhibit A, any severance payments that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments provided under the Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code ("Section 409A"). Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the letter agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

- (i) Each installment of the severance payments due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Agreement; and
- (ii) Each installment of the severance payments due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not

provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of Section 2 of this Exhibit A, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in the Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

4. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit A) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

5. The Agreement is intended to comply with, or be exempt from, Section 409A and shall be interpreted accordingly.

[Remainder of page intentionally left blank.]

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to the Employment Agreement (“First Amendment”) effective as of August 14, 2025 (“Effective Date”) is made and entered by and between Solid Biosciences Inc. (the “Company”) and Ty Howton (the “Executive”) (together, the “Parties”).

WHEREAS, the Parties wish to amend that certain Employment Agreement by and between Company and Executive effective September 29, 2022 (“Agreement”).

NOW THEREFORE, in consideration of the mutual promises set forth herein, the Parties agree as follows:

1. Section 7(b) of the Agreement shall be deleted in its entirety and replaced with the following:

(b) Termination by the Company Without Cause or by the Executive With Good Reason More than Three (3) Months Prior to or More Than Twelve Months Following a Change in Control. If the Executive’s employment is terminated by the Company without Cause pursuant to Section 6(b) or by the Executive with Good Reason pursuant to Section 6(c) (in either case, a “Qualifying Termination”) more than three (3) months prior to or more than twelve (12) months following a Change in Control (as defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedures, the Executive’s Base Salary for a period of twelve (12) months, (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 100% of the Executive’s Target Bonus pro-rated for the year in which such Qualifying Termination occurs based on the number of full weeks the Executive has work for the Company in such year through the date of such termination; and (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than twelve (12) months following the Executive’s termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company’s provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply (collectively, the “Severance Benefits”).”

2. Section 7(c) of the Agreement shall be deleted in its entirety and replaced with the following:

(c) Termination by the Company Without Cause or by the Executive With Good Reason Within Three (3) Months Prior to or Within Twelve Months Following a Change in Control. If a Qualifying Termination occurs within three (3) months prior to or within twelve (12) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedures, the Executive’s Base Salary for a period of twelve (12) months; (ii) pay to the Executive, in a single lump sum on the Payment Date an amount equal to 100% of the Executive’s Target Bonus for the year in which such Qualifying Termination occurs or the Executive’s Target Bonus immediately prior to the Change in Control, if higher, (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than twelve (12) months following the Executive’s termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company’s provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, (iv) provide that the vesting of the Executive’s then-unvested equity awards that vest based solely on the passage of

time shall be accelerated, such that all then unvested time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the later of the termination date and the closing of the Change in Control; and (v) if any Executive equity awards are canceled, terminated, or otherwise extinguished in connection with the Change in Control (whether in exchange for cash, securities, or other consideration), and are not assumed or continued by the acquiring or successor entity, then upon the termination of Executive's employment as described above, Executive shall be entitled to receive a lump-sum cash payment equal to the transaction value of the unvested portion of such awards as if such portion had fully vested immediately prior to the Change in Control (collectively, the "Change in Control Severance Benefits").

3. Section 7(d) of the Agreement shall be deleted in its entirety and replaced with the following:

(d) *Severance and Release of Claims Agreement.* As a condition of the Executive's receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the "Severance Agreement") (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of the Executive's continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following the Executive's separation from employment), which Severance Agreement must become irrevocable within 60 days following the date of the Executive's termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive's employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the "Payment Date"). For the avoidance of doubt, if the Executive experiences a Qualifying Termination prior to a Change in Control, (i) any then-outstanding and unvested equity awards that vest based solely on the passage of time held by the Executive shall remain outstanding (but any vesting shall be suspended) for up to (but no longer than) three (3) months following the date of termination so that, if it is later determined that such termination occurred during the three (3)-month period prior to the closing of a Change in Control and that the Executive is entitled to Change in Control acceleration and/or Change in Control Severance Benefits rather than Severance Benefits, the vesting of such awards may be accelerated, in accordance with Section 7(c) hereof, immediately prior to the closing of the Change in Control and (ii) any Change in Control Severance Benefits shall be reduced by any Severance Benefits previously paid to you, if it is later determined that the termination occurred during the three (3)-month period prior to the closing of a Change in Control and that you are entitled to Change in Control Severance Benefits rather than Severance Benefits.
 4. All capitalized terms used but not defined herein shall have the respective meanings given to them in the Agreement.
 5. Except as amended herein, all provisions of the Agreement shall remain in full force and effect.
 6. This First Amendment may be executed in two counterparts, both of which shall constitute one and the same legal instrument, and delivery of an executed copy of this First Amendment by a Party via pdf or other electronic transmission shall be as effective as delivery of a manually executed copy of this First Amendment by such Party.
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IN WITNESS WHEREOF, the Parties have entered into this First Amendment as of the Effective Date.

Solid Biosciences Inc.

Executive

By: /s/ Bo Cumbo
Name: Bo Cumbo
Title: President & CEO
Date: 10/28/2025

By: /s/ Ty Howton
Name: Ty Howton
Title: Chief Operating Officer
Date: 10/30/2025

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the “Agreement”) is made as of January 9, 2023 (the “Effective Date”) by and between Solid Biosciences Inc. (the “Company”) and Kevin Tan (the “Executive”) (together, the “Parties”).

RECITALS

WHEREAS, the Company desires to employ the Executive as its Chief Financial Officer and Treasurer; and

WHEREAS, the Executive has agreed to accept such employment with the Company on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements of the Parties herein contained, the Parties hereto agree to the following terms, which shall govern the Executive’s employment:

1. *Agreement.* This Agreement shall be effective as of the Effective Date. The Executive’s employment on the terms contained in this Agreement shall commence on the Effective Date and shall continue until such employment relationship is terminated in accordance with Section 6 hereof (the “Term of Employment”).

2. *Position.* During the Term of Employment, the Executive shall serve as the Chief Financial Officer and Treasurer of the Company, working out of the Company’s office in Charlestown, Massachusetts, and travelling as reasonably required by the Executive’s job duties.

3. *Scope of Employment.* During the Term of Employment, the Executive shall be responsible for the performance of those duties consistent with the Executive’s position as Chief Financial Officer and Treasurer. The Executive shall report to the Chief Executive Officer of the Company and/or the Company’s board of directors (the “Board”) and shall perform and discharge faithfully, diligently, and to the best of the Executive’s ability, the Executive’s duties and responsibilities hereunder. The Executive shall devote substantially all of the Executive’s business time, loyalty, attention and efforts to the business and affairs of the Company and its affiliates. Membership on boards of directors of up to two other companies will be permitted only with the express approval of the Chief Executive Officer, and membership on boards of directors of community, charitable or industry organizations will be permitted only provided that such activities do not create a conflict of interest or otherwise interfere with the Executive’s performance of the Executive’s duties hereunder, as determined by the Chief Executive Officer in the Chief Executive Officer’s sole discretion. The Executive agrees to abide by the written rules, regulations, instructions, personnel practices and policies of the Company and any changes therein that may be adopted from time to time by the Company.

4. *Compensation.* As full compensation for all services rendered by the Executive to the Company and any affiliate thereof, during the Term of Employment, the Company will provide to the Executive the following:

(a) *Base Salary.* The Executive shall receive a base salary at the annualized rate of \$425,000 (the “Base Salary”). The Executive’s Base Salary shall be paid in equal installments in accordance with the Company’s regularly established payroll procedures. The Executive’s Base Salary will be reviewed from time to time by the Board and is subject to change in the discretion of the Board.

(b) *Annual Discretionary Bonus.* The Executive will be eligible to earn an annual performance bonus targeted at 40% of the Executive’s Base Salary (the “Target Bonus”), based upon the Board’s assessment of the Executive’s performance against objective criteria and the Company’s attainment of targeted goals as set by the Board in its sole discretion. The Board may determine to provide the bonus in the form of cash, equity award(s), or a combination of cash and equity. Following the close of each calendar year, the Board will determine whether the Executive has earned a performance bonus, and the amount of any performance bonus, based on the set objective criteria. No amount of the annual bonus is guaranteed, and the Executive must be an employee in good standing on the date of payment in order to be eligible for any annual bonus, as such bonus also serves as an incentive for the Executive to remain employed by the Company, except as specifically set forth below; provided that if the Executive is terminated by the Company without Cause after January 1 but prior to the payment of any annual bonus that would have been paid under this Section 4(b) for the year prior to the year in which the Executive’s employment is terminated, the Executive shall be entitled to receive, on the payment date, one hundred percent of the Target Bonus (which for the avoidance of doubt, shall not be less than 40% of Executive’s Base Salary on the date of termination), less all applicable taxes and withholdings. Any bonus determined by the Board to be payable to the Executive for 2023 shall not be prorated based on the starting date and, for the avoidance of doubt, the Company acknowledges and agrees that Executive shall be entitled to the full amount of the annual bonus determined by the Board to be payable for 2023. The objective criteria used to assess Executive’s performance will be reviewed from time to time by the Board and is subject to change in the discretion of the Board.

(c) *Equity Award.* Subject to approval by the compensation committee of the Board or a majority of the Company’s Independent Directors as defined in Nasdaq Listing Rule 5605(a)(2), and in consideration of and contingent upon the Executive entering into the Noncompetition Agreement following the Executive’s commencement of employment as set forth in Section 9 below and adhering to the non-competition provisions set forth therein, the Company will grant to the Executive:

(i) a non-qualified stock option (the “Option”) to purchase 90,000 shares of the Company’s common stock, such Option to (1) have an exercise price per share equal to the fair market value of the Company’s common stock on the date of grant, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date, at a rate of 25% of the total shares underlying the Option on the first anniversary of the grant date and, following that, as to an additional 1/48th of the total shares underlying the Option upon the Executive’s completion of each additional month of service over the 36-month period measured from the first anniversary of the grant date, (3) have a term of up to 10 years and (4) have such other terms as are set forth in the applicable Option agreement.

(ii) 45,000 restricted stock units (the “RSUs” and, together with the Option, the “Equity Awards”), which RSUs shall (1) entitle the Executive to receive one share of the Company’s common stock for each RSU that vests, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date, at a

rate of 25% of the total shares underlying the RSUs on each anniversary of the grant date and (3) have such other terms as are set forth in the applicable RSU agreement.

(iii) The Equity Awards will be granted outside of the Company's equity incentive plans as "inducement grants" within the meaning of Nasdaq Listing Rule 5635(c)(4). The Equity Awards are subject to adjustment for stock splits, combinations or other changes in capitalization.

(iv) The Executive shall also be eligible to receive additional equity awards, if any, at such times and on such terms and conditions as the Board shall, in its sole discretion, determine.

(d) *Paid Time Off.* The Executive shall receive paid vacation time plus sick time, consistent with the Company's policies as in effect from time to time, but in no event shall Executive receive less than fifteen (15) days of paid vacation each calendar year. In addition, the Executive shall receive paid time off for Company holidays which are set annually and in accordance with Company policy.

(e) *Benefits.* Subject to eligibility requirements and the Company's policies, the Executive shall have the right, on the same basis as other employees of the Company, to participate in, and to receive benefits under, any medical, vision and dental insurance policy maintained by the Company and the Company shall pay a portion of the cost of the premiums for such medical, vision and dental insurance that is consistent with the Company's then current employee benefit policy if the Executive elects to participate in such plans. Benefits are subject to change at any time in the Company's sole discretion.

(f) *Withholdings.* All compensation payable to the Executive shall be subject to applicable taxes and withholdings.

5. *Expenses.* The Executive will be reimbursed for the Executive's actual, necessary and reasonable business expense pursuant to Company policy, subject to the provisions of Section 3 of Exhibit A attached hereto.

6. *Employment Termination.* This Agreement and the employment of the Executive shall terminate upon the occurrence of any of the following:

(a) Upon the death of the Executive or at the election of the Company due to the Executive's "Disability". As used in this Agreement, the term "Disability" shall mean a physical or mental illness or disability that prevents the Executive from performing the duties of the Executive's position for a period of more than any three consecutive months or for periods aggregating more than twenty-six weeks during any twelve-month period. The Company shall determine in good faith and in its sole discretion whether the Executive is unable to perform the services provided for herein.

(b) At the election of the Company, with or without "Cause" (as defined below), immediately upon written notice by the Company to the Executive. As used in this Agreement, "Cause" shall mean a finding by the Company's Chief Executive Officer or the Board that the Executive:

- (i) performed the Executive's duties, in the good faith opinion of the Company's Chief Executive Officer or the Board, in a grossly negligent or reckless manner or with willful malfeasance;

- (ii) exhibited habitual drunkenness or engaged in substance abuse;
- (iii) committed any (A) material violation of any state or federal law relating to the workplace environment (including, without limitation, laws relating to sexual harassment or age, sex or other prohibited discrimination) or (B) material violation of any material written Company policy which remains uncured for seven (7) days following written notice setting forth in reasonable detail of such material violation by the Company to Executive;
- (iv) willfully failed or refused to perform in the usual manner at the usual time those duties which the Executive regularly and routinely performed in connection with the business of the Company or such other lawful duties reasonably related to the capacity in which the Executive is employed hereunder which may be assigned to the Executive by the Company's Chief Executive Officer or the Board, which failure or refusal continues for a period of more than seven (7) days after written notice thereof has been provided to the Executive by the Company's Chief Executive Officer or the Board, such notice to set forth in reasonable detail the nature of such failure or refusal;
- (v) performed any material action when specifically and reasonably instructed in writing (email being sufficient) not to do so by the Company's Chief Executive Officer or the Board;
- (vi) committed any fraud or used or appropriated for the Executive's personal use or benefit any funds, properties or opportunities of the Company not authorized by the Company's Chief Executive Officer or the Board to be so used or appropriated;
- (vii) breached the terms of (A) the Invention, Nondisclosure and Nonsolicitation Agreement, (B) the Non-Competition Agreement, (C) or any other restrictive covenant or confidentiality agreement between Executive and Company; or
- (vii) was convicted of, or pled guilty or "no contest" to, any felony or any other crime related to the Executive's employment or involving moral turpitude.

(c) At the election of the Executive, with or without "Good Reason" (as defined below), immediately upon written notice by the Executive to the Company (subject, if it is with Good Reason, to the timing provisions set forth in the definition of Good Reason). As used in this Agreement, "Good Reason" shall mean (without the Executive's consent):

- (i) a material diminution in the nature or scope of Executive's duties, responsibilities, or authority;
 - (ii) any reduction in the Executive's base compensation or target bonus percentage, other than a reduction of not more than 3% to the Executive's base compensation that affects all senior executives of the Company or reductions in base compensation that are the result of the annual number of regular payroll cycles;
 - (iii) the Company's requiring Executive to relocate Executive's primary office more than fifty (50) miles from the Executive's then-current primary office; or
 - (iv) any material breach of this Agreement (or any other agreement between
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Executive and Company) by the Company not otherwise covered by this paragraph;

provided, however, that in each case, the Company shall have a period of not less than thirty (30) days to cure any act constituting Good Reason following Executive's delivery to the Company of written notice (email being sufficient) within sixty (60) days of the action or omission constituting Good Reason and that the Executive actually terminates employment within thirty (30) days following the expiration of the Company's cure period.

7. Effect of Termination.

(a) *All Terminations Other Than by the Company Without Cause or by the Executive With Good Reason.* If the Executive's employment is terminated under any circumstances other than a Qualifying Termination (as defined below) (including a voluntary termination by the Executive without Good Reason pursuant to Section 6(c), a termination by the Company for Cause pursuant to Section 6(b) or due to the Executive's death or Disability pursuant to Section 6(a)), the Company's obligations under this Agreement shall immediately cease and the Executive shall only be entitled to receive (i) the Base Salary that has accrued and to which the Executive is entitled as of the effective date of such termination and to the extent consistent with general Company policy, accrued but unused paid time off through and including the effective date of such termination, to be paid in accordance with the Company's established payroll procedure and applicable law but no later than the next regularly scheduled pay period, (ii) unreimbursed business expenses for which expenses the Executive has timely submitted appropriate documentation in accordance with Section 5 hereof, (iii) accrued but unused vacation time earned through the date of termination and (iv) any amounts or benefits to which the Executive is then entitled under the terms of the benefit plans then-sponsored by the Company in accordance with their terms (and not accelerated to the extent acceleration does not satisfy Section 409A of the Internal Revenue Code of 1986, as amended, (the "Code") (the payments described in this sentence, the "Accrued Obligations").

(b) *Termination by the Company Without Cause or by the Executive With Good Reason Prior to or More Than Twelve Months Following a Change in Control.* If the Executive's employment is terminated by the Company without Cause pursuant to Section 6(b) or by the Executive with Good Reason pursuant to Section 6(c) (in either case, a "Qualifying Termination") prior to or more than twelve (12) months following a Change in Control (as

defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of twelve (12) months, and (ii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no event longer than twelve (12) months following the Executive's termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply (collectively, the "Severance Benefits").

(c) *Termination by the Company Without Cause or by the Executive With Good Reason*

Within Twelve Months Following a Change in Control. If a Qualifying Termination occurs within twelve (12) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of twelve (12) months; (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 100% of the Executive's Target Bonus for the year in which termination occurs or the Executive's Target Bonus immediately prior to the Change in Control, if higher (for the avoidance of doubt, the minimum amount paid pursuant to this Section shall equal 40% of Executive's Base Salary immediately prior to the termination of the Agreement pursuant to this Section), (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no event longer than twelve (12) months following the Executive's termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, and (iv) provide that the vesting of the Executive's then-unvested equity awards that vest based solely on the passage of time shall be accelerated, such that all then unvested time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the termination date (collectively, the "Change in Control Severance Benefits").

(d) *Severance and Release of Claims Agreement.* As a condition of the Executive's receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in substantially the form attached hereto as Exhibit D (the "Severance Agreement"), which Severance Agreement must become irrevocable within 60 days following the date of the Executive's termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive's employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the "Payment Date").

(e) *Change in Control Definition.* For purposes of this Agreement, "Change in Control" shall mean the occurrence of any of the following events, provided that such event or occurrence constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the assets of the Company, as defined in Treasury Regulation §§ 1.409A-3(i)(5)(v), (vi) and (vii): (i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934 (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) fifty percent (50%) or more of either (x) the then-outstanding shares of common stock of the Company (the "Outstanding Company Common Stock") or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the "Outstanding Company Voting Securities"); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (1) any acquisition directly from the Company or (2) any acquisition by any entity pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or (ii) a change in the composition of the Board that

results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term “Continuing Director” means at any date a member of the Board (x) who was a member of the Board on the Effective Date or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or (iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a “Business Combination”), unless, immediately following such Business Combination, each of the following two (2) conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company’s assets either directly or through one (1) or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the “Acquiring Corporation”) in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, fifty percent (50%) or more of the then-outstanding shares of common stock of the Acquiring Corporation, or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or (iv) the liquidation or dissolution of the Company.

8.Modified Section 280G Cutback. Notwithstanding any other provision of this Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a “Change in Ownership or Control” (as defined below), the following provisions shall apply:

(a) The Company shall not be obligated to provide to the Executive any portion of any “Contingent Compensation Payments” (as defined below) that the Executive would otherwise be entitled to receive to the extent necessary to eliminate any “excess parachute payments” (as defined in Section 280G(b)(1) of the Code) for the Executive. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Payments” and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Amount.”

(b) Notwithstanding the provisions of Section 8(a), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that would be incurred by the Executive if the Eliminated

Payments (determined without regard to this sentence) were paid to the Executive (including state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of the Executive's "base amount" (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a "Section 8(b) Override." For purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(c) For purposes of this Section 8 the following terms shall have the following respective meanings:

(i) "Change in Ownership or Control" shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.

(ii) "Contingent Compensation Payment" shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to or for the benefit of a "disqualified individual" (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(d) Any payments or other benefits otherwise due to the Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the "Potential Payments") shall not be made until the dates provided for in this Section 8(d). Within thirty (30) days after each date on which the Executive first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify the Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 8(b) Override is applicable. Within thirty (30) days after delivery of such notice to the Executive, the Executive shall deliver a response to the Company (the "Executive Response") stating either (A) that the Executive agrees with the Company's determination pursuant to the preceding sentence or (B) that the Executive disagrees with such determination, in which case the Executive shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y) the Eliminated Amount, and (z) whether the Section 8(b) Override is applicable. In the event that the Executive fails to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If the Executive states in the Executive Response that the Executive agrees with the Company's determination, the Company shall make the Potential Payments to the Executive within three (3) business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If the Executive states in the Executive Response that the Executive disagrees with the Company's determination, then, for a period of sixty (60) days following delivery of the Executive Response, the Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such 60-day period, such dispute shall be settled exclusively by arbitration in Charlestown, Massachusetts, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three (3) business days following delivery to the

Company of the Executive Response, make to the Executive those Potential Payments as to which there is no dispute between the Company and the Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three (3) business days following the resolution of such dispute.

(e) The Contingent Compensation Payments to be treated as Eliminated Payments shall be determined by the Company by determining the “Contingent Compensation Payment Ratio” (as defined below) for each Contingent Compensation Payment and then reducing the Contingent Compensation Payments in order beginning with the Contingent Compensation Payment with the highest Contingent Compensation Payment Ratio. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio, such Contingent Compensation Payment shall be reduced based on the time of payment of such Contingent Compensation Payments with amounts having later payment dates being reduced first. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio and the same time of payment, such Contingent Compensation Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Contingent Compensation Payment with a lower Contingent Compensation Payment Ratio. The term “Contingent Compensation Payment Ratio”

shall mean a fraction the numerator of which is the value of the applicable Contingent Compensation Payment that must be taken into account by the Executive for purposes of Section 4999(a) of the Code, and the denominator of which is the actual amount to be received by the Executive in respect of the applicable Contingent Compensation Payment. For example, in the case of an equity grant that is treated as contingent on the Change in Ownership or Control because the time at which the payment is made or the payment vests is accelerated, the denominator shall be determined by reference to the fair market value of the equity at the acceleration date, and not in accordance with the methodology for determining the value of accelerated payments set forth in Treasury Regulation Section 1.280G-1 Q/A-24(b) or (c)).

(f) The provisions of this Section 8 are intended to apply to any and all payments or benefits available to the Executive under this Agreement or any other agreement or plan under which the Executive receives Contingent Compensation Payments.

9.Restrictive Covenants Agreements. As a condition of the Executive’s employment, the Executive shall execute and comply with the terms of the Invention, Nondisclosure and Nonsolicitation Agreement attached hereto as Exhibit B. The Executive also will be required, following the Executive’s commencement of employment and as a condition of the Executive’s receipt of the equity grant set forth in Section 4(c) above, to enter into the Company’s standard form of Noncompetition Agreement, a copy of which form is attached hereto as Exhibit C for the Executive’s review.

10.Absence of Restrictions. The Executive represents and warrants that the Executive is not bound by any employment contracts, restrictive covenants or other restrictions that prevent the Executive from entering into employment with, or carrying out the Executive’s responsibilities for, the Company, or which are in any way inconsistent with any of the terms of this Agreement.

11.Notice. Any notice delivered under this Agreement shall be deemed duly delivered three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent for next-business day delivery via a reputable nationwide overnight courier service, or immediately upon hand delivery, in each case to the address of the recipient set forth below.

To Executive:

At the address set forth in the Executive's personnel file

To Company:

Solid Biosciences Inc.
500 Rutherford Avenue
Third Floor
Charlestown, MA 02129

Either Party may change the address to which notices are to be delivered by giving notice of such change to the other Party in the manner set forth in this Section 11.

12.Applicable Law; Jury Trial Waiver. This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware (without reference to the conflict of laws provisions thereof). Any action, suit or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the State of Delaware (or, if appropriate, a federal court located within the State of Delaware), and the Company and the Executive each consents to the jurisdiction of such a court. The Company and the Executive each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

13.Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both Parties and their respective successors and assigns, including any corporation with which or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Executive are personal and shall not be assigned by the Executive.

14.At-Will Employment. During the Term of Employment, the Executive will continue to be an at-will employee of the Company, which means that, notwithstanding any other provision set forth herein, the employment relationship can be terminated by either Party for any reason, at any time, with or without prior notice and with or without Cause.

15.Acknowledgment. The Executive states and represents that the Executive has had an opportunity to fully discuss and review the terms of this Agreement with an attorney. The Executive further states and represents that the Executive has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs the Executive's name of the Executive's own free act.

16.No Oral Modification, Waiver, Cancellation or Discharge. This Agreement may be amended or modified only by a written instrument executed by both the Company and the Executive. No delay or omission by the Company in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

17.Captions and Pronouns. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

18.*Interpretation.* The Parties agree that this Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the drafting Party. References in this Agreement to “include” or “including” should be read as though they said “without limitation” or equivalent forms. References in this Agreement to the “Board” shall include any authorized committee thereof.

19.*Severability.* Each provision of this Agreement must be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement. Moreover, if a court of competent jurisdiction determines any of the provisions contained in this Agreement to be unenforceable because the provision is excessively broad in scope, whether as to duration, activity, geographic application, subject or otherwise, it will be construed, by limiting or reducing it to the extent legally permitted, so as to be enforceable to the extent compatible with then applicable law to achieve the intent of the Parties.

20.*Entire Agreement.* This Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement.

21.*Legal Fees.* The Company will reimburse the Executive, or pay directly on the Executive’s behalf, for the reasonable and documented attorneys’ fees the Executive incurs in connection with the review and negotiation of this Agreement and any related agreements between the parties, up to a maximum of \$5,000.00.

[Signatures on Page Following]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the day and year set forth above.

SOLID BIOSCIENCES INC.

By: /s/ Bo Cumbo

Name: Bo Cumbo

Title: Chief Executive Officer

Executive

/s/ Kevin Tan

EXHIBIT A

Payments Subject to Section 409A

1. Subject to this Exhibit A, any severance payments that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below) which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to distribution of the severance payments, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments provided under the Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code ("Section 409A"). Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the letter agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

- (i) Each installment of the severance payments due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Agreement; and
 - (ii) Each installment of the severance payments due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would, absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that that such installment is deemed to be paid under a separation pay plan that does not
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provide for a deferral of compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with, and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of Section 2 of this Exhibit A, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in the Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

4. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person if any of the provisions of the Agreement (including this Exhibit A) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

5. The Agreement is intended to comply with, or be exempt from, Section 409A and shall be interpreted accordingly.

[Remainder of page intentionally left blank.]

EXHIBIT B

Invention, Nondisclosure and Nonsolicitation Agreement

EXHIBIT B – INVENTION, NONDISCLOSURE AND NONSOLICITATION AGREEMENT

This Invention, Nondisclosure and Nonsolicitation Agreement (this “Agreement”) is made by and between Solid Biosciences Inc., a Delaware corporation (together with its subsidiaries, the “Company”), and Kevin Tan (the “Employee”).

In consideration of the employment or continued employment of the Employee by the Company, the Employee and the Company agree as follows:

1. Condition of Employment.

The Employee acknowledges that the Employee’s employment and/or the continuance of that employment with the Company is contingent upon the Employee’s agreement to sign and adhere to the provisions of this Agreement. The Employee further acknowledges that the nature of the Company’s business is such that protection of its proprietary and confidential information is critical to the survival and success of the Company’s business.

2. Proprietary and Confidential Information.

(a) The Employee agrees that all information and know-how, whether or not in writing, of a private, secret or confidential nature concerning the Company’s business or financial affairs (collectively, “Proprietary Information”), whether disclosed to or otherwise learned by the Employee prior to or following the date of this Agreement, is and shall be the exclusive property of the Company. By way of illustration, but not limitation, Proprietary Information may include discoveries, ideas, inventions, products, product improvements, product enhancements, processes, methods, techniques, formulas, compositions, compounds, negotiation strategies and positions, projects, developments, plans (including business and marketing plans), research data, clinical data, financial data (including sales costs, profits, pricing methods), personnel data obtained pursuant to the Employee’s duties and responsibilities, computer programs (including software used pursuant to a license agreement), customer, prospect and supplier lists, and contacts at or knowledge of customers or prospective customers of the Company. Except as otherwise permitted by Section 5 below, the Employee has not and will not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of the Employee’s duties as an employee of the Company) without written approval by an officer of the Company, either during or after the Employee’s employment with the Company, unless and until such Proprietary Information has become public knowledge without fault by the Employee. While employed by the Company, the Employee has used and will use the Employee’s reasonable best efforts to prevent unauthorized publication or disclosure of any of the Company’s Proprietary Information.

(b)The Employee agrees that all files, documents, letters, memoranda, reports, records, data, sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible or intangible material containing Proprietary Information, whether created by the Employee or others, which have come and which come into the Employee's custody or possession, shall be and are the exclusive property of the Company and have been and will be used by the Employee only in the performance of the Employee's duties for the Company and have not and shall not be copied or removed from the Company's premises except in the pursuit of the business of the Company. All such materials or copies thereof and all tangible property of the Company (including, without limitation, computers, cellular telephones, credit cards, keys, access cards and the like) in the custody or possession of the Employee shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) termination of the Employee's employment for any reason. After such delivery, the Employee shall not retain any such materials or copies thereof or any such tangible property.

(c)The Employee agrees that the Employee's obligation not to disclose or to use information and materials of the types set forth in Sections 2(a) and 2(b) above, and the Employee's obligation to return materials and tangible property, set forth in Section 2(b) above, also extends to such types of information, materials and tangible property of customers of the Company or suppliers to the Company or other third parties who may have disclosed or entrusted the same to the Company or to the Employee in the course of the Company's business.

3. Developments.

(a)The Employee has attached hereto, as Schedule 1, a list describing all discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which were created, made, conceived or reduced to practice by the Employee prior to the Employee's employment by the Company and which are owned by the Employee, which relate directly or indirectly to the current or anticipated future business of the Company, and which are not assigned to the Company hereunder (collectively, "Prior Developments"); or, if no such list is attached, the Employee represents that there are no Prior Developments. The Employee agrees not to incorporate any Prior Developments into any Company product, material, process or service without prior written consent of an officer of the Company. If the Employee has incorporated or does incorporate any Prior Development into any Company product, material, process or service, the Employee hereby grants to the Company a nonexclusive, worldwide, perpetual, transferable, irrevocable, royalty-free, fully-paid right and license to make, have made, use, offer for sale, sell, import, reproduce, modify, prepare derivative works, display, perform, transmit, distribute and otherwise exploit such Prior Development and to practice any method related thereto.

(b)The Employee has made and will make full and prompt disclosure to the Company of all discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which have been or are created, made, conceived or reduced to practice by the Employee or under the Employee's direction or jointly with others during the Employee's employment by the Company, whether or not during normal working hours or on the premises of the Company (all of which are collectively referred to in this Agreement as "Developments"). The Employee acknowledges that each original work of

authorship which has been or is made by the Employee (solely or jointly with others) within the scope of and during the period of the Employee's employment with the Company and which is protectable by copyright is a "work made for hire," as that term is defined in the United States Copyright Act. The Employee agrees to assign and does hereby assign to the Company (or any person or entity designated by the Company) all the Employee's right, title and interest in and to all Developments (other than Prior Developments listed on Schedule 1, if any) and all related patents, patent applications, copyrights and copyright applications. However, this Section 3(b) shall not apply to Developments which do not relate to the business or research and development conducted or planned to be conducted by the Company at the time such Development is created, made, conceived or reduced to practice and which are made and conceived by the Employee not during normal working hours, not on the Company's premises and not using the Company's tools, devices, equipment or Proprietary Information. The Employee understands that, to the extent this Agreement shall be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 3(b) shall be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. The Employee also hereby waives all claims to moral rights in any Developments.

(c) The Employee agrees to cooperate fully with the Company, both during and after the Employee's employment with the Company, with respect to the procurement, maintenance and enforcement of copyrights, patents and other intellectual property rights (both in the United States and foreign countries) relating to Developments. The Employee shall sign all papers, including, without limitation, copyright applications, patent applications, declarations, oaths, formal assignments, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its rights and interests in any Development. The Employee further agrees that if the Company is unable, after reasonable effort, to secure the signature of the Employee on any such papers, any executive officer of the Company shall be entitled to execute any such papers as the agent and the attorney-in-fact of the Employee, and the Employee hereby irrevocably designates and appoints each executive officer of the Company as the Employee's agent and attorney-in-fact to execute any such papers on the Employee's behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Development, under the conditions described in this sentence.

4. Obligations to Third Parties.

The Employee represents that, except as the Employee has disclosed in writing to the Company on Schedule 1 attached hereto, the Employee is not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of the Employee's employment with the Company, to refrain from competing, directly or indirectly, with the business of such previous employer or any other party or to refrain from soliciting employees, customers or suppliers of such previous employer or other party. The Employee further represents that the Employee's performance of all the terms of this Agreement and the performance of the Employee's duties as an employee of the Company do not and will not conflict with or breach any agreement with any prior employer or other party (including, without limitation, any nondisclosure or noncompetition agreement), and that the Employee will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

5. Scope of Disclosure Restrictions.

Nothing in this Agreement prohibits the Employee from communicating with government agencies about possible violations of federal, state, or local laws or otherwise providing information to government agencies, filing a complaint with government agencies, or participating in government agency investigations or proceedings. The Employee is not required to notify the Company of any such communications; provided, however, that nothing herein authorizes the disclosure of information the Employee obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding the Employee's confidentiality and nondisclosure obligations, the Employee is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order."

6. United States Government Obligations.

The Employee acknowledges that the Company from time to time may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such

agreements or regarding the confidential nature of such work. The Employee agrees to be bound by all such obligations and restrictions which are made known to the Employee and to take all action necessary to discharge the obligations of the Company under such agreements.

7. Customer Nonsolicitation. The Employee agrees that during the period of the Employee's employment and the one year period following the termination thereof, regardless of the reason for such termination, the Employee will not, directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, contact, solicit, divert, do business with, take away, or attempt to contact, solicit, divert, do business with, or take away, any clients, customers, or accounts, or prospective clients, customers, or accounts, of the Company, or any of the Company's business with such clients, customers, or accounts. As used in this section, the term "client," "customer," or "account" shall include: (i) any person or entity that is a client, customer or account of the Company on the date of this Agreement or becomes a client, customer or account of the Company during the period of the Employee's employment with the Company or the one year period thereafter; (ii) any person or entity that was a client, customer or account of the Company at any time during the two year period preceding the date of termination of the Employee's employment; and (iii) any prospective client, customer or account to whom the Company has made a presentation (or similar offering of services) within a period of two years preceding the date of termination of the Employee's employment.

8. Nonsolicitation of Employees and Consultants. The Employee agrees that during the period of the Employee's employment and the one year period following the termination thereof, regardless of the

reason for such termination, the Employee will not, directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, seek to solicit or induce any Company employee or consultant, or any such person whose employment or consultancy with the Company has terminated within six months prior to or after the Employee's termination from the Company, to leave his or her employment or consultancy with the Company, or assist in the recruitment or hiring of any such person.

9. Nondisparagement. The Employee agrees that he or she shall not at any time, whether during or after the termination of his or her employment, regardless of the reason for such termination, make to any person or entity (including via social media) disparaging comments relating to the Company's services and products. Notwithstanding the foregoing, nothing in this Agreement precludes Employee from (i) making any report or disclosure to a government agency to the extent required or protected by statute, regulation or other applicable law; or (ii) testifying truthfully in any legal proceedings to the extent compelled by a valid subpoena.

10. Miscellaneous.

(a)Equitable Remedies. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement may result in the Company incurring substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies which may be available, shall have the right to seek an injunction from a court restraining such a breach or threatened breach without posting a bond and the right to specific performance of the provisions of this Agreement and the Employee hereby waives the adequacy of a remedy at law as a defense to such relief.

(b)Disclosure of this Agreement. The Employee hereby authorizes the Company to notify others, including but not limited to customers of the Company and any of the Employee's future employers or prospective business associates, of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder.

(c)Not Employment Contract. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue the Employee's employment for any period of time and does not change the at-will nature of the Employee's employment.

(d)Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by the Employee. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

(e)Severability. In case any provision of this Agreement shall be invalid, illegal or

otherwise unenforceable, the validity, legality and enforceability of the remaining provisions shall in no way be affected or impaired thereby. If one or more provisions of this Agreement shall for any reason be held to be excessively broad as to scope, activity, subject or otherwise so as to be unenforceable at law, such provision or provision shall be construed by the appropriate judicial body by limiting or reducing it or them, so as to be enforceable to the maximum extent compatible with the applicable law as it shall then appear. The language of all parts of this Agreement shall in all cases be construed as a whole according to its fair meaning and not strictly for or against either of the parties.

(f)Waivers. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(g)Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to the jurisdiction of such a court. The Company and the Employee each hereby irrevocably waive any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

(h)Entire Agreement; Amendment. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in the Employee's duties, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

(i)Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

The employee acknowledges that he/she has carefully read this Agreement, understands and agrees to all of the provisions in this Agreement, and hereby executes this Agreement under seal.

Solid Biosciences Inc.

By: /s/ Alexander Cumbo
Alexander Cumbo
President and Chief Executive Officer

Employee:
/s/ Kevin Tan 1/9/2023
Name Date

SCHEDULE 1

List of prior developments and original works of authorship excluded under Section 3(a) or conflicting agreements disclosed under Section 4.

Title	Date	Identifying Number or Brief Description
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Separation Agreement and Release dated November 23, 2022 between Employee and Selecta Biosciences, Inc. containing non-solicitation and confidentiality terms similar to those set forth in this Agreement.		
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Employment Agreement and Restrictive Covenant Agreement each dated September 20, 2021 between Employee and Selecta Biosciences, Inc. containing non-solicitation and confidentiality terms similar to those set forth in this Agreement.		
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Except as indicated above on this Schedule 1, I have no Prior Developments to disclose pursuant to Section 3(a) of this Agreement and no agreements to disclose pursuant to Section 4 of this Agreement.

Employee:

/s/ Kevin Tan	1/9/2023
Name	Date

EXHIBIT C

Form of Noncompetition Agreement

EXHIBIT C - NONCOMPETITION AGREEMENT

This Noncompetition Agreement (the “Agreement”) is made between Solid Biosciences Inc., a Delaware corporation (including its subsidiaries, the “Company”), and the undersigned employee (the “Employee”).

For good consideration, including, with respect to the noncompetition restrictions, the additional consideration set forth in Section 1(c), the Employee and the Company agree as follows:

1. Noncompetition.

(a) During the Restricted Period (as defined below), the Employee will not, in the Applicable Territory (as defined below), directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, except as the passive holder of not more than 1% of the outstanding stock of a publicly-held company, engage or assist others in engaging in any business or enterprise that is competitive with the Company’s business, including but not limited to any business or enterprise that develops, manufactures, researches, markets, licenses, sells or provides any product or service that competes with any product or service developed, researched, manufactured, marketed, licensed, sold or provided, or planned to be developed, manufactured, researched, marketed, licensed, sold or provided by the Company (a “Competitive Company”), if the Employee would be performing a job or job duties or services for the Competitive Company that are the same as or substantially similar to the job or job duties or services that the Employee performed for the Company at any time during the last two years of the Employee’s employment.

(b) Certain Definitions. Solely for purposes of this Section 1:

i. the “Restricted Period” shall include the duration of the Employee’s employment with the Company and the twelve month period thereafter. Notwithstanding the foregoing, the Restricted Period shall end immediately upon the Employee’s last day of employment with the Company if: (x) the Company terminates the Employee’s employment without Cause (as defined below); (y) the Company notifies the Employee in writing that it is waiving the post-employment restrictions set forth in this Section or (z) Employee terminates his employment for Good Reason (as such term is defined in the Employment Agreement).

ii. “Applicable Territory” shall mean the geographic areas in which the Employee provided services or had a material presence or influence at any time during his/her last two years of employment.

iii. “Cause” shall have the meaning ascribed to such term in the Employment Agreement.

iv. “Employment Agreement” shall mean that certain Employment Agreement between Company and the Employee dated effective as of [], 2023.

(c)Additional Consideration for Noncompetition Restrictions. In exchange for the Employee's compliance with the restrictions set forth in this Section 1, the Company will grant the Employee an equity award, as is more fully set forth in Section 4(c) of the Employment Agreement, and, further, during the post-employment portion of the Restricted Period, the Company will pay the Employee one thousand dollars (\$1,000) per month (the "Noncompete Consideration"). The Noncompete Consideration will be paid ratably in accordance with the Company's regular payroll practices, commencing with the first payroll cycle beginning after the Employee's separation date, except as may otherwise be required by Section 3(h) below. The Employee understands and agrees that the Company may discontinue or otherwise not provide the Noncompete Consideration (i) if the Restricted Period expires upon the termination of the employment relationship pursuant to the last sentence of Section 1(b) (i), (ii) if the Employee breaches this Agreement, or (iii) during any portion of the Restricted Period that has been extended in accordance with Section 1(b)(i); provided, however, that with respect to (ii) or (iii), any such cessation shall not excuse the Employee's compliance with his/her obligations under this Section 1 or otherwise in this Agreement. The Employee understands and agrees that the above-stated consideration has been mutually agreed upon by the Company and the Employee, is fair and reasonable, and is sufficient consideration in exchange for the restrictions set forth in this Section 1.

2.Notice of New Business Activities. The Employee agrees that during any period of time when the Employee is subject to restrictions pursuant to Section 1, the Employee will notify any prospective employer or business associate of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder. The Employee further agrees, during such period, to give notice to the Company of each new business activity the Employee plans to undertake, at least ten business days prior to beginning any such activity that could reasonably be viewed to be in conflict with the Employee's obligations under this Agreement. The notice shall state the name and address of the individual, corporation, association or other entity or organization ("Entity") for whom such activity is undertaken and the name of the Employee's business relationship or position with the Entity. The Employee also agrees to provide the Company with other pertinent information concerning such business activity as the Company may reasonably request in order to determine the Employee's continued compliance with his/her obligations under this Agreement.

3. Miscellaneous.

(a)Equitable Remedies. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement may result in the Company incurring substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to any and all other remedies which may be available, shall have the right to seek an injunction from a court restraining such a breach or threatened breach without posting a bond and the right to specific performance of the provisions of this Agreement and the Employee hereby waives the adequacy of a remedy at law as a defense to such relief.

(b)Not Employment Contract. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue his/her employment for any period of time, and does not change the at-will nature of his/her employment.

(c)Acknowledgments. The Company hereby advises the Employee and the Employee hereby acknowledges that he or she has the right to consult with counsel prior to signing this Agreement. The Employee further acknowledges that this Agreement is supported by fair and reasonable consideration independent from the Employee's continued employment, that the Employee has been provided at least ten

(10) business days to review this Agreement, and that this Agreement shall not take effect until the eleventh (11th) business day following the date on which the Company provided it to the Employee for review and execution.

(d)Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by him or her. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

(e)Interpretation. If any restriction or definition set forth in this Agreement is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of conduct, activities, or geographic area, it shall be interpreted to extend only over the maximum period of time, range of conduct, activities or geographic area as to which it may be enforceable.

(f)Severability. If any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, and cannot be reformed to make it enforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall in no way be affected or impaired thereby.

(g)Waivers. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(h)Tax Withholding; Section 409A. Any compensatory payments under or referred to in this Agreement will be subject to all required tax and other withholdings. This Agreement is intended to comply with or be exempt from the provisions of Section 409A of the Internal Revenue Code of 1986, as amended ("Section 409A") and the Agreement will, to the extent practicable, be construed in accordance therewith. Terms defined in this Agreement will have the meanings given such terms under Section 409A if and to the extent required to comply with Section 409A and a termination of employment will mean a "separation from service" as defined in Section 409A. For purposes of this Agreement, each amount to be paid or benefit to be provided, including a series of installment payments, will be construed as a separate identified payment for purposes of Section 409A. If and to the extent any portion of any payment, compensation or other benefit provided to the Employee in connection with his/her separation from service (as defined in Section 409A) is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Employee is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, as determined by the Company in accordance with its procedures, by which determination the

Employee hereby agrees that he/she is bound, such portion of the payment, compensation or other benefit will not be paid before the earlier of (i) the day that is six months plus one day after the date of separation from service (as determined under Section 409A) or (ii) the tenth day after the date of his/her death (as applicable, the "New Payment Date"). The aggregate of any payments that otherwise would have been paid to the Employee during the period between the date of separation from service and the New Payment Date will be paid to the Employee in a lump sum in the first payroll period beginning after such New Payment Date (or, with respect to payment after death, as soon as reasonably practicable and within the time limits permitted by Section 409A), and any remaining payments will be paid on their original schedule. In any event, the Company makes no representations or warranty and will have no liability to the Employee or any other person if any provisions of or payments under this Agreement are determined to constitute deferred compensation subject to Section 409A but not to satisfy the conditions of that section

(i)Governing Law and Consent To Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court in Suffolk County, Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to the jurisdiction of such courts. The Company and the

Employee each hereby irrevocably waives any right to a trial by jury in any action, suit or other legal proceeding arising under or relating to any provision of this Agreement.

(j)Entire Agreement; Amendment. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in his/her duties, authority, title, reporting relationship, territory, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

(k)Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

The employee acknowledges that he/she has carefully read this agreement, understands and agrees to all of the provisions in this agreement, and hereby executes this agreement under seal.

Solid Biosciences Inc.

By: AlexanderCumbo
President and Chief Executive Officer

Employee:

[Name] Date

EXHIBIT D

Form of Release

EXHIBIT D TO EMPLOYMENT AGREEMENT

VIA HAND DELIVERY

[Insert Date]

Kevin Tan

[Insert Employee Address]

Dear Kevin Tan:

As we discussed, your employment with Solid Biosciences Inc. (the “Company”) **[is ending][has ended]** effective **[insert Separation Date]** (the “Separation Date”). As we also discussed, you will be eligible to receive the severance benefits described in **[Section 7(b) or 7(c)]** of the Employment Agreement dated **[insert date]** between you and the Company to which this letter agreement is attached as Exhibit D (the “Employment Agreement”), and referenced in paragraph 1 below, if you sign and return this letter agreement to me on or before **[insert return date²]**, but no earlier than the Separation Date, and do not revoke your agreement (as described below). By signing and returning this letter agreement and not revoking your acceptance, you will be entering into a binding agreement with the Company and will be agreeing to the terms and conditions set forth in the numbered paragraphs below, including the release of claims set forth in paragraph 2. Therefore, you are advised to consult with an attorney before signing this letter agreement and you have been given at least **[twenty-one (21)][forty-five (45)³]** days to do so. If you sign this letter agreement, you may change your mind and revoke your agreement during the seven (7) business day period after you have signed it (the “Revocation Period”) by notifying me in writing. If you do not so revoke, this letter agreement will become a binding agreement between you and the Company upon the expiration of the Revocation Period.

Although your receipt of the severance benefits is expressly conditioned on your entering into this letter agreement, the following will apply regardless of whether or not you do so:

- As of the Separation Date, all salary payments from the Company will cease and any benefits you had as of the Separation Date under Company-provided benefit plans, programs, or practices will terminate, except as required by federal or state law.
 - You will receive payment for your final wages and any unused vacation time accrued through the Separation Date.
-

- You may, if eligible and at your own cost, elect to continue receiving group medical insurance pursuant to the “COBRA” law. Please consult the COBRA materials to be provided under separate cover for details regarding these benefits.
- You are obligated to keep confidential and not to use or disclose any and all non-public information concerning the Company that you acquired during the course of your employment with the Company, including any non-public information concerning the Company’s business affairs, business prospects, and financial condition, except as otherwise permitted by paragraph 8 below. Further, you remain subject to your continuing obligations to the Company as set forth in the Invention, Nondisclosure and Nonsolicitation Agreement and Noncompetition Agreement attached to the Employment Agreement as Exhibits B and C (the “Restrictive Covenants Agreements”), which remain in full force and effect.
- You must return to the Company no later than the Separation Date all Company property.

If you elect to timely sign and return this letter agreement and do not revoke your acceptance within the Revocation Period, the following terms and conditions will also apply:

1. **Severance Benefits** –The Company will provide you with the pay and benefits set forth in [Section 7(b) or 7(c)] of the Employment Agreement (the “severance benefits”), in accordance with and subject to the terms thereof.

You will not be eligible for, nor shall you have a right to receive, any payments or benefits from the Company following the Separation Date other than as set forth in this paragraph.

2. **Release of Claims** – In consideration of the severance benefits, which you acknowledge you would not otherwise be entitled to receive, you hereby fully, forever, irrevocably and unconditionally release, remise and discharge the Company, its past and present affiliates, subsidiaries, parent companies, predecessors, and successors, and all of their respective past and present officers, directors, stockholders, partners, members, employees, agents, representatives, plan administrators, attorneys, insurers and fiduciaries (each in their individual and corporate capacities) (collectively, the “Released Parties”) from any and all claims, charges, complaints, demands, actions, causes of action, suits, rights, debts, sums of money, costs, accounts, reckonings, covenants, contracts, agreements, promises, doings, omissions, damages, executions, obligations, liabilities, and expenses (including attorneys’ fees and costs), of every kind and nature that you ever had or now have against any or all of the Released Parties, whether known or unknown, including, but not limited to, any and all claims arising out of or relating to your employment with or separation from, and/or ownership of securities of the Company, including, but not limited to, all claims under Title VII of the Civil Rights Act of 1964, 42 U.S.C. § 2000e et seq., the Americans With Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., the Age Discrimination in Employment Act, 29 U.S.C. § 621 et seq., the Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff et seq., the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq., the Worker Adjustment and Retraining Notification Act (“WARN”), 29 U.S.C. § 2101 et seq., the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141, the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 (“ERISA”), 29 U.S.C. § 1001 et seq., all as amended; all claims arising out of the Massachusetts Fair Employment Practices Act, Mass. Gen. Laws ch. 151B, § 1 et seq., the Massachusetts Civil Rights Act, Mass. Gen. Laws ch. 12, §§ 11H and 11I, the Massachusetts Equal Rights Act, Mass. Gen. Laws. ch. 93, § 102, Mass. Gen. Laws

ch. 214, § 1C (Massachusetts right to be free from sexual harassment law), the Massachusetts

Labor and Industries Act, Mass. Gen. Laws ch. 149, § 1 et seq., Mass. Gen. Laws ch. 214, § 1B (Massachusetts right of privacy law), the Massachusetts Parental Leave Act, Mass. Gen. Laws ch. 149, § 105D, and the Massachusetts Small Necessities Leave Act, Mass. Gen. Laws ch. 149, § 52D, all as amended; all rights and claims under the Massachusetts Wage Act, Mass. Gen. Laws ch. 149, § 148 et seq., as amended (Massachusetts law regarding payment of wages and overtime), including any rights or claims thereunder to unpaid wages, including overtime, bonuses, commissions, and accrued, unused vacation time; all common law claims including, but not limited to, actions in defamation, intentional infliction of emotional distress, misrepresentation, fraud, wrongful discharge, and breach of contract (including, without limitation, all claims arising out of or related to the Employment Agreement); all claims to any non-vested ownership interest in the Company, contractual or otherwise; all state and federal whistleblower claims to the maximum extent permitted by law; and any claim or damage arising out of your employment with and/or separation from the Company (including a claim for retaliation) under any common law theory or any federal, state or local statute or ordinance not expressly referenced above; provided, however, that this release of claims shall not (i) prevent you from filing a charge with, cooperating with, or participating in any investigation or proceeding before, the Equal Employment Opportunity Commission or a state fair employment practices agency (except that you acknowledge that you may not recover any monetary benefits in connection with any such claim, charge, investigation, or proceeding, and you further waive any rights or claims to any payment, benefit, attorneys' fees or other remedial relief in connection with any such claim, charge, investigation or proceeding), (ii) deprive you of your rights with respect to any vested rights under any employee benefit plan or policy, stock plan or deferred compensation arrangement, or any health care continuation to the extent required by applicable law; (iii) deprive you of any rights you may have to be indemnified by the Company as provided in any agreement between the Company and you or pursuant to the Company's Certificate of Incorporation or by-laws. Notwithstanding anything to the contrary in this Agreement, it is understood and agreed by the parties that the claims released pursuant to this Section are not intended to and do not release, restrict, or impair any claim arising out of the Company's breach of this Agreement and any and all agreements contemplated or executed in connection herewith.

3. **Continuing Obligations** – You acknowledge and reaffirm your obligation, except as otherwise permitted by paragraph 8 below, to keep confidential and not to use or disclose any and all non-public information concerning the Company acquired by you during the course of your employment with the Company, including, but not limited to, any non-public information concerning the Company's business, operations, products, programs, affairs, performance, personnel, technology, science, intellectual property, plans, strategies, approaches, prospects, financial condition or development related matters. You also acknowledge all of your continuing obligations pursuant to the Restrictive Covenant Agreements you executed in connection with your employment, which survive your separation from employment with the Company and shall remain in full force and effect. [In addition, as an express condition of your receipt of the severance benefits, you agree that, for a period of one (1) year following the Separation Date, you will not, in the Applicable Territory (as defined in the Noncompetition Agreement dated **[insert date]**), directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, except as the passive holder of not more than 1% of the outstanding stock of a publicly-held company, engage or assist others in engaging in any business or enterprise that is competitive with the Company's business, including but not limited to any Competitive Company (as defined in the Noncompetition Agreement), if you would be performing a job or job duties or services for the Competitive Company that are the same as or substantially similar to the job or job duties or services that you performed for the Company at any time during the last two (2) years of your employment. If any restriction set forth in this

paragraph is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of activities or in too broad a geographic area, it shall be interpreted to extend only over the maximum period of time, range of activities or

geographic area as to which it may be enforceable. If you violate the non-competition provisions set forth in this paragraph, you shall continue to be bound by such restrictions until a period of one (1) year has expired without any violation of such provisions.]⁴

4. **Non-Disparagement** – You understand and agree that, to the extent permitted by law and except as otherwise permitted by paragraph 8 below, you will not, in public or private, make any false, disparaging, derogatory or defamatory statements, online (including, without limitation, on any social media, networking, or employer review site) or otherwise, to any person or entity, including, but not limited to, any media outlet, industry group, financial institution or current or former employee, board member, consultant, client or customer of the Company, regarding the Company or its affiliates or any of their respective officers, directors, managers or employees, or regarding the Company's business affairs, business prospects, or financial condition. The Company agrees that the Board of Directors and senior management of the Company shall refrain from making any false, disparaging, derogatory or defamatory statements, online (including, without limitation, on any social media, networking, or employer review site) or otherwise, to any person or entity, regarding you.

5. **Return of Company Property** – You confirm that you have returned to the Company all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software, printers, flash drives and other storage devices, wireless handheld devices, cellular phones, tablets, etc.), Company identification, and any other Company owned property in your possession or control, and that you have left intact, and have otherwise not destroyed, deleted, or made inaccessible to the Company, all electronic Company documents, including, but not limited to, those that you developed or helped to develop during your employment, and that you have not (a) retained any copies in any form or media; (b) maintained access to any copies in any form, media, or location; (c) stored any copies in any physical or electronic locations that are not readily accessible or not known to the Company or that remain accessible to you; or (d) sent, given, or made accessible any copies to any persons or entities that the Company has not authorized to receive such electronic or hard copies. You further confirm that you have cancelled all accounts for your benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone accounts, and computer accounts.

6. **Business Expenses and Final Compensation** – You acknowledge that you have been reimbursed by the Company for all business expenses incurred in conjunction with the performance of your employment and that no other reimbursements are owed to you. You further acknowledge that you have received payment in full for all services rendered in conjunction with your employment by the Company, including payment for all wages, bonuses, and accrued, unused vacation time, and that no other compensation, benefit or consideration is owed to you except as provided herein.

7. **Confidentiality** – You understand and agree that, to the extent permitted by law and except as otherwise permitted by paragraph 8 below, the terms and contents of this letter agreement, and the contents of the negotiations and discussions resulting in this letter agreement, shall be maintained as confidential by you and your agents and representatives and shall not be disclosed except as otherwise agreed to in writing by the Company.

8. **Scope of Disclosure Restrictions** – You understand that nothing in this letter agreement or elsewhere prohibits you from filing a charge or complaint with the Securities and Exchange Commission or any other federal, state, or local governmental regulatory or law enforcement agency (“Government Agencies”). You further understand that nothing in this letter agreement or elsewhere limits your ability to, without notice or approval from the Company, communicate with any Government Agencies or otherwise participate in or fully cooperate with any investigation or proceeding that may be conducted by any Government Agency, including providing documents or other information to a Government Agency, nor does it limit your right to participate in the Securities and Exchange Commission’s whistleblower program. Further, notwithstanding your confidentiality and nondisclosure obligations, you are hereby advised as follows pursuant to the Defend Trade Secrets Act: “An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order.”

9. **Cooperation** – You agree that, to the extent permitted by law, you shall cooperate fully with the Company in the investigation, defense or prosecution of any claims or actions which already have been brought, are currently pending, or which may be brought in the future against the Company by a third party or by or on behalf of the Company against any third party, whether before a state or federal court, any state or federal government agency, or a mediator or arbitrator. Your full cooperation in connection with such claims or actions shall include, but not be limited to, being available to meet with the Company’s counsel, at reasonable times and locations designated by the Company, to investigate or prepare the Company’s claims or defenses, to prepare for trial or discovery or an administrative hearing, mediation, arbitration or other proceeding, to provide any relevant information in your possession, and to act as a witness when requested by the Company. You further agree that, to the extent permitted by law, you will notify the Company promptly in the event that you are served with a subpoena (other than a subpoena issued by a government agency), or in the event that you are asked to provide a third party (other than a government agency) with information concerning any actual or potential complaint or claim against the Company.

10. **Amendment and Waiver** – This letter agreement shall be binding upon the parties and may not be modified in any manner, except by an instrument in writing of concurrent or subsequent date signed by duly authorized representatives of the parties hereto. This letter agreement is binding upon and shall inure to the benefit of the parties and their respective agents, assigns, heirs, executors, successors and administrators. No delay or omission by the Company in exercising any right under this letter agreement shall operate as a waiver of that or any other right.

A waiver or consent given by the Company on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

11. **Validity** – Should any provision of this letter agreement be declared or be determined by any court of competent jurisdiction to be illegal or invalid, the validity of the remaining parts, terms or provisions shall not be affected thereby and said illegal or invalid part, term or provision shall be deemed not to be a part of this letter agreement.

12. **Nature of Agreement** – You understand and agree that this letter agreement is a severance agreement and does not constitute an admission of liability or wrongdoing on the part of the Company.

13. **Acknowledgments** – You acknowledge that you have been given at least **[twenty-one (21)/forty-five (45)]⁵** days to consider this letter agreement, and that the Company is hereby advising you to consult with an attorney of your own choosing prior to signing this letter agreement. You understand that you may revoke this letter agreement for a period of seven (7) business days after you sign this letter agreement by notifying me in writing, and the letter agreement shall not be effective or enforceable until the expiration of this seven (7) business day revocation period. You understand and agree that by entering into this letter agreement, you are waiving any and all rights or claims you might have under the Age Discrimination in Employment Act, as amended by the Older Workers Benefit Protection Act, and that you have received consideration beyond that to which you were previously entitled.

14. **[Eligibility for Severance Program⁶ – Attached to this letter agreement as Attachment A is a description of (i) any class, unit or group of individuals covered by the program of severance benefits which the Company has offered to you, and any applicable time limits regarding such severance benefit program; and (ii) the job titles and ages of all individuals eligible or selected for such severance benefit program, and the job titles and ages of all individuals in the same job classification or organizational unit who are not eligible or who were not selected for such severance benefit program.]**

15. **Voluntary Assent** – You affirm that no other promises or agreements of any kind have been made to or with you by any person or entity whatsoever to cause you to sign this letter agreement, and that you fully understand the meaning and intent of this letter agreement. You further state and represent that you have carefully read this letter agreement, understand the contents herein, freely and voluntarily assent to all of the terms and conditions hereof, and sign your name of your own free act.

16. **Applicable Law; Equitable Remedies** – This letter agreement shall be interpreted and construed by the laws of the Commonwealth of Massachusetts, without regard to conflict of laws provisions. You hereby irrevocably submit to and acknowledge and recognize the jurisdiction of the courts of the Commonwealth of Massachusetts, or if appropriate, a federal court located in the Commonwealth of Massachusetts (which courts, for purposes of this letter agreement, are the only courts of competent jurisdiction), over any suit, action or other proceeding arising out of, under or in connection with this letter agreement or the subject matter hereof. Further, you acknowledge that the restrictions referenced and contained in paragraph 3 of this letter agreement are necessary for the protection of the business and goodwill of the Company and are considered

by you to be reasonable for such purpose. You agree that any breach or threatened breach of such provisions is likely to cause the Company substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, you agree that the Company, in addition to such other remedies that may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach without posting a bond, and the right to specific performance of such provisions, and you hereby waive the adequacy of a remedy at law as a defense to such relief.

17. **Entire Agreement** – This letter agreement contains and constitutes the entire understanding and agreement between the parties hereto with respect to your severance benefits

and the settlement of claims against the Company and cancels all previous oral and written negotiations, agreements, and commitments in connection therewith.

18. **Tax Acknowledgement** – In connection with the severance benefits provided to you pursuant to this letter agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and you shall be responsible for all applicable taxes with respect to such severance benefits under applicable law. You acknowledge that you are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the severance benefits.

If you have any questions about the matters covered in this letter agreement, please call me at **[Insert Phone Number]**.

Very truly yours,

By: ____

[Insert Name]

[Insert Title]

I hereby agree to the terms and conditions set forth above. I have been given at least **[twenty-one (21)/forty-five (45)]⁷** days to consider this letter agreement, and I have chosen to execute this on the date below. I intend that this letter agreement will become a binding agreement between me and the Company if I do not revoke my acceptance in seven (7) business days.

Kevin Tan

Date

To be returned in a timely manner as set forth on the first page of this letter agreement.

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to the Employment Agreement (“First Amendment”) effective as of August 14, 2025 (“Effective Date”) is made and entered by and between Solid Biosciences Inc. (the “Company”) and Kevin Tan (the “Executive”) (together, the “Parties”).

WHEREAS, the Parties wish to amend that certain Employment Agreement by and between Company and Executive effective January 9, 2023 (“Agreement”).

NOW THEREFORE, in consideration of the mutual promises set forth herein, the Parties agree as follows:

1. Section 7(b) of the Agreement shall be deleted in its entirety and replaced with the following:

(b) Termination by the Company Without Cause or by the Executive With Good Reason More than Three (3) Months Prior to or More Than Twelve Months Following a Change in Control. If the Executive’s employment is terminated by the Company without Cause pursuant to Section 6(b) or by the Executive with Good Reason pursuant to Section 6(c) (in either case, a “Qualifying Termination”) more than three (3) months prior to or more than twelve (12) months following a Change in Control (as defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedures, the Executive’s Base Salary for a period of twelve (12) months, (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 100% of the Executive’s Target Bonus pro-rated for the year in which such Qualifying Termination occurs based on the number of full weeks the Executive has work for the Company in such year through the date of such termination; and (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than twelve (12) months following the Executive’s termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company’s provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply (collectively, the “Severance Benefits”).”

2. Section 7(c) of the Agreement shall be deleted in its entirety and replaced with the following:

(c) Termination by the Company Without Cause or by the Executive With Good Reason Within Three (3) Months Prior to or Within Twelve Months Following a Change in Control. If a Qualifying Termination occurs within three (3) months prior to or within twelve (12) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedures, the Executive’s Base Salary for a period of twelve (12) months; (ii) pay to the Executive, in a single lump sum on the Payment Date an amount equal to 100% of the Executive’s Target Bonus for the year in which such Qualifying Termination occurs or the Executive’s Target Bonus immediately prior to the Change in Control, if higher, (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than twelve (12) months following the Executive’s termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage,

unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, (iv) provide that the vesting of the Executive's then-unvested equity awards that vest based solely on the passage of time shall be accelerated, such that all then unvested time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the later of the termination date and the closing of the Change in Control; and (v) if any Executive equity awards are canceled, terminated, or otherwise extinguished in connection with the Change in Control (whether in exchange for cash, securities, or other consideration), and are not assumed or continued by the acquiring or successor entity, then upon the termination of Executive's employment as described above, Executive shall be entitled to receive a lump-sum cash payment equal to the transaction value of the unvested portion of such awards as if such portion had fully vested immediately prior to the Change in Control (collectively, the "Change in Control Severance Benefits").

3. Section 7(d) of the Agreement shall be deleted in its entirety and replaced with the following:

(d) *Severance and Release of Claims Agreement.* As a condition of the Executive's receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the "Severance Agreement") (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of the Executive's continuing obligations under any existing restrictive covenant agreements, and an agreement not to compete with the Company for twelve (12) months following the Executive's separation from employment), which Severance Agreement must become irrevocable within 60 days following the date of the Executive's termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive's employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the "Payment Date"). For the avoidance of doubt, if the Executive experiences a Qualifying Termination prior to a Change in Control, (i) any then-outstanding and unvested equity awards that vest based solely on the passage of time held by the Executive shall remain outstanding (but any vesting shall be suspended) for up to (but no longer than) three (3) months following the date of termination so that, if it is later determined that such termination occurred during the three (3)-month period prior to the closing of a Change in Control and that the Executive is entitled to Change in Control acceleration and/or Change in Control Severance Benefits rather than Severance Benefits, the vesting of such awards may be accelerated, in accordance with Section 7(c) hereof, immediately prior to the closing of the Change in Control and (ii) any Change in Control Severance Benefits shall be reduced by any Severance Benefits previously paid to you, if it is later determined that the termination occurred during the three (3)-month period prior to the closing of a Change in Control and that you are entitled to Change in Control Severance Benefits rather than Severance Benefits.

4. All capitalized terms used but not defined herein shall have the respective meanings given to them in the Agreement.
 5. Except as amended herein, all provisions of the Agreement shall remain in full force and effect.
 6. This First Amendment may be executed in two counterparts, both of which shall constitute one and the same legal instrument, and delivery of an executed copy of this First Amendment by a Party via pdf or other electronic
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transmission shall be as effective as delivery of a manually executed copy of this First Amendment by such Party.

IN WITNESS WHEREOF, the Parties have entered into this First Amendment as of the Effective Date.

Solid Biosciences Inc.

Executive

By: /s/ Bo Cumbo

By: /s/ Kevin Tan

Name: Bo Cumbo

Name: Kevin Tan

Title: President & CEO

Title: Chief Executive Officer

Date: 10/28/2025

Date: 10/28/2025

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (the “Agreement”) is made as of the Effective Date by and between Solid Biosciences Inc. (the “Company”) and Gabriel Brooks (the “Executive”) (together, the “Parties”).

RECITALS

WHEREAS, the Parties desire to enter into an agreement whereby the Executive will be employed as an employee of the Company on the terms contained in this Agreement, subject to, and contingent and effective upon October 2, 2023 (the “Effective Date”); and

WHEREAS, the Executive has agreed to accept such employment with the Company upon the Effective Date on the terms and conditions set forth in this Agreement.

NOW, THEREFORE, in consideration of the foregoing and of the respective covenants and agreements of the Parties herein contained, the Parties hereto agree to the following terms, which shall govern the Executive’s employment upon the Effective Date:

1. *Agreement.* This Agreement shall be effective as of the Effective Date. The Executive’s employment on the terms contained in this Agreement shall commence on the Effective Date and shall continue until such employment relationship is terminated in accordance with Section 6 hereof (the “Term of Employment”).

2. *Position.* During the Term of Employment, the Executive shall serve as the Chief Medical Officer of the Company, working out of the Company’s office in Charlestown, Massachusetts, and traveling as reasonably required by the Executive’s job duties. The Company has agreed to permit the Executive to work remotely outside of the United States for up to four (4) weeks annually. The dates shall be mutually agreed upon in advance by the Company and the Executive.

3. *Scope of Employment.* During the Term of Employment, the Executive shall be responsible for the performance of those duties consistent with the Executive’s position as Chief Medical Officer. The Executive shall report to the Chief Executive Officer of the Company and shall perform and discharge faithfully, diligently, and to the best of the Executive’s ability the Executive’s duties and responsibilities hereunder. The Executive shall devote substantially all of the Executive’s business time, loyalty, attention, and efforts to the business and affairs of the Company and its affiliates. Membership on boards of directors of up to two other companies will be permitted only with the express approval of the Chief Executive Officer, and membership on boards of directors of community, charitable or industry organizations will be permitted only provided that such activities do not create a conflict of interest or otherwise interfere with the Executive’s performance of the Executive’s duties hereunder, as reasonably determined by the Chief Executive Officer in the Chief Executive Officer’s sole discretion. The Executive agrees to abide by the rules, regulations, instructions, personnel practices, and policies of the Company and any changes therein that may be adopted from time to time by the Company.

4. *Compensation.* As full compensation for all services rendered by the Executive to the

Company and any affiliate thereof during the Term of Employment, the Company will provide to the Executive the following:

(a) *Base Salary*. The Executive shall receive a base salary at the annualized rate of \$450,00.00 (the “Base Salary”). The Executive’s Base Salary shall be paid in equal installments in accordance with the Company’s regularly established payroll procedures. The Executive’s Base Salary will be reviewed from time to time by the Board and is subject to reasonable change in the discretion of the Board.

(b) *Annual Discretionary Bonus*. The Executive will be eligible to earn an annual performance bonus of up to 40% of the Executive’s Base Salary (the “Target Bonus”), based upon the Board’s assessment of the Executive’s performance and the Company’s attainment of written targeted goals as set by the Board in its sole and reasonable discretion. The Board may determine to provide the bonus in the form of cash, equity award(s), or a combination of cash and equity. Within 90 days of the close of each calendar year, the Board will determine whether the Executive has earned a performance bonus, and the amount of any performance bonus, based on the set criteria. No amount of the annual bonus is guaranteed, and the Executive must be an employee in good standing on the date of payment in order to be eligible for any annual bonus, as such bonus also serves as an incentive for the Executive to remain employed by the Company, except as specifically set forth below; provided that if the Company terminates the Executive without Cause or Executive Resigns for Good Reason after January 1 but prior to the payment of any annual bonus that would have been paid under this Section 4(b) for the year prior to the year in which the Executive’s employment is terminated, the Executive shall be entitled to receive, on the payment date, 100% of Executive’s Target Bonus for the year prior to termination had the Executive remained employed on the payment date, less all applicable taxes and withholdings. The Executive’s bonus eligibility will be reviewed from time to time by the Board and is subject to change with advance notice to the Executive in the reasonable discretion of the Board. The Executive is eligible to earn a pro-rated performance bonus for 2023.

(c) *Equity Award*. Subject to approval by the compensation committee of the Board (such approval may not be unreasonably withheld) or a majority of the Company’s Independent Directors as defined in Nasdaq Listing Rule 5605(a)(2), and as a material inducement to the Executive entering into employment with the Company, the Company will grant to the Executive within ninety (90) days of the Effective Date:

- (i) a non-qualified stock option (the “Option”) to purchase 78,000 shares of the Company’s common stock, such Option to (1) have an exercise price per share equal to the fair market value of the Company’s common stock on the date of grant, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date unless otherwise stated below, at a rate of 25% of the total shares underlying the Option on the first anniversary of the grant date and, following that, as to an additional 1/48th of the total shares underlying the Option upon the Executive’s completion of each additional month of service over the 36-month period measured from the first anniversary of the grant date, (3) have a term of up to 10 years and (4) have such other terms as are set forth in the applicable Option agreement; and
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- (ii) 39,000 restricted stock units (the “RSUs” and, together with the Option, the “Equity Awards”), which RSUs shall (1) entitle the Executive to receive one share of the Company’s common stock for each RSU that vests, (2) vest and become exercisable, subject to the Executive’s continued employment on each applicable vesting date unless otherwise stated below, at a rate of 25% of the total shares underlying the RSUs on each anniversary of the grant date and (3) have such other terms as are set forth in the applicable RSU agreement.
- (iii) The Equity Awards will be granted outside of the Company’s equity incentive plans as “inducement grants” within the meaning of Nasdaq Listing Rule 5635(c)(4). The Equity Awards are subject to adjustment for stock splits, combinations or other changes in capitalization.

In addition, the Executive shall also be eligible to receive additional equity awards, if any, at such times and on such terms and conditions as the Board shall, in its sole and reasonable discretion, determine.

(d) *Paid Time Off.* The Executive shall receive paid vacation time plus sick time, consistent with the Company’s policies as in effect from time to time. In addition, the Executive shall receive paid time off for Company holidays which are set annually and in accordance with Company policy.

(e) *Benefits.* Subject to eligibility requirements and the Company’s policies, the Executive shall have the right, on the same basis as other employees of the Company, to participate in, and to receive benefits under, any medical, vision and dental insurance policy maintained by the Company and the Company shall pay a portion of the cost of the premiums for such medical, vision and dental insurance that is consistent with the Company’s then current employee benefit policy if the Executive elects to participate in such plans. Benefits are subject to change at any time in the Company’s sole and reasonable discretion.

(f) *Withholdings.* All compensation payable to the Executive shall be subject to applicable taxes and withholdings.

5. *Expenses.* The Executive will be reimbursed for the Executive’s actual, necessary, and reasonable business expense pursuant to Company policy, subject to the provisions of Section 3 of Exhibit A attached hereto.

6. *Employment Termination.* This Agreement and the employment of the Executive shall terminate upon the occurrence of any of the following:

(a) Upon the death of the Executive or at the election of the Company due to the Executive’s “Disability”. As used in this Agreement, the term “Disability” shall mean a physical or mental illness or disability that prevents the Executive from performing the duties of the Executive’s position for a period of more than any three consecutive months or for periods aggregating more than twenty-six weeks during any twelve-month period. The Company shall determine in good faith and in its sole and reasonable discretion whether the Executive is unable to perform the services provided for herein.

(b) At the election of the Company, with or without “Cause” (as defined below), immediately upon written notice by the Company to the Executive. As used in this Agreement, “Cause” shall mean a finding by the Company’s Chief Executive Officer or the Board that the Executive:

- (i) performed the Executive’s duties, in the good faith and reasonable opinion of the Company’s Chief Executive Officer or the Board, in a grossly negligent or reckless manner or with willful malfeasance which conduct continues for a period of more than seven (7) days after written notice thereof has been provided to the Executive by the Company’s Chief Executive Officer or the Board, such notice to set forth in reasonable detail the nature of such conduct;
- (ii) exhibited habitual drunkenness or engaged in substance abuse;
- (iii) committed any material violation of any state or federal law relating to the workplace environment (including, without limitation, laws relating to sexual harassment or age, sex or other prohibited discrimination) or any material violation of any material Company policy;
- (iv) willfully failed or refused to perform in the usual manner at the usual time those duties which the Executive regularly and routinely performed in connection with the business of the Company or such other duties reasonably related to the capacity in which the Executive is employed hereunder which may be assigned to the Executive by the Company’s Chief Executive Officer or the Board, which failure or refusal continues for a period of more than seven (7) days after written notice thereof has been provided to the Executive by the Company’s Chief Executive Officer or the Board, such notice to set forth in reasonable detail the nature of such failure or refusal;
- (v) performed any material action when specifically and reasonably instructed not to do so by the Company’s Chief Executive Officer or the Board;
- (vi) committed any fraud or used or appropriated for the Executive’s personal use or benefit any funds, properties or opportunities of the Company not authorized by the Company’s Chief Executive Officer or the Board to be so used or appropriated; or
- (vii) was convicted of, or pled guilty or “no contest” to, any felony or any other crime related to the Executive’s employment or involving moral turpitude;

(c) At the election of the Executive, with or without “Good Reason” (as defined below), immediately upon written notice by the Executive to the Company (subject, if it is with Good Reason, to the timing provisions set forth in the definition of Good Reason). As used in this Agreement, “Good Reason” shall mean (without the Executive’s consent):

- (i) a material diminution in the nature or scope of the Executive’s duties, responsibilities, or authority;
 - (ii) a material diminution of the Executive’s compensation;
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- (iii) the Company's requiring the Executive to relocate the Executive's primary office more than fifty (50) miles from the Executive's then-current primary office;
- (iv) any material breach of this Agreement or any other agreement entered into with the Executive by the Company not otherwise covered by this paragraph; or
- (v) a failure of the Chief Executive Officer or the Board of Directors to comply with applicable state and/or federal law.

provided, however, that for sections (i)-(iii), the Company shall have a period of thirty (30) days to cure any act constituting Good Reason following the Executive's delivery to the Company of written notice of the action or omission constituting Good Reason and that the Executive actually terminates employment within sixty (60) days following the expiration of the Company's cure period.

7. Effect of Termination.

(a) *All Terminations Other Than by the Company Without Cause or by the Executive With Good Reason.* If the Executive's employment is terminated under any circumstances other than a Qualifying Termination (as defined below) (including a voluntary termination by the Executive without Good Reason pursuant to Section 6(c), a termination by the Company for Cause pursuant to Section 6(b) or due to the Executive's death or Disability pursuant to Section 6(a)), the Company's obligations under this Agreement shall immediately cease and the Executive shall only be entitled to receive (i) the Base Salary that has accrued and to which the Executive is entitled as of the effective date of such termination and to the extent consistent with general Company policy, accrued but unused paid time off through and including the effective date of such termination, to be paid in accordance with the Company's established payroll procedure and applicable law but no later than the next regularly scheduled pay period, (ii) unreimbursed business expenses for which expenses the Executive has timely submitted appropriate documentation in accordance with Section 5 hereof, and (iii) any amounts or benefits to which the Executive is then entitled under the terms of the benefit plans then-sponsored by the Company in accordance with their terms (and not accelerated to the extent acceleration does not satisfy Section 409A of the Internal Revenue Code of 1986, as amended, (the "Code") (the payments described in this sentence, the "Accrued Obligations").

(b) *Termination by the Company Without Cause or by the Executive With Good Reason Prior to or More Than Eighteen Months Following a Change in Control.* If the Executive's employment is terminated by the Company without Cause pursuant to Section 6(b) or by the Executive with Good Reason pursuant to Section 6(c) (in either case, a "Qualifying Termination") prior to or more than eighteen (18) months following a Change in Control (as defined below), the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of twelve (12) months, (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 100% of the Executive's Target Bonus for the year in which termination occurs or the Executive's Target Bonus immediately prior to the Change in Control, if higher, prorated through the date of termination; and (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no

event longer than twelve (12) months following the Executive's termination date) the share of the premium for health coverage that the Company pays for active and similarly-situated employees who receive the same type of coverage unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply (collectively, the "Severance Benefits").

(c) *Termination by the Company Without Cause or by the Executive With Good Reason Within Eighteen Months Following a Change in Control.* If a Qualifying Termination occurs within eighteen (18) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company's regularly established payroll procedures, the Executive's Base Salary for a period of twelve (12) months; (ii) pay to the Executive, in a single lump sum on the Payment Date (as defined below) an amount equal to 100% of the Executive's Target Bonus for the year in which termination occurs or the Executive's Target Bonus immediately prior to the Change in Control, if higher, (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the "COBRA" law, continue to pay (but in no event longer than twelve (12) months following the Executive's termination date) the share of the premium for health coverage that the Company pays for active and similarly-situated employees who receive the same type of coverage, unless the Company's provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, and (iv) provide that the vesting of the Executive's then-unvested equity awards that vest based solely on the passage of time shall be accelerated, such that all then unvested time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the termination date (collectively, the "Change in Control Severance Benefits."

(d) *Severance and Release of Claims Agreement.* As a condition of the Executive's receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the "Severance Agreement") (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, and a reaffirmation of the Executive's continuing obligations under any existing restrictive covenant agreements), which Severance Agreement must become irrevocable within 60 days following the date of the Executive's termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60-day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive's employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the "Payment Date").

(e) *Change in Control Definition.* For purposes of this Agreement, "Change in Control" shall mean the occurrence of any of the following events, provided that such event or occurrence constitutes a change in the ownership or effective control of the Company, or a change in the ownership of a substantial portion of the assets of the Company, as defined in Treasury Regulation §§ 1.409A-3(i)(5)(v), (vi) and (vii): (i) the acquisition by an individual, entity or group (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934 (the "Exchange Act")) (a "Person") of beneficial ownership of any capital stock of

the Company if, after such acquisition, such Person beneficially owns (within the meaning of Rule 13d-3 under the Exchange Act) fifty percent (50%) or more of either (x) the then-outstanding shares of common stock of the Company (the “Outstanding Company Common Stock”) or (y) the combined voting power of the then-outstanding securities of the Company entitled to vote generally in the election of directors (the “Outstanding Company Voting Securities”); provided, however, that for purposes of this subsection (i), the following acquisitions shall not constitute a Change in Control: (1) any acquisition directly from the Company or (2) any acquisition by any entity pursuant to a Business Combination (as defined below) which complies with clauses (x) and (y) of subsection (iii) of this definition; or (ii) a change in the composition of the Board that results in the Continuing Directors (as defined below) no longer constituting a majority of the Board (or, if applicable, the Board of Directors of a successor corporation to the Company), where the term “Continuing Director” means at any date a member of the Board (x) who was a member of the Board on the Effective Date or (y) who was nominated or elected subsequent to such date by at least a majority of the directors who were Continuing Directors at the time of such nomination or election or whose election to the Board was recommended or endorsed by at least a majority of the directors who were Continuing Directors at the time of such nomination or election; provided, however, that there shall be excluded from this clause (y) any individual whose initial assumption of office occurred as a result of an actual or threatened election contest with respect to the election or removal of directors or other actual or threatened solicitation of proxies or consents, by or on behalf of a person other than the Board; or (iii) the consummation of a merger, consolidation, reorganization, recapitalization or share exchange involving the Company, or a sale or other disposition of all or substantially all of the assets of the Company (a “Business Combination”), unless, immediately following such Business Combination, each of the following two (2) conditions is satisfied: (x) all or substantially all of the individuals and entities who were the beneficial owners of the Outstanding Company Common Stock and Outstanding Company Voting Securities immediately prior to such Business Combination beneficially own, directly or indirectly, more than fifty percent (50%) of the then-outstanding shares of common stock and the combined voting power of the then-outstanding securities entitled to vote generally in the election of directors, respectively, of the resulting or acquiring corporation in such Business Combination (which shall include, without limitation, a corporation which as a result of such transaction owns the Company or substantially all of the Company’s assets either directly or through one (1) or more subsidiaries) (such resulting or acquiring corporation is referred to herein as the “Acquiring Corporation”) in substantially the same proportions as their ownership of the Outstanding Company Common Stock and Outstanding Company Voting Securities, respectively, immediately prior to such Business Combination and (y) no Person (excluding any employee benefit plan (or related trust) maintained or sponsored by the Company or by the Acquiring Corporation) beneficially owns, directly or indirectly, fifty percent (50%) or more of the then-outstanding shares of common stock of the Acquiring Corporation or of the combined voting power of the then-outstanding securities of such corporation entitled to vote generally in the election of directors (except to the extent that such ownership existed prior to the Business Combination); or (iv) the liquidation or dissolution of the Company.

8. *Modified Section 280G Cutback.* Notwithstanding any other provision of this Agreement, except as set forth in Section 8(b), in the event that the Company undergoes a “Change in Ownership or Control” (as defined below), the following provisions shall apply:

(a) The Company shall not be obligated to provide to the Executive any portion of any “Contingent Compensation Payments” (as defined below) that the Executive would otherwise be entitled to receive to the extent necessary to eliminate any “excess parachute payments” (as

defined in Section 280G(b)(1) of the Code) for the Executive. For purposes of this Section 8, the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Payments,” and the aggregate amount (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-30 or any successor provision) of the Contingent Compensation Payments so eliminated shall be referred to as the “Eliminated Amount.”

(b) Notwithstanding the provisions of Section 8(a), no such reduction in Contingent Compensation Payments shall be made if (1) the Eliminated Amount (computed without regard to this sentence) exceeds (2) 100% of the aggregate present value (determined in accordance with Treasury Regulation Section 1.280G-1, Q/A-31 and Q/A-32 or any successor provisions) of the amount of any additional taxes that the Executive would incur if the Eliminated Payments (determined without regard to this sentence) were paid to the Executive (including state and federal income taxes on the Eliminated Payments, the excise tax imposed by Section 4999 of the Code payable with respect to all of the Contingent Compensation Payments in excess of the Executive’s “base amount” (as defined in Section 280G(b)(3) of the Code), and any withholding taxes). The override of such reduction in Contingent Compensation Payments pursuant to this Section 8(b) shall be referred to as a “Section 8(b) Override.” For the purpose of this paragraph, if any federal or state income taxes would be attributable to the receipt of any Eliminated Payment, the amount of such taxes shall be computed by multiplying the amount of the Eliminated Payment by the maximum combined federal and state income tax rate provided by law.

(c) For purposes of this Section 8 the following terms shall have the following respective meanings:

- (i) “Change in Ownership or Control” shall mean a change in the ownership or effective control of the Company or in the ownership of a substantial portion of the assets of the Company determined in accordance with Section 280G(b)(2) of the Code.
- (ii) “Contingent Compensation Payment” shall mean any payment (or benefit) in the nature of compensation that is made or made available (under this Agreement or otherwise) to or for the benefit of a “disqualified individual” (as defined in Section 280G(c) of the Code) and that is contingent (within the meaning of Section 280G(b)(2)(A)(i) of the Code) on a Change in Ownership or Control of the Company.

(d) Any payments or other benefits otherwise due to the Executive following a Change in Ownership or Control that could reasonably be characterized (as determined by the Company) as Contingent Compensation Payments (the “Potential Payments”) shall not be made until the dates provided for in this Section 8(d). Within thirty (30) days after each date on which the Executive first becomes entitled to receive (whether or not then due) a Contingent Compensation Payment relating to such Change in Ownership or Control, the Company shall determine and notify the Executive (with reasonable detail regarding the basis for its determinations) (1) which Potential Payments constitute Contingent Compensation Payments, (2) the Eliminated Amount and (3) whether the Section 8(b) Override is applicable. Within thirty (30) days after delivery of such notice to the Executive, the Executive shall deliver a response to the Company (the “Executive Response”) stating either (A) that the Executive agrees with the Company’s determination pursuant to the preceding sentence or (B) that the Executive disagrees with such determination, in which case the Executive shall set forth (x) which Potential Payments should be characterized as Contingent Compensation Payments, (y)

the Eliminated Amount, and (z) whether the Section 8(b) Override is applicable. In the event that the Executive fails to deliver an Executive Response on or before the required date, the Company's initial determination shall be final. If the Executive states in the Executive Response that the Executive agrees with the Company's determination, the Company shall make the Potential Payments to the Executive within three (3) business days following delivery to the Company of the Executive Response (except for any Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). If the Executive states in the Executive Response that the Executive disagrees with the Company's determination, then, for a period of sixty (60) days following delivery of the Executive Response, the Executive and the Company shall use good faith efforts to resolve such dispute. If such dispute is not resolved within such a 60-day period, such dispute shall be settled exclusively by arbitration in Boston, Massachusetts or a mutually agreed-upon location, in accordance with the rules of the American Arbitration Association then in effect. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall, within three (3) business days following delivery to the Company of the Executive Response, make to the Executive those Potential Payments as to which there is no dispute between the Company and the Executive regarding whether they should be made (except for any such Potential Payments which are not due to be made until after such date, which Potential Payments shall be made on the date on which they are due). The balance of the Potential Payments shall be made within three (3) business days following the resolution of such dispute.

(e) The Contingent Compensation Payments to be treated as Eliminated Payments shall be determined by the Company by determining the "Contingent Compensation Payment Ratio" (as defined below) for each Contingent Compensation Payment and then reducing the Contingent Compensation Payments in order beginning with the Contingent Compensation Payment with the highest Contingent Compensation Payment Ratio. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio, such Contingent Compensation Payment shall be reduced based on the time of payment of such Contingent Compensation Payments, with amounts having later payment dates being reduced first. For Contingent Compensation Payments with the same Contingent Compensation Payment Ratio and the same time of payment, such Contingent Compensation Payments shall be reduced on a pro rata basis (but not below zero) prior to reducing Contingent Compensation Payment with a lower Contingent Compensation Payment Ratio. The term "Contingent Compensation Payment Ratio" shall mean a fraction, the numerator of which is the value of the applicable Contingent Compensation Payment that must be taken into account by the Executive for purposes of Section 4999(a) of the Code, and the denominator of which is the actual amount to be received by the Executive in respect of the applicable Contingent Compensation Payment. For example, in the case of an equity grant that is treated as contingent on the Change in Ownership or Control because the time at which the payment is made or the payment vests is accelerated, the denominator shall be determined by reference to the fair market value of the equity at the acceleration date, and not in accordance with the methodology for determining the value of accelerated payments set forth in Treasury Regulation Section 1.280G-1 Q/A-24(b) or (c)).

(f) The provisions of this Section 8 are intended to apply to any and all payments or benefits available to the Executive under this Agreement or any other agreement or plan under which the Executive receives Contingent Compensation Payments.

9. Restrictive Covenants Agreements. As a condition of the Executive's employment pursuant to the terms set forth in this Agreement, the Executive shall execute and comply with the terms of (a) the Invention, Nondisclosure and Nonsolicitation Agreement and (b) the Noncompetition

Agreement attached hereto as Exhibit B and Exhibit C, respectively.

10. *Absence of Restrictions.* The Executive represents and warrants that the Executive is not bound by any employment contracts, restrictive covenants, or other restrictions that prevent the Executive from entering into employment with or carrying out the Executive's responsibilities for, the Company or which are in any way inconsistent with any of the terms of this Agreement.

11. *Notice.* Any notice delivered under this Agreement shall be deemed duly delivered three (3) business days after it is sent by registered or certified mail, return receipt requested, postage prepaid, one (1) business day after it is sent for next-business-day delivery via a reputable nationwide overnight courier service, or immediately upon hand delivery, in each case to the address of the recipient set forth below.

To Executive:

At the address set forth in the Executive's personnel file To
Company:
Solid Biosciences Inc.
500 Rutherford Avenue
Third Floor
Charlestown, MA
02129
ATTN: Legal
legalnotices@solidbio.com

Either Party may change the address to which notices are to be delivered by giving notice of such change to the other Party in the manner set forth in this Section 11.

12. *Applicable Law; Jury Trial Waiver.* This Agreement shall be governed by and construed in accordance with the laws of the State of Massachusetts (without reference to the conflict of laws provisions thereof). Any action, suit, or other legal proceeding arising under or relating to any provision of this Agreement shall be commenced only in a court of the State of Massachusetts (or, if appropriate, a federal court located within the State of Massachusetts) and the Company and the Executive each consents to the jurisdiction of such a court.

13. *Successors and Assigns.* This Agreement shall be binding upon and inure to the benefit of both Parties and their respective successors and assigns, including any corporation with which or into which the Company may be merged or which may succeed to its assets or business; provided, however, that the obligations of the Executive are personal and shall not be assigned by the Executive.

14. *At-Will Employment.* During the Term of Employment, the Executive will continue to be an at-will employee of the Company, which means that, notwithstanding any other provision set forth herein, the employment relationship can be terminated by either Party for any reason, at any time, with or without prior notice and with or without Cause.

15. *Acknowledgment.* The Executive states and represents that the Executive has been provided with an opportunity to fully discuss and review the terms of this Agreement with an attorney.

The Executive further states and represents that the Executive has carefully read this Agreement, understands the contents herein, freely and voluntarily assents to all of the terms and conditions hereof, and signs the Executive's name of the Executive's own free act.

16. *No Oral Modification, Waiver, Cancellation or Discharge.* This Agreement may be amended or modified only by a written instrument executed by both the Company and the Executive. No delay or omission by either party in exercising any right under this Agreement shall operate as a waiver of that or any other right. A waiver or consent given by either party on any one occasion shall be effective only in that instance and shall not be construed as a bar to or waiver of any right on any other occasion.

17. *Captions and Pronouns.* The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement. Whenever the context may require, any pronouns used in this Agreement shall include the corresponding masculine, feminine or neuter forms, and the singular forms of nouns and pronouns shall include the plural, and vice versa.

18. *Interpretation.* The Parties agree that this Agreement will be construed without regard to any presumption or rule requiring construction or interpretation against the drafting Party. References in this Agreement to "include" or "including" should be read as though they said "without limitation" or equivalent forms. References in this Agreement to the "Board" shall include any authorized committee thereof.

19. *Severability.* Each provision of this Agreement must be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement. Moreover, if a court of competent jurisdiction determines any of the provisions contained in this Agreement to be unenforceable because the provision is excessively broad in scope, whether as to duration, activity, geographic application, subject, or otherwise, a court of competent jurisdiction may limit or reduce it to the extent legally permitted, so as to be enforceable to the extent compatible with then applicable law to achieve the intent of the Parties.

20. *Entire Agreement.* This Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements and understandings, whether written or oral, relating to the subject matter of this Agreement, including, but not limited to any prior Employment Agreements.

[Signatures on Page Following]

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the day and year set forth above.

SOLID BIOSCIENCES INC.

By: Name: Bo Cumbo

Title: President and CEO

Date: 09/22/2023

EXECUTIVE:

/s/ Gabriel Brooks

Name: Gabriel Brooks

Date: 09/23/2023

[Signature Page to the Executive Employment Agreement]

EXHIBIT A

Payments Subject to Section 409A

1. Subject to this Exhibit A, any severance payments that may be due under the Agreement shall begin only upon the date of the Executive's "separation from service" (determined as set forth below), which occurs on or after the termination of the Executive's employment. The following rules shall apply with respect to the distribution of the severance payments, if any, to be provided to the Executive under the Agreement, as applicable:

(a) It is intended that each installment of the severance payments provided under the Agreement shall be treated as a separate "payment" for purposes of Section 409A of the Internal Revenue Code ("Section 409A"). Neither the Company nor the Executive shall have the right to accelerate or defer the delivery of any such payments except to the extent specifically permitted or required by Section 409A.

(b) If, as of the date of the Executive's "separation from service" from the Company, the Executive is not a "specified employee" (within the meaning of Section 409A), then each installment of the severance payments shall be made on the dates and terms set forth in the letter agreement.

(c) If, as of the date of the Executive's "separation from service" from the Company, the Executive is a "specified employee" (within the meaning of Section 409A), then:

- (i) Each installment of the severance payments due under the Agreement that, in accordance with the dates and terms set forth herein, will in all circumstances, regardless of when the Executive's separation from service occurs, be paid within the short-term deferral period (as defined under Section 409A) shall be treated as a short-term deferral within the meaning of Treasury Regulation Section 1.409A-1(b)(4) to the maximum extent permissible under Section 409A and shall be paid on the dates and terms set forth in the Agreement; and
 - (ii) Each installment of the severance payments due under the Agreement that is not described in this Exhibit A, Section 1(c)(i) and that would absent this subsection, be paid within the six-month period following the Executive's "separation from service" from the Company shall not be paid until the date that is six months and one day after such separation from service (or, if earlier, the Executive's death), with any such installments that are required to be delayed being accumulated during the six-month period and paid in a lump sum on the date that is six months and one day following the Executive's separation from service and any subsequent installments, if any, being paid in accordance with the dates and terms set forth herein; provided, however, that the preceding provisions of this sentence shall not apply to any installment of payments if and to the maximum extent that such installment is deemed to be paid under a separation pay plan that does not provide for a deferral of
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compensation by reason of the application of Treasury Regulation 1.409A-1(b)(9)(iii) (relating to separation pay upon an involuntary separation from service). Any installments that qualify for the exception under Treasury Regulation Section 1.409A-1(b)(9)(iii) must be paid no later than the last day of the Executive's second taxable year following the taxable year in which the separation from service occurs.

2. The determination of whether and when the Executive's separation from service from the Company has occurred shall be made and in a manner consistent with and based on the presumptions set forth in, Treasury Regulation Section 1.409A-1(h). Solely for purposes of Section 2 of this Exhibit A, "Company" shall include all persons with whom the Company would be considered a single employer under Section 414(b) and 414(c) of the Code.

3. All reimbursements and in-kind benefits provided under the Agreement shall be made or provided in accordance with the requirements of Section 409A to the extent that such reimbursements or in-kind benefits are subject to Section 409A, including, where applicable, the requirements that (i) any reimbursement is for expenses incurred during the Executive's lifetime (or during a shorter period of time specified in the Agreement), (ii) the amount of expenses eligible for reimbursement during a calendar year may not affect the expenses eligible for reimbursement in any other calendar year, (iii) the reimbursement of an eligible expense will be made on or before the last day of the calendar year following the year in which the expense is incurred and (iv) the right to reimbursement is not subject to set off or liquidation or exchange for any other benefit.

4. The Company makes no representation or warranty and shall have no liability to the Executive or to any other person unless a court of competent jurisdiction or governing body determines otherwise if any of the provisions of the Agreement (including this Exhibit A) are determined to constitute deferred compensation subject to Section 409A but that do not satisfy an exemption from, or the conditions of, that section.

5. The Agreement is intended to comply with, or be exempt from, Section 409A and shall be interpreted accordingly.

[Remainder of page intentionally left blank.]

EXHIBIT B

Invention, Nondisclosure and Nonsolicitation Agreement

EXHIBIT B – INVENTION, NONDISCLOSURE AND NONSOLICITATION AGREEMENT

This Invention, Nondisclosure and Nonsolicitation Agreement (this “Agreement”) is made by and between Solid Biosciences Inc., a Delaware corporation (together with its subsidiaries, the “Company”), and Gabriel Brooks (the “Employee”).

In consideration of the employment or continued employment of the Employee by the Company, the Employee and the Company agree as follows:

1. **Condition of Employment.**

The Employee acknowledges that the Employee’s employment and/or the continuance of that employment with the Company is contingent upon the Employee’s agreement to sign and adhere to the provisions of this Agreement. The Employee further acknowledges that the nature of the Company’s business is such that protection of its proprietary and confidential information is critical to the survival and success of the Company’s business.

2. **Proprietary and Confidential Information.**

(a) The Employee agrees that all information and know-how, whether or not in writing, of a private, secret, or confidential nature concerning the Company’s business or financial affairs (collectively, “Proprietary Information”), whether disclosed to or otherwise learned by the Employee prior to or following the date of this Agreement, is and shall be the exclusive property of the Company. By way of illustration, but not limitation, Proprietary Information may include discoveries, ideas, inventions, products, product improvements, product enhancements, processes, methods, techniques, formulas, compositions, compounds, negotiation strategies and positions, projects, developments, plans (including business and marketing plans), research data, clinical data, financial data (including sales costs, profits, pricing methods), personnel data obtained pursuant to the Employee’s duties and responsibilities, computer programs (including software used pursuant to a license agreement), customer, prospect and supplier lists, and contacts at or knowledge of customers or prospective customers of the Company. Except as otherwise permitted by Section 5 below, the Employee has not and will not disclose any Proprietary Information to any person or entity other than employees of the Company or use the same for any purposes (other than in the performance of the Employee’s duties as an employee of the Company) without written approval by an officer of the Company, either during or after the Employee’s employment with the Company, unless and until such Proprietary Information has become public knowledge without fault by the Employee. While employed by the Company, the Employee has used and will use the Employee’s best efforts to prevent unauthorized publication or disclosure of any of the Company’s Proprietary Information.

(b) The Employee agrees that all files, documents, letters, memoranda, reports, records, data, sketches, drawings, models, laboratory notebooks, program listings, computer equipment or devices, computer programs or other written, photographic, or other tangible or intangible material containing Proprietary Information, whether created by the Employee or

others, which have come and which come into the Employee's custody or possession, shall be and are the exclusive property of the Company and have been and will be used by the Employee only in the performance of the Employee's duties for the Company and have not and shall not be copied or removed from the Company's premises except in the pursuit of the business of the Company. All such materials or copies thereof and all tangible property of the Company (including, without limitation, computers, cellular telephones, credit cards, keys, access cards and the like) in the custody or possession of the Employee shall be delivered to the Company, upon the earlier of (i) a request by the Company or (ii) termination of the Employee's employment for any reason. After such delivery, the Employee shall not retain any such materials or copies thereof or any such tangible property.

(c) The Employee agrees that the Employee's obligation not to disclose or to use information and materials of the types set forth in Sections 2(a) and 2(b) above, and the Employee's obligation to return materials and tangible property, set forth in Section 2(b) above, also extends to such types of information, materials and tangible property of customers of the Company or suppliers to the Company or other third parties who may have disclosed or entrusted the same to the Company or to the Employee in the course of the Company's business.

3. Developments.

(a) The Employee has attached hereto, as Schedule 1, a list describing all discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which were created, made, conceived or reduced to practice by the Employee prior to the Employee's employment by the Company and which are owned by the Employee, which relate directly or indirectly to the current or anticipated future business of the Company, and which are not assigned to the Company hereunder (collectively, "Prior Developments"); or, if no such list is attached, the Employee represents that there are no Prior Developments. The Employee agrees not to incorporate any Prior Developments into any Company product, material, process or service without prior written consent of an officer of the Company. If the Employee has incorporated or does incorporate any Prior Development into any Company product, material, process or service, the Employee hereby grants to the Company a nonexclusive, worldwide, perpetual, transferable, irrevocable, royalty-free, fully-paid right and license to make, have made, use, offer for sale, sell, import, reproduce, modify, prepare derivative works, display, perform, transmit, distribute and otherwise exploit such Prior Development and to practice any method related thereto.

(b) The Employee has made and will make full and prompt disclosure to the Company of all discoveries, ideas, inventions, improvements, enhancements, processes, methods, techniques, developments, software, and works of authorship, whether patentable or not, which have been or are created, made, conceived or reduced to practice by the Employee or under the Employee's direction or jointly with others during the Employee's employment by the Company, whether or not during normal working hours or on the premises of the Company (all of which are collectively referred to in this Agreement as "Developments"). The Employee acknowledges that each original work of authorship which has been or is made by the Employee

(solely or jointly with others) within the scope of and during the period of the Employee's employment with the Company and which is protectable by copyright is a "work made for hire," as that term is defined in the United States Copyright Act. The Employee agrees to assign and does hereby assign to the Company (or any person or entity designated by the Company) all the Employee's right, title and interest in and to all Developments (other than Prior Developments listed on Schedule 1, if any) and all related patents, patent applications, copyrights and copyright applications. However, this Section 3(b) shall not apply to Developments which do not relate to the business or research and development conducted or planned to be conducted by the Company at the time such Development is created, made, conceived or reduced to practice and which are made and conceived by the Employee not during normal working hours, not on the Company's premises and not using the Company's tools, devices, equipment or Proprietary Information. The Employee understands that, to the extent this Agreement shall be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 3(b) shall be interpreted not to apply to any invention which a court rules and/or the Company agrees falls within such classes. The Employee also hereby waives all claims to moral rights in any Developments.

(c) The Employee agrees to cooperate fully with the Company, both during and after the Employee's employment with the Company, with respect to the procurement, maintenance and enforcement of copyrights, patents and other intellectual property rights (both in the United States and foreign countries) relating to Developments. The Employee shall sign all papers, including, without limitation, copyright applications, patent applications, declarations, oaths, formal assignments, assignments of priority rights, and powers of attorney, which the Company may deem necessary or desirable in order to protect its rights and interests in any Development. The Employee further agrees that if the Company is unable, after reasonable effort, to secure the signature of the Employee on any such papers, any executive officer of the Company shall be entitled to execute any such papers as the agent and the attorney-in-fact of the Employee, and the Employee hereby irrevocably designates and appoints each executive officer of the Company as the Employee's agent and attorney-in-fact to execute any such papers on the Employee's behalf, and to take any and all actions as the Company may deem necessary or desirable in order to protect its rights and interests in any Development, under the conditions described in this sentence.

4. Obligations to Third Parties.

The Employee represents that, except as the Employee has disclosed in writing to the Company on Schedule 1 attached hereto, the Employee is not bound by the terms of any agreement with any previous employer or other party to refrain from using or disclosing any trade secret or confidential or proprietary information in the course of the Employee's employment with the Company, to refrain from competing, directly or indirectly, with the business of such previous employer or any other party or to refrain from soliciting employees, customers or suppliers of such previous employer or other party. The Employee further represents that the Employee's performance of all the terms of this Agreement and the performance of the Employee's duties as an employee of the Company do not and will not

conflict with or breach any agreement with any prior employer or other party (including, without limitation, any nondisclosure or noncompetition agreement), and that the Employee will not disclose to the Company or induce the Company to use any confidential or proprietary information or material belonging to any previous employer or others.

5. Scope of Disclosure Restrictions.

Nothing in this Agreement prohibits the Employee from communicating with government agencies about possible violations of federal, state, or local laws or otherwise providing information to government agencies, filing a complaint with government agencies, or participating in government agency investigations or proceedings. The Employee is not required to notify the Company of any such communications, provided, however, that nothing herein authorizes the disclosure of information the Employee obtained through a communication that was subject to the attorney-client privilege. Further, notwithstanding the Employee's confidentiality and nondisclosure obligations, the Employee is hereby advised as follows pursuant to the Defend Trade Secrets Act: "An individual shall not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. An individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to a court order."

6. United States Government Obligations.

The Employee acknowledges that the Company, from time to time, may have agreements with other persons or with the United States Government, or agencies thereof, which impose obligations or restrictions on the Company regarding inventions made during the course of work under such

agreements or regarding the confidential nature of such work. The Employee agrees to be bound by all such obligations and restrictions which are made known to the Employee and to take all reasonable action necessary to discharge the obligations of the Company under such agreements.

7. Customer Nonsolicitation. The Employee agrees that during the period of the Employee's employment and the one-year period following the termination thereof, regardless of the reason for such termination, the Employee will not, directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, solicit any clients, customers, or accounts, or prospective clients, customers, or accounts, of the Company to stop doing business with the Company, or diminish their services to the Company. As used in this section, the term "client," "customer," or "account" shall include: (i) any person or entity that was a client, customer or account of the Company at any time during the two year period preceding the date of termination of the Employee's employment and with whom the Employee

came in contact with during his employment; and (ii) any prospective client, customer or account to whom the Company has made a presentation (or similar offering of services) within a period of two years preceding the date of termination of the Employee's employment and with whom the Employee came in contact with during his employment.

8. Nonsolicitation of Employees and Consultants. The Employee agrees that during the period of the Employee's employment and the one-year period following the termination thereof, regardless of the reason for such termination, the Employee will not, directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, seek to solicit or induce any Company employee or consultant to leave his or her employment or consultancy with the Company, or assist in the recruitment or hiring of any employee.

9. Nondisparagement. The Employee agrees that he or she shall not at any time, whether during or after the termination of his or her employment, regardless of the reason for such termination, make to any person or entity (including via social media) disparaging comments relating to the Company's services and products.

10. Miscellaneous.

(a) Equitable Remedies. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement is likely to cause the Company substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to such other remedies which may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach without posting a bond and the right to seek specific performance of the provisions of this Agreement.

(b) Disclosure of this Agreement. The Employee hereby authorizes the Company to notify others during the restrictive period, including but not limited to customers of the Company and any of the Employee's future employers or prospective business associates, of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder.

(c) Not Employment Contract. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue the Employee's employment for any period of time, and does not change the at-will nature of the Employee's employment.

(d) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by the Employee. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or

affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

(e) Severability. In case any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, the validity, legality, and enforceability of the remaining provisions shall in no way be affected or impaired thereby. If one or more provisions of this Agreement shall for any reason be held to be excessively broad as to scope, activity, subject or otherwise so as to be unenforceable at law, such provision or provision shall be construed by the appropriate judicial body by limiting or reducing it or them, so as to be enforceable to the maximum extent compatible with the applicable law as it shall then appear. The language of all parts of this Agreement shall in all cases be construed as a whole according to its fair meaning and not strictly for or against either of the parties.

(f) Waivers. No delay or omission by the Company in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent given by the Company on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(g) Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court of the Commonwealth of Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to the jurisdiction of such a court.

(h) Entire Agreement; Amendment. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed, or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in the Employee's duties, salary, or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement.

(i) Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit, or affect the scope or substance of any section of this Agreement.

The employee acknowledges that he/she has carefully read this Agreement, understands and agrees to all of the provisions in this Agreement, and hereby executes this Agreement under seal.
Solid Biosciences Inc.

By: /s/ Bo Cumbo
Bo Cumbo
President and CEO
Date: 09/22/2023

Employee:

/s/ Gabriel Brooks 09/23/2023
Name: Gabriel Brooks Date

SCHEDULE 1

List of prior developments and original works of authorship excluded under Section 3(a) or conflicting agreements disclosed under Section 4.

Title	Date	Identifying Number or Brief Description
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Except as indicated above on this Schedule 1, I have no Prior Developments to disclose pursuant to Section 3(a) of this Agreement and no agreements to disclose pursuant to Section 4 of this Agreement.

Employee:

<u>/s/ Gabriel Brooks</u>	<u>09/23/2023</u>
Name: Gabriel Brooks	Date

EXHIBIT C

Noncompetition Agreement

EXHIBIT C - NON-COMPETITION AGREEMENT

This Noncompetition Agreement (the “Agreement”) is made between Solid Biosciences Inc., a Delaware corporation (including its subsidiaries, the “Company”), and the undersigned employee (the “Employee”).

For good consideration, including, without limitation, the continued employment of the Employee by the Company and, with respect to the non-competition restrictions, the additional consideration set forth in Section 1(c), the Employee and the Company agree as follows:

1. Noncompetition.

(a) During the Restricted Period (as defined below), the Employee will not, in the Applicable Territory (as defined below), directly or indirectly, whether as an owner, partner, officer, director, employee, consultant, investor, lender or otherwise, except as the passive holder of not more than 1% of the outstanding stock of a publicly-held company, engage or assist others in engaging in any business or enterprise that is competitive with the Company’s business, including but not limited to any business or enterprise that develops, manufactures, researches, markets, licenses, sells or provides any product or service that competes with any product or service developed, researched, manufactured, marketed, licensed, sold or provided, or planned to be developed, manufactured, researched, marketed, licensed, sold or provided by the Company (a “Competitive Company”), if the Employee would be performing a job or job duties or services for the Competitive Company that are the same as or substantially similar to the job or job duties or services that the Employee performed for the Company at any time during the last two years of the Employee’s employment.

(b) Certain Definitions. Solely for purposes of this Section 1:

i. the “Restricted Period” shall include the duration of the Employee’s employment with the Company and the twelve month period thereafter; provided, however, that the Restricted Period shall automatically be extended to two years following the cessation of the Employee’s employment if a Court of competent jurisdiction determines the Employee breached a fiduciary duty to the Company or the Employee unlawfully took, physically or electronically, any property belonging to the Company. Notwithstanding the foregoing, the Restricted Period shall end immediately upon the Employee’s last day of employment with the Company if: (a) the Company terminates the Employee’s employment without Cause (as defined below); (b) the Employee resigns for Good Reason (as defined below); or (c) the Company notifies the Employee in writing that it is waiving the post-employment restrictions set forth in this Section.

ii. “Applicable Territory” shall mean the geographic areas in which the Employee provided services or had a material presence or influence at any time during his/her last two years of employment.

iii. "Cause" shall mean any of: (a) the Employee's conviction of, or plea of guilty or nolo contendere to, any crime involving dishonesty or moral turpitude, or any felony; (b) a good faith finding by the Company in its sole and reasonable discretion that the Employee has (1) engaged in dishonesty, misconduct or gross negligence; (2) committed an act that injures or would reasonably be expected to injure the reputation, business or business relationships of the

Company; (3) breached the material terms of this Agreement or any other restrictive covenant or confidentiality agreement with or policy of the Company; or (4) failed or refused to comply with any of the Company's policies or procedures; or (c) the Company has any other grounds that constitute "cause" under Massachusetts law.

iv. "Good Reason" shall mean any of: (a) a material diminution in the nature or scope of the Executive's duties, responsibilities, or authority; (b) a material diminution of the Executive's compensation; (c) the Company's requiring the Executive to relocate the Executive's primary office more than fifty (50) miles from the Executive's then-current primary office; (d) any material breach of this Agreement or any other agreement entered into with the Executive by the Company not otherwise covered by this paragraph; or (e) a failure of the Chief Executive Officer or the Board of Directors to comply with applicable state and/or federal law.

(c) Additional Consideration for Noncompetition Restrictions. In exchange for the Employee's compliance with the restrictions set forth in this Section 1, the Company will grant the Employee an equity award, as is more fully set forth in Section 4(c) of the Employment Agreement to which this Agreement is attached, and, further, during the post-employment portion of the Restricted Period, the Company will pay the Employee one thousand dollars (\$1,000) per month (the "Noncompete Consideration"). The Noncompete Consideration will be paid ratably in accordance with the Company's regular payroll practices, commencing with the first payroll cycle beginning after the Employee's separation date, except as may otherwise be required by Section 3(h) below. The Employee understands and agrees that the Company may discontinue or otherwise not provide the Noncompete Consideration

(i) if the Restricted Period expires upon the termination of the employment relationship pursuant to the last sentence of Section 1(b)(i), (ii) if the Employee breaches this Agreement as determined by a Court of competent jurisdiction, or (iii) during any portion of the Restricted Period that has been extended in accordance with Section 1(b)(i); provided, however, that with respect to (ii) or (iii), any such cessation shall not excuse the Employee's compliance with his/her obligations under this Section 1 or otherwise in this Agreement. The Employee understands and agrees that the above-stated consideration has been mutually agreed upon by the Company and the Employee, is fair and reasonable, and is sufficient consideration in exchange for the restrictions set forth in this Section 1.

2. Notice of New Business Activities. The Employee agrees that during any period of time when the Employee is subject to restrictions pursuant to Section 1, the Employee will notify any prospective employer or business associate of the terms and existence of this Agreement and the Employee's continuing obligations to the Company hereunder. The Employee further agrees, during such period, to give notice to the Company of each new business activity the Employee plans to undertake. The notice shall state the name and address of the individual, corporation, association or other entity or organization ("Entity") for whom such activity is undertaken and the name of the Employee's business relationship or position with the Entity. The Employee also agrees to provide the Company with other pertinent information concerning such business activity

as the Company may reasonably request in order to determine the Employee's continued compliance with his/her obligations under this Agreement.

3. Miscellaneous.

(a) Equitable Remedies. The Employee acknowledges that the restrictions contained in this Agreement are necessary for the protection of the business and goodwill of the Company and are considered by the Employee to be reasonable for such purpose. The Employee agrees that any breach or threatened breach of this Agreement is likely to cause the Company substantial and irrevocable damage which is difficult to measure. Therefore, in the event of any such breach or threatened breach, the Employee agrees that the Company, in addition to any and all other remedies which may be available, shall have the right to obtain an injunction from a court restraining such a breach or threatened breach without posting a bond and the right to specific performance of the provisions of this Agreement.

(b) Not Employment Contract. The Employee acknowledges that this Agreement does not constitute a contract of employment, does not imply that the Company will continue his/her employment for any period of time, and does not change the at-will nature of his/her employment.

(c) Acknowledgments. The Company hereby advises the Employee and the Employee hereby acknowledges that he or she has the right to consult with counsel prior to signing this Agreement. The Employee further acknowledges that this Agreement is supported by fair and reasonable consideration independent from the Employee's continued employment, that the Employee has been provided at least ten (10) business days to review this Agreement, and that this Agreement shall not take effect until the eleventh (11th) business day following the date on which the Company provided it to the Employee for review and execution.

(d) Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of both parties and their respective successors and assigns, including any corporation with which, or into which, the Company may be merged or which may succeed to the Company's assets or business, provided, however, that the obligations of the Employee are personal and shall not be assigned by him or her. The Employee expressly consents to be bound by the provisions of this Agreement for the benefit of the Company or any subsidiary or affiliate thereof to whose employ the Employee may be transferred without the necessity that this Agreement be re-signed at the time of such transfer.

(e) Interpretation. If any restriction or definition set forth in this Agreement is found by any court of competent jurisdiction to be unenforceable because it extends for too long a period of time or over too great a range of conduct, activities, or geographic area, it shall be interpreted by said court to extend only over the maximum period of time, range of conduct, activities or geographic area as to which it may be enforceable.

(f) Severability. If any provision of this Agreement shall be invalid, illegal or otherwise unenforceable, and cannot be reformed to make it enforceable, the validity, legality and enforceability of the remaining provisions of this Agreement shall in no way be affected or impaired thereby.

(g) Waivers. No delay or omission by the either party in exercising any right under this Agreement will operate as a waiver of that or any other right. A waiver or consent

given by a party on any one occasion is effective only in that instance and will not be construed as a bar to or waiver of any right on any other occasion.

(h) Tax Withholding; Section 409A. Any compensatory payments under or referred to in this Agreement will be subject to all required tax and other withholdings. This Agreement is intended to comply with or be exempt from the provisions of Section 409A of the Internal Revenue Code of 1986,

as amended ("Section 409A") and the Agreement will, to the extent practicable, be construed in accordance therewith. Terms defined in this Agreement will have the meanings given such terms under Section 409A if and to the extent required to comply with Section 409A and a termination of employment will mean a "separation from service" as defined in Section 409A. For purposes of this Agreement, each amount to be paid or benefit to be provided, including a series of installment payments, will be construed as a separate identified payment for purposes of Section 409A. If and to the extent any portion of any payment, compensation or other benefit provided to the Employee in connection with his/her separation from service (as defined in Section 409A) is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A and the Employee is a specified employee as defined in Section 409A(a)(2)(B)(i) of the Code, as reasonably determined by the Company in accordance with its procedures, by which determination the Employee hereby agrees that he/she is bound, such portion of the payment, compensation or other benefit will not be paid before the earlier of (i) the day that is six months plus one day after the date of separation from service (as determined under Section 409A) or (ii) the tenth day after the date of his/her death (as applicable, the "New Payment Date"). The aggregate of any payments that otherwise would have been paid to the Employee during the period between the date of separation from service and the New Payment Date will be paid to the Employee in a lump sum in the first payroll period beginning after such New Payment Date (or, with respect to payment after death, as soon as reasonably practicable and within the time limits permitted by Section 409A), and any remaining payments will be paid on their original schedule. In any event, the Company makes no representations or warranty and will have no liability to the Employee or any other person unless a court of competent jurisdiction or governing body determines otherwise if any provisions of or payments under this Agreement are determined to constitute deferred compensation subject to Section 409A but not to satisfy the conditions of that section.

(i) Governing Law and Consent To Jurisdiction. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts (without reference to the conflicts of laws provisions thereof). Any action, suit, or other legal proceeding which is commenced to resolve any matter arising under or relating to any provision of this Agreement shall be commenced only in a court in Suffolk County, Massachusetts (or, if appropriate, a federal court located within Massachusetts), and the Company and the Employee each consents to the jurisdiction of such courts.

(j) Entire Agreement; Amendment. This Agreement supersedes all prior agreements, written or oral, between the Employee and the Company relating to the subject matter of this Agreement. This Agreement may not be modified, changed or discharged in whole or in part, except by an agreement in writing signed by the Employee and the Company. The Employee agrees that any change or changes in his/her duties, authority, title, reporting relationship, territory, salary or compensation after the signing of this Agreement shall not affect the validity or scope of this Agreement unless otherwise prohibited by law.

(k)Captions. The captions of the sections of this Agreement are for convenience of reference only and in no way define, limit or affect the scope or substance of any section of this Agreement.

The employee acknowledges that he/she has carefully read this agreement, understands and agrees to all of the provisions in this agreement, and hereby executes this agreement under seal.

Solid Biosciences Inc.

By: /s/ Bo Cumbo
Bo Cumbo
President and CEO
Date: 09/22/2023

Employee:

/s/ Gabriel Brooks
Name: Gabriel Brooks

09/23/2023
Date

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to the Employment Agreement (“First Amendment”) effective as of August 14, 2025 (“Effective Date”) is made and entered by and between Solid Biosciences Inc. (the “Company”) and Gabriel Brooks (the “Executive”) (together, the “Parties”).

WHEREAS, the Parties wish to amend that certain Employment Agreement by and between Company and Executive effective October 2, 2023 (“Agreement”).

NOW THEREFORE, in consideration of the mutual promises set forth herein, the Parties agree as follows:

1. Section 7(c) of the Agreement shall be deleted in its entirety and replaced with the following:

(c) Termination by the Company Without Cause or by the Executive With Good Reason Within Three (3) Months Prior to or Within Eighteen (18) Months Following a Change in Control. If a Qualifying Termination occurs within three (3) months prior to or within eighteen (18) months following a Change in Control, then the Executive shall be entitled to the Accrued Obligations. In addition, and subject to Exhibit A and the conditions of Section 7(d), the Company shall: (i) continue to pay to the Executive, in accordance with the Company’s regularly established payroll procedures, the Executive’s Base Salary for a period of twelve (12) months; (ii) pay to the Executive, in a single lump sum on the Payment Date an amount equal to 100% of the Executive’s Target Bonus for the year in which such Qualifying Termination occurs or the Executive’s Target Bonus immediately prior to the Change in Control, if higher, (iii) provided the Executive is eligible for and timely elects to continue receiving group medical insurance pursuant to the “COBRA” law, continue to pay (but in no event longer than twelve (12) months following the Executive’s termination date) the share of the premium for health coverage that is paid by the Company for active and similarly-situated employees who receive the same type of coverage, unless the Company’s provision of such COBRA payments will violate the nondiscrimination requirements of applicable law, in which case this benefit will not apply, (iv) provide that the vesting of the Executive’s then-unvested equity awards that vest based solely on the passage of time shall be accelerated, such that all then unvested time-based equity awards shall vest and become fully exercisable or non-forfeitable as of the termination date; and (v) if any Executive equity awards are canceled, terminated, or otherwise extinguished in connection with the Change in Control (whether in exchange for cash, securities, or other consideration), and are not assumed or continued by the acquiring or successor entity, then upon the termination of Executive’s employment as described above, Executive shall be entitled to receive a lump-sum cash payment equal to the transaction value of the unvested portion of such awards as if such portion had fully vested immediately prior to the Change in Control (collectively, the “Change in Control Severance Benefits”).

2. Section 7(d) of the Agreement shall be deleted in its entirety and replaced with the following:

(d) Severance and Release of Claims Agreement. As a condition of the Executive’s receipt of the Severance Benefits or the Change in Control Severance Benefits, as applicable, the Executive must execute and deliver to the Company a severance and release of claims agreement in a form to be provided by the Company (the “Severance Agreement”) (which will include, at a minimum, a release of all releasable claims, non-disparagement and cooperation obligations, a reaffirmation of the Executive’s continuing obligations under any existing restrictive covenant agreements, which Severance Agreement must become irrevocable within 60 days following the date of the

Executive's termination of employment (or such shorter period as may be directed by the Company). The Severance Benefits or the Change in Control Severance Benefits, as applicable, will be paid or commence to be paid in the first regular payroll beginning after the Severance Agreement becomes effective, provided that if the foregoing 60 day period (or shorter period as may be directed by the Company) would end in a calendar year subsequent to the year in which the Executive's employment ends, the Severance Benefits or Change in Control Severance Benefits, as applicable, will not be paid or begin to be paid before the first payroll of the subsequent calendar year (the date the Severance Benefits or Change in Control Severance Benefits, as applicable, commence pursuant to this sentence, the "Payment Date"). For the avoidance of doubt, if the Executive experiences a Qualifying Termination prior to a Change in Control, (i) any then-outstanding and unvested equity awards that vest based solely on the passage of time held by the Executive shall remain outstanding (but any vesting shall be suspended) for up to (but no longer than) three (3) months following the date of termination so that, if it is later determined that such termination occurred during the three (3)-month period prior to the closing of a Change in Control and that the Executive is entitled to Change in Control acceleration and/or Change in Control Severance Benefits rather than Severance Benefits, the vesting of such awards may be accelerated, in accordance with Section 7(c) hereof, immediately prior to the closing of the Change in Control and (ii) any Change in Control Severance Benefits shall be reduced by any Severance Benefits previously paid to you, if it is later determined that the termination occurred during the three (3)-month period prior to the closing of a Change in Control and that you are entitled to Change in Control Severance Benefits rather than Severance Benefits.

3. All capitalized terms used but not defined herein shall have the respective meanings given to them in the Agreement.
 4. Except as amended herein, all provisions of the Agreement shall remain in full force and effect.
 5. This First Amendment may be executed in two counterparts, both of which shall constitute one and the same legal instrument, and delivery of an executed copy of this First Amendment by a Party via pdf or other electronic transmission shall be as effective as delivery of a manually executed copy of this First Amendment by such Party.
-

IN WITNESS WHEREOF, the Parties have entered into this First Amendment as of the Effective Date.

Solid Biosciences Inc.

Executive

By: /s/ Alexander Cumbo

By: /s/ Gabriel Brooks

Name: Bo Cumbo

Name: Gabriel Brooks

Title: President & CEO

Title: Chief Medical Officer

Date: 11/5/2025

Date: 11/5/2025

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) is the type of information that the registrant treats as private or confidential. Double asterisks denote omissions.

Dated as of September 19, 2024

by and between

SOLID BIOSCIENCES INC.

and

FA212 LLC

TABLE OF CONTENTS

ARTICLE I DEFINITIONS; INTERPRETATION	1
Section 1.1. Definitions	1
Section 1.2. Interpretation	15
ARTICLE II PURCHASE AND SALE	16
Section 2.1. Purchase and Sale of Purchased Assets	16
Section 2.2. Purchased Assets; Excluded Assets	16
Section 2.3. Assumption of Certain Liabilities	17
Section 2.4. Excluded Liabilities	17
Section 2.5. Closing; Closing Deliverables	18
Section 2.6. Developmental and Sales Milestones	19
Section 2.7. Royalties	24
Section 2.8. Late Payments	24
Section 2.9. Accounting	24
Section 2.10. Records and Audit Rights	25
Section 2.11. Purchase Price Allocation	25
Section 2.12. Voting Agreement	25
ARTICLE III REPRESENTATIONS AND WARRANTIES OF SELLER	26
Section 3.1. Organization, Standing and Power	26
Section 3.2. Authority; Noncontravention	26
Section 3.3. No Undisclosed Liabilities; Debt	27
Section 3.4. Good Title; Sufficiency of Assets	27
Section 3.5. Books and Records	28
Section 3.6. Intellectual Property	28
Section 3.7. Compliance with Law; Regulatory Approvals	30
Section 3.8. Litigation	30
Section 3.9. Taxes	31
Section 3.10. FDA Regulatory Matters	32
Section 3.11. Product Inventory	33
Section 3.12. Brokers and Other Advisors	33
Section 3.13. Solvency	33
Section 3.14. Contracts	34

Section 3.15. Affiliate Transactions	34
Section 3.16. No Other Representations or Warranties	34
Section 3.17. Non-Reliance	34
ARTICLE IV REPRESENTATIONS AND WARRANTIES OF BUYER	35
Section 4.1. Organization, Standing and Power	35
Section 4.2. Authority; Noncontravention	35
Section 4.3. Buyer Capitalization; Valid Issuance	36
Section 4.4. Financing	36
Section 4.5. Litigation	36
Section 4.6. No Buyer Vote Required	36
Section 4.7. Issuance of Solid Shares	37
Section 4.8. Financial Statements	37
Section 4.9. Compliance with Nasdaq Continued Listing Requirements	37
Section 4.10. SEC Filings; Securities Law and Other Matters	37
Section 4.11. No Other Representations or Warranties	38
Section 4.12. Non-Reliance	38
ARTICLE V ADDITIONAL AGREEMENTS	38
Section 5.1. Diligence Efforts	38
Section 5.2. Anti-Shelving	38
Section 5.3. Joint Steering Committee	39
Section 5.4. Technology Transfer and Assistance	40
Section 5.5. Confidentiality; Non-Solicitation	40
Section 5.6. Certain Tax Matters	42
Section 5.7. Public Announcements	43
Section 5.8. Expenses; UPenn IND Payment	44
Section 5.9. Further Assurances and Approvals	44
Section 5.10. Lock-Up	44
Section 5.11. Reversion Rights	45
ARTICLE VI INDEMNIFICATION	47
Section 6.1. Indemnification of Buyer	47
Section 6.2. Indemnification of Seller Indemnified Parties	48

Section 6.3. Indemnification Claims	49
Section 6.4. Termination of Indemnification Obligations	51
Section 6.5. Damages; Remedies	51
Section 6.6. Right of Set-off	52
Section 6.7. Purchase Price Adjustments	53
Section 6.8. Indemnity Payments	53
ARTICLE VII GENERAL PROVISIONS	53
Section 7.1. Rules of Construction	53
Section 7.2. Notices	53
Section 7.3. Consents and Approvals	54
Section 7.4. Counterparts	54
Section 7.5. Entire Agreement; No Third-Party Beneficiaries	55
Section 7.6. Assignment	55
Section 7.7. GOVERNING LAW	55
Section 7.8. Dispute Resolution; Enforcement; Waiver of Jury Trial	55
Section 7.9. Specific Enforcement	56
Section 7.10. Severability	56
Section 7.11. Amendment	56
Section 7.12. Release	56

Annexes

Annex 1.1(a)	Books and Records
Annex 1.1(b)	Product Inventory
Annex 1.1(c)	Seller Intellectual Property
Annex 1.1(d)	FA Asset Sequence
Annex 1.1(e)	UPenn IND Payments
Annex 2.1	Permitted Liens
Annex 2.2(a)(iii)	Assigned Agreements
Annex 2.3	Assumed Liabilities
Annex 2.5(b)(v)	Consents

Schedules

Buyer Disclosure Schedules
Seller Disclosure Schedules

Exhibits

Exhibit A	Bill of Sale
Exhibit B-1	Form of Seller Representation Letter
Exhibit B-2	Form of Buyer Representation Letter
Exhibit C	Voting Rights Agreement

ASSET PURCHASE AGREEMENT

This Asset Purchase Agreement (this “Agreement”) dated as of September 19, 2024, is entered into by and between Solid Biosciences Inc., a Delaware corporation (“Buyer”), and FA212 LLC, a Delaware limited liability company (“Seller”). Buyer and Seller are sometimes individually referred to herein as a “Party” and are sometimes collectively referred to herein as the “Parties.”

RECITALS

WHEREAS, Seller desires to sell to Buyer, and Buyer wishes to purchase from Seller, all of Seller’s right, title and interest in, to and under the Purchased Assets upon the terms and subject to the conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement, and of the representations, warranties, conditions, agreements and promises contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

ARTICLE I

DEFINITIONS; INTERPRETATION

Section 1.1Definitions. For purposes of this Agreement, the following terms will have the corresponding meanings set forth below:

“Acquisition” has the meaning set forth in Section 2.1.

“Act” has the meaning set forth in Section 2.6(d)(iii).

“Action” means any claim, action, cause of action or suit, litigation, assessment, arbitration, mediation, investigation, audit, hearing, charge, complaint, demand, notice or proceeding (in each case, whether in contract, tort or otherwise, whether at law or in equity, and whether civil or criminal or administrative) to, from, by or before any Governmental Authority.

“Affiliate” of any Person means another Person that directly or indirectly, through one or more intermediaries, Controls, is Controlled by or is under common Control with, such first Person.

“Agreement” has the meaning set forth in the preamble hereof.

“Annual Net Sales” means, with respect to a Calendar Year, the aggregate Net Sales by Buyer and its Affiliates and its or their licensees of all Products to Third Parties in the Territory during such Calendar Year.

“Assigned Agreements” has the meaning set forth in Section 2.2(a)(iii).

“Assumed Liabilities” has the meaning set forth in Section 2.3.

“Bill of Sale” means the bill of sale and assignment and assumption agreement by and between Buyer or its Affiliate, on the one hand, and Seller, on the other hand, substantially in the form of Exhibit A.

“BLA” means (a) a Biologics License Application as defined in the PHSA and the regulations promulgated thereunder, (b) a Marketing Authorization Application in the European Union or (c) any equivalent or comparable application, registration or certification in any other country or region.

“Books and Records” means all books, reports (including laboratory reports), records, files and documents in the possession or under the control of Seller related to the Business and the Purchased Assets (including research and development, Regulatory Documentation, correspondence with Governmental Authorities) other than corporate minute books. The Books and Records existing as of the Closing Date are described on Annex 1.1(a).

“Business” means all business of Seller relating to or arising out of the UPenn License, including the Exploitation of the FA Asset and Products.

“Business Day” means any day other than (a) a Saturday or Sunday or (b) a day on which banking institutions located in New York, New York are permitted or required by applicable Law to remain closed.

“Business Partner” has the meaning set forth in Section 5.5(b).

“Buyer” has the meaning set forth in the preamble hereof.

“Buyer Charter” means the Certificate of Incorporation of Buyer as in effect from time to time.

“Buyer Disclosure Schedules” means the Schedules delivered by Buyer to Seller contemporaneously with this Agreement and appended hereto, setting forth disclosures in respect of the representations and warranties contained in Article IV of this Agreement.

“Buyer Indemnified Party” has the meaning set forth in Section 6.1(a).

“Buyer Indemnity Threshold” has the meaning set forth in Section 6.1(b).

“Buyer Representation Letter” has the meaning set forth in Section 2.6(d)(iii).

“Calendar Year” means a period of twelve consecutive months beginning on January 1 and ending on December 31.

“CARES Act” means the Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), any current federal, state or local Laws or guidance relating to the COVID-19 pandemic, any similar or successor legislation, as well as any applicable guidance issued thereunder or relating thereto (including, without limitation, IRS Notice 2020-65 and IRS Notice 2021-11), in any United States jurisdiction, and any subsequent legislation relating to the COVID-19 pandemic, including any executive memoranda or executive orders relating to the COVID-19 pandemic, the Health and Economic Recovery Omnibus Emergency Solutions Act and the Health, Economic Assistance, Liability, and Schools Act, and the Memorandum for the Secretary of the Treasury signed on August 8, 2020.

“Clinical Trial” means a human clinical trial conducted for the purpose of gaining evidence of the safety, tolerability, pharmacokinetics, pharmacodynamics or efficacy of a Product required by applicable Law or otherwise recommended or required by a Regulatory Authority to obtain or maintain any Regulatory Approval for a Product.

“Closing” has the meaning set forth in Section 2.5(a).

“Closing Date” has the meaning set forth in Section 2.5(a).

“Closing Purchase Price” means an amount in cash equal to \$1,000,000.

“Code” means the Internal Revenue Code of 1986, as amended.

“Combination Product” means a Product that is delivered with one or more additional active ingredients and/or other patentable items (which are themselves not products for a single price) incident to the administration of any such Product, including companion diagnostics, in each such case when any of the foregoing are co-formulated, copackaged or sold under one pricing scheme (whether payment of such price is paid to the same or to more than one seller).

“Commercially Reasonable Efforts” means, with respect to the efforts to be expended, or considerations to be undertaken, by Buyer with respect to any objective, activity or decision to be undertaken hereunder, reasonable, good faith efforts to accomplish such objective, activity or decision as Buyer would normally use to accomplish a similar objective, activity or decision under similar circumstances, it being understood and agreed that with respect to Buyer’s obligations under Section 5.1 such efforts and resources shall be [**]. “Commercially Reasonable Efforts” will be determined on a country-by- country basis for a particular Product in the Territory and is expected to change over time, reflecting changes in the status of such Product and the markets or countries in the Territory involved. For the avoidance of doubt, Buyer’s use of “Commercially Reasonable Efforts” will not require Buyer to reperform any preclinical activities that were previously performed by Seller.

“Confidential Information” has the meaning set forth in Section 5.5(a)(ii).

“Confidentiality Agreement” means the Confidential Disclosure Agreement between Seller and Buyer, dated [**].

“Contemplated Transactions” means the transactions contemplated by this Agreement and any Related Document, including the Acquisition.

“Contracts” means any loan or credit agreement, bond, debenture, note, mortgage, indenture, lease, supply agreement, license agreement, development agreement, distribution agreement or other legally binding contract, agreement, obligation, commitment, arrangement, understanding, instrument, permit, franchise or license, whether oral or written.

“Control” including its various tenses and derivatives (such as “controlled” and “controlling”) means (a) when used with respect to any Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such entity, whether through the ownership of voting securities, or by Contract, (b) when used with respect to any security, the possession, directly or indirectly, of the power to vote, or to direct the voting of, such security or the power to dispose of, or to direct the disposition of, such security and (c) when used with respect to any Intellectual Property Rights, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign or grant a license, sublicense or other right to or under such Intellectual Property Rights or to compel another to do so.

“Cover” “Covers” “Covered” or “Covering” means, with respect to a Product or other subject matter at issue and a relevant Patent, that Exploitation of such Product or other subject matter by such Person would, absent a license thereto, infringe such Patent (or, in the case of a claim of a patent application that has not yet issued, would infringe such claim if it were to issue without change).

“CTA” has the meaning set forth in the definition of IND.

“Dollars” or “\$” means United States dollars.

“Enforceable” means, with respect to any Contract stated to be “Enforceable” by or against any Person, that such Contract is a legal, valid and binding obligation of such Person enforceable by or against such Person in accordance with its terms, except to the extent that enforcement of the rights and remedies created thereby is subject to bankruptcy, insolvency, reorganization, moratorium and other similar Laws of general application affecting the rights and remedies of creditors and to general principles of equity (regardless of whether enforceability is considered in a proceeding in equity or at law).

“European Territory” means the United Kingdom and any country in the EU.

“European Union” or “EU” means the economic, scientific and political organization of Member States of the European Union, as its membership may be constituted from time to time.

“Exchange Act” means the United States Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

“Excluded Assets” has the meaning set forth in Section 2.2(b).

“Excluded Liabilities” has the meaning set forth in Section 2.4(a).

“Exploit” or “Exploiting” means to make, have made, import, use, sell, offer for sale, and otherwise dispose of, including to discover, research, develop, test, register, modify, enhance, improve, manufacture, have manufactured, store, formulate, optimize, export, transport, distribute, commercialize, promote, market, have sold and otherwise dispose of. “Exploitation” means the act of Exploiting a product or product candidate.

“FA Asset” means Seller’s proprietary gene therapy asset having the sequence set forth on Annex 1.1(d).

“FDA” means the United States Food and Drug Administration or any successor entity thereto.

“FDA Laws” has the meaning set forth in Section 3.10.

“FDCA” means the United States Federal Food, Drug, and Cosmetic Act, as amended, and the rules and regulations promulgated by FDA thereunder.

“Field” means the treatment or prevention of Friedreich’s Ataxia.

“First Commercial Sale” means, with respect to a particular Product, the first sale of such Product to a Third Party in a country or region following receipt of Regulatory Approval in such country or region.

“First Stock Consideration Issuance” has the meaning set forth in Section 2.12.

“Fraud” means, with respect to any Person, an actual and intentional common law fraud with the intent to deceive another Person (including as an element that the other Person relied thereon to its detriment).

“Fully-Diluted As-Converted Basis” means the aggregate number of Solid Shares equal to (a) the number of outstanding Solid Shares, plus (b) the number of Solid Shares issuable pursuant to (i) vested and unvested restricted stock units, (ii) vested and unvested options (calculated using the treasury method of accounting), (iii) outstanding warrants (calculated using the treasury method of accounting), and (iv) the conversion of any then outstanding shares of Solid Preferred Stock, but in all cases excluding any restricted stock units issued and outstanding as of the Closing Date, the vesting of which is subject to the achievement of certain performance conditions, until such time as vesting conditions have been satisfied in accordance with the terms of such award.

“Fundamental Representations” means the representations and warranties set forth in Section 3.1 (Organization; Standing and Power), Section 3.2(a) (Authority), Section 3.2(d)(i) (Noncontravention of Seller’s Certificate of Formation and Seller’s Operating Agreement), Section 3.4 (Good Title; Sufficiency of Assets), Section 3.6 (excluding subsections (d), (e) and (k) thereof) (Intellectual Property), Section 3.9 (Taxes) and Section 3.12 (Brokers and Other Advisors).

“GAAP” means the United States generally accepted accounting principles in effect from time to time.

“Governmental Authority” means any instrumentality, subdivision, court, administrative agency, commission, bureau, department, official or other authority of any country, state, province, prefect, municipality, locality or other government or political subdivision thereof, or any multinational organization or authority, or any quasi-governmental, private body, mediator, arbitrator or arbitral body exercising any executive, legislative, judicial, quasi-judicial, regulatory, taxing, importing, administrative or other governmental or quasi-governmental authority on behalf of a government or political subdivision thereof.

“Grant-Back Intellectual Property” means, with respect to a Reversion Product, all Technology and Intellectual Property Rights generated, developed, conceived or reduced to practice by or on behalf of Buyer or its Affiliates after the Closing Date that are (a) owned by Buyer or any of its Affiliates, and (b) necessary for or used with respect to, or Covering, such Reversion Product, in each case ((a) and (b)), as of the date of Buyer’s receipt of the Reversion Notice, but specifically excluding any third party Intellectual Property Rights and any background or platform Technology not exclusively used for the Reversion Product.

“Greater Liability Cap” means an amount equal to (a) prior to IND Clearance, \$[**], and (b) following IND Clearance, \$[**].

“IND” means (a) with respect to the US Territory, an Investigational New Drug Application, as such term is defined under the FDCA and 21 CFR Part 312, (b) with respect to the European Union, a clinical trial authorization application (“CTA”), and (c) with respect to the UK or any other regulatory jurisdiction, the equivalent application to the applicable Regulatory Authority in each case ((a), (b) and (c)), the filing of which is necessary to initiate or conduct Clinical Trials of a pharmaceutical or biological product in such jurisdiction.

“IND Clearance” means, with respect to a Product, that (a) with respect to the US Territory, a particular IND for the Product has been allowed to go into effect by the FDA, as evidenced by the passage of a thirty (30) calendar day period after the date of the IND submission (or any amended submission if such amendment restarted the applicable thirty (30)-day period) without the FDA placing the IND on clinical hold, (b) with respect to the European Union, that a Member State to which an application for clinical trial authorization has been submitted (Member States concerned) has either: (i) notified the sponsor through the EU portal (the Clinical Trials Information System) that the Clinical Trial is authorized (including an authorization subject to conditions) in accordance with Article 8(1) of Regulation (EU) No. 536/2014, or (ii) not notified the sponsor that the clinical trial is authorized within the relevant periods referred to in Article 8(1) of Regulation (EU) No. 536/2014, with the result that the clinical trial is deemed to be authorized in accordance with Article 8(6) of Regulation (EU) No. 536/2014, and (c) with respect to the United Kingdom, the Medicines and Healthcare Products Regulatory Agency has confirmed its acceptance of an application for clinical trial authorization (including an acceptance subject to conditions) pursuant to the Medicines for Human Use (Clinical Trials) Regulations 2004.

“Indemnified Party” has the meaning set forth in Section 6.3(a).

“Indemnifying Party” has the meaning set forth in Section 6.3(a).

“Indemnity Liability Cap” means as of the date that any claim for indemnification is made by an Indemnified Party pursuant to Section 6.3, an amount equal to the aggregate amount of any payments actually received by Seller pursuant to Article II. For purposes of calculating the Indemnity Liability Cap with respect to Section 6.1(b)(ii), any Solid Shares will be valued at the VWAP (with the date of measurement being the date that the applicable Milestone Shares were issued pursuant to Section 2.6, if any). For purposes of calculating the Indemnity Liability Cap with respect to Buyer’s exercise of the set-off rights set forth in Section 6.5, if applicable, any Solid Shares will be valued at the VWAP (with the date of measurement being the date that the applicable indemnification claim has been made by a Buyer Indemnified Party pursuant to Section 6.3).

“Intellectual Property Rights” means all rights, title and interests in and to all intellectual property rights and proprietary rights of every kind and nature however denominated, throughout the world, including: (a) patents, patent applications, (including in each case any provisional, continuation, continuation-in-part, division, renewal, extension, supplemental protection certificate, reexamination or reissue thereof), industrial design rights, and statutory invention registrations (collectively, “Patents”); (b) registered and unregistered trademarks, trade dress, trade names, logos, brands, design rights, service marks, together with all common law rights and the goodwill pertaining to the foregoing, and all applications, registrations and renewals therefor; (c) registered and unregistered copyrights, works of authorship, copyrightable works (published or unpublished), software, moral rights and all applications and registrations therefore; (d) domain names and social media accounts and handles; (e) software, computer programs and applications (whether in source code, object code, firmware or other form) algorithms, data and databases (including clinical data), together with all specifications, designs, documentation and Technology supporting the foregoing and all other proprietary rights in Technology; (f) trade secrets, invention disclosures, technical know-how (including processes, methods, techniques, designs, protocols, formulae, algorithms, compositions, specifications, and research and development information), and other proprietary information (“Trade Secrets”) and other proprietary rights and intellectual property rights; and (g) any and all registrations, applications, recordings, licenses, common-law rights, statutory rights, administrative rights, and contractual rights relating to any of the foregoing, including the right to sue and collect for past, present and future damages.

“IRS” means the Internal Revenue Service of the United States.

“JSC” has the meaning set forth in Section 5.3(a).

“Law” means any federal, state, local or foreign constitution, treaty, law (including common law), statute, ordinance, rule, regulation, interpretation, binding guidance, advisory, published opinion, directive, policy, Order, writ, award, decree, injunction, judgment, stay or restraining order of any Governmental Authority, the terms of any permit, and any other ruling or decision of, agreement with or by, or any other requirement of, any Governmental Authority.

“Liability” or “Liabilities” means, with respect to any Person, any and all damages, debts, liabilities, obligations, losses, claims, Taxes, interest obligations, deficiencies, judgments,

assessments, awards, fines, fees, penalties, costs and expenses, whether accrued or fixed, absolute or contingent, known or unknown, matured or unmatured or determined or determinable, due or to become due, whether directly incurred or consequential, whether or not required under GAAP to be accrued on the financial statements of such Person, and including those arising under any Law, Action or Order and those arising under any Contract, agreement, arrangement, commitment or undertaking.

“Lien” means any lien (statutory or otherwise), security interest, pledge, hypothecation, mortgage, assessment, lease, claim, levy, license, defect in title, charge, or any other Third Party right, license or property interest of any kind, or any conditional sale or other title retention agreement, right of first option, right of first refusal or similar restriction, any covenant not to sue, or any restriction on use, transfer, receipt of income or exercise of any other attribute of ownership or any agreement to give any of the foregoing in the future or similar encumbrance of any kind or nature whatsoever.

“Lock-Up Period” has the meaning set forth in Section 5.10(a).

“Losses” of a Person means any and all losses, debts, obligations, Liabilities, Liens, penalties, damages, awards, judgments, Taxes, costs and expenses (including reasonable and documented attorneys’ and experts’ fees) of such Person.

“Member Approval” has the meaning set forth in Section 3.2(c).

“Milestone 1 Cash Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 1 Private Cash Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 1 Share Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 2 Cash Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 2 Private Cash Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 2 Share Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 3 Cash Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 3 Private Cash Consideration” has the meaning set forth in Section 2.6(a).

“Milestone 3 Share Consideration” has the meaning set forth in Section 2.6(a).

“Milestone Consideration” has the meaning set forth in Section 2.6(a).

“Milestone Event” has the meaning set forth in Section 2.6(a).

“Milestone Invoice” has the meaning set forth in Section 2.6(b).

“Milestone Shares” means the Solid Shares issuable by Buyer as Milestone 1 Share Consideration, Milestone 2 Share Consideration or Milestone 3 Share Consideration (as applicable).

“Milestones” means each of the Milestone Events set forth in Section 2.6.

“Nasdaq” means the Nasdaq Global Select Market.

“Negotiation Period” has the meaning set forth in Section 5.11(a).

“Net Sales” means with respect to a Product sold to a Third Party, the gross consideration invoiced or received by Buyer or any of its Affiliates or licensees for Sales of Products (including any cash amounts plus the fair market value of any other forms of consideration), less the following deductions (to the extent included in and not already deducted from the gross amounts invoiced or otherwise charged) to the extent reasonable and customary:

[**].

Even if there is overlap between any of deductions described above, a particular deduction shall only be deducted once in the overall Net Sales calculation.

In the case of a Combination Product, Buyer and Seller shall negotiate in good faith, but in no event later than [**] before the expected launch of such Combination Product, an allocation of Net Sales of such Combination Product to the respective Product components and other component(s) thereof, as the case may be, based on the fair market value of such components for the purposes of determining a Product specific allocation of such Net Sales. Payments related to such Combination Product under this Agreement, including Royalties and Milestone Consideration, will be calculated, due and payable based only on such allocated Net Sales.

In case of disagreement and failure by the Parties to agree upon an allocation of Net Sales of such Combination Product to the respective Product components and other component(s) thereof, an independent expert agreed upon and paid by both Parties shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

“Order” means any writ, judgment, injunction, order, decree, stipulation, ruling, decision, verdict, determination or award, of or by, or any settlement under the jurisdiction of, any Governmental Authority (in each such case whether preliminary or final).

“Outstanding Solid Shares” means all Solid Capital Stock, determined on a Fully-Diluted As-Converted Basis, measured as of the date of the achievement of the applicable Milestone Event.

“Owed Damages” has the meaning set forth in Section 6.3(c).

“Owed Intellectual Property” means all Seller Intellectual Property that is owned by Seller as of the Closing Date.

“Party” or “Parties” has the meaning set forth in the preamble hereof.

“Patents” has the meaning set forth in the definition of Intellectual Property Rights.

“Permitted Liens” has the meaning set forth in Section 2.1.

“Person” means an individual, corporation, partnership, limited liability company, joint venture, association, trust, unincorporated organization or other entity or any Governmental Authority.

“PHSA” means the Public Health Service Act, as amended, and the rules and regulations promulgated by FDA thereunder.

“Pre-Closing Tax Period” means (a) any Tax period ending on or before the Closing Date, and (b) with respect to a Tax period that commences on or before but ends after the Closing Date, the portion of such period up to and including the Closing Date.

“Pricing and Reimbursement Approval” means, in a country or other jurisdiction where Governmental Authorities in such country or jurisdiction approve or determine the price that can be charged for a product in such country or jurisdiction, or that can be reimbursed by Governmental Authorities for such product in such country or jurisdiction, (a) the approval, agreement, determination, or decision by the relevant Governmental Authority(ies) establishing the price that can be legally charged to consumers for such product in such country or jurisdiction; or (b) the approval, agreement, determination, or decision by the relevant Governmental Authority(ies) establishing the level of reimbursement that will be reimbursed by Governmental Authorities for such product in such country or jurisdiction.

“Prime Rate” means, as of the date of this Agreement, the rate of interest which is identified in The Wall Street Journal as the “Prime Rate” in the United States.

“Product Inventory” means all inventory of the Products, including inventory of work-in-process, finished goods, raw materials, supplies, parts, labels and packaging, working prototypes, and samples (including rights and interests in goods in transit, consigned inventory, inventory sold on approval and rental inventory), in each case, in the possession or control of Seller or its Affiliates. The Product Inventory existing as of the Closing Date is set forth on Annex 1.1(b).

“Products” means any product (a) containing or comprising the FA Asset, whether alone or in combination with one or more additional components, in all forms, formulations and dosage forms, and (b) any product, service, article, composition, apparatus, chemical, substance or any other material made, used or sold by utilizing or practicing Seller Intellectual Property.

“Purchase Price Allocation” has the meaning set forth in Section 2.11.

“Purchased Assets” has the meaning set forth in Section 2.1.

“Registrable Securities” has the meaning set forth in Section 2.6(d)(v).

“Registration Statement” has the meaning set forth in Section 2.6(d)(v).

“Registrational Clinical Trial” means a Phase III Clinical Trial or other Clinical Trial of a Product that would satisfy the requirements of 21 C.F.R. 312.21(c) and that is designed or intended to (a) establish that the product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the product in the dosage range to be prescribed, and (c) support the submission of a BLA or similar application for Regulatory Approval for such Product in the Territory.

“Regulatory Approval” means, with respect to a country or jurisdiction in the Territory, any approval, authorization, or permit granted by the applicable Regulatory Authority that is necessary for the manufacture, marketing, importation and sale of a Product in such country or jurisdiction, which may include satisfaction of all applicable regulatory and notification requirements, including, where applicable, (a) Pricing and Reimbursement Approval(s), solely to the extent necessary to commence marketing in such jurisdiction, (b) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto) or (c) approval of product labeling.

“Regulatory Authority” means any applicable Governmental Authority with authority over the distribution, importation, exportation, manufacture, production, use, storage, transport, clinical testing or sale of a pharmaceutical or biological product, including any Governmental Authority having the authority to grant Regulatory Approval or Pricing and Reimbursement Approval.

“Regulatory Documentation” means, with respect to a Product, all applications for and documentation relating to INDs or Regulatory Approvals for such Product, all material correspondence submitted to or received from Governmental Authorities in connection with INDs or Regulatory Approvals for such Product, and all source clinical trial data and safety data submitted to Governmental Authorities in connection with INDs or Regulatory Approvals for such Product.

“Regulatory Exclusivity” means, with respect to any country or other jurisdiction in the Territory, an additional market protection granted by a Governmental Authority in such country or other jurisdiction that confers an exclusive commercialization period during which a Person has the exclusive right to market and sell a Product in such country or other jurisdiction.

“Related Documents” means, other than this Agreement, all agreements, certificates and documents signed and delivered by either Party in connection with the signing of this Agreement or the Closing.

“Releasee” has the meaning set forth in Section 7.12.

“Releasors” has the meaning set forth in Section 7.12.

“Representatives” means, with respect to any Person, such Person’s directors, officers, equity holders, members, managers, employees, counsel, consultants, accountants, financial advisors, lenders and other agents and representatives.

“Reversion Agreement” has the meaning set forth in Section 5.11(a)(i).

“Reversion Notice” has the meaning set forth in Section 5.11(a).

“Reversion Product” means any Product in the form such Product exists as of the date of Buyer’s receipt of the Reversion Notice.

“Reversion Rights” has the meaning set forth in Section 5.11(a).

“Royalties” has the meaning set forth in Section 2.7(a)(i).

“Royalty Report” has the meaning set forth in Section 2.7(c).

“Royalty Term” has the meaning set forth in Section 2.7(a)(ii).

“Sale” means any transaction (other than a license or sublicense) for which consideration is received or invoiced by Buyer, its Affiliates or licensees for sale, use, lease, transfer or other disposition of a Product to or for the benefit of a Third Party. For clarity, the sale, use, lease, transfer or other disposition of a Product by Buyer or any of its Affiliates or licensees to another of these entities for resale by such entity to a Third Party shall not be deemed a Sale.

“SEC” means the United States Securities and Exchange Commission.

“SEC Filings” has the meaning set forth in Section 4.10(a).

“Second UPenn Amendment” has the meaning set forth in the definition of the “UPenn License.”

“Securities Act” means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

“Seller” has the meaning set forth in the preamble hereof.

“Seller Disclosure Schedules” means the Schedules delivered by Seller to Buyer contemporaneously with this Agreement and appended hereto, setting forth disclosures in respect of the representations and warranties contained in Article III of this Agreement.

“Seller Indemnified Party” has the meaning set forth in Section 6.2(a).

“Seller Indemnity Threshold” has the meaning set forth in Section 6.1(b).

“Seller Intellectual Property” means (a) all Technology owned, leased, licensed, or Controlled by Seller, including all such Technology that is related to the Business or the FA Asset or used, or held for use, by Seller in connection with the Exploitation of FA Asset, and (b) all Intellectual Property Rights (other than Intellectual Property Rights constituting Excluded Assets) owned, licensed by or otherwise Controlled by Seller, including all such Intellectual Property Rights that are related to the Business or used, or held for use, by Seller in connection with the Exploitation of the FA Asset, and the right to recover for past, present and future infringement of

any of the foregoing. The Seller Intellectual Property Rights existing as of the Closing Date are set forth on Annex 1.1(c).

“Seller Representation Letter” has the meaning set forth in Section 2.6(d)(iii).

“Seller’s Certificate of Formation” has the meaning set forth in Section 3.1.

“Seller’s Knowledge” (and similar phrases) means, with respect to any matter in question, the actual knowledge of Thomas Hamilton as of the Closing Date after reasonable inquiry of all Seller’s officers and managers reasonably expected to have actual knowledge of such fact or matter.

“Seller’s Operating Agreement” has the meaning set forth in Section 3.1.

“Seller’s Secretary’s Certificate” means a certificate, dated as of the Closing Date, duly executed by the secretary of Seller, certifying that: (a) all documents to be executed by Seller and delivered at the Closing have been executed by a duly authorized officer of Seller, (b) (i) Seller’s Certificate of Formation and Seller’s Operating Agreement, attached to the certificate, are true, accurate and complete, (ii) such organizational documents have been in full force and effect in the form attached since the date of the adoption of the resolutions referred to in clause (iii) below and no amendment, rescission or modification to such organizational documents has occurred since the date thereof, (iii) the resolutions adopted by the board of managers of Seller, authorizing the execution, delivery and performance of this Agreement and the Related Documents to which Seller is a party, as attached to the certificate, were duly adopted by unanimous written consent of the board of managers of Seller, remain in full force and effect, and have not been amended, rescinded or modified and (iv) the resolutions adopted by the members of Seller necessary to approve and adopt this Agreement and the Related Documents to which Seller is a party, authorizing the execution, delivery and performance of this Agreement and the Related Documents to which Seller is a party, as attached to the certificate, were duly adopted by such members at a duly convened meeting of the members or by written consent of the members of Seller duly adopted, remain in full force and effect, and have not been amended, rescinded or modified and (c) Seller’s officer executing this Agreement, and each of the other documents necessary for consummation of the Contemplated Transactions, is an incumbent officer, and the specimen signature on such certificate is a genuine signature.

“Share Issuance Cap” has the meaning set forth in Section 2.6(c).

“Solid Capital Stock” means, collectively, the Solid Shares and Solid Preferred Stock.

“Solid Preferred Stock” means the preferred stock, par value \$0.001 per share, of Buyer.

“Solid Shares” means the common stock, par value \$0.001 per share, of Buyer.

“Subsidiary” of any Person means another Person, an amount of the voting securities, other voting rights or voting partnership interests of which is sufficient to elect at least a majority of its board of directors or other governing body (or, if there are no such voting interests, 50% or more of the equity interests of which) is owned directly or indirectly by such first Person.

“Tax” or “Taxes” means (whether disputed or not) all (a) federal, state, local and foreign income, franchise, windfall or other profits, gross receipts, property, escheat or unclaimed property, ad valorem, sales, use, excise, withholding, payroll, employment, social security, unemployment compensation, disability, severance, capital gain, alternative minimum, estimated, transfer and other taxes and similar governmental charges, including any interest, penalties and additions with respect thereto, (b) Liability for the payment of any amounts of the type described in clause (a) as a result of being a member of an affiliated, consolidated, combined, unitary or aggregate group or as a transferee or successor and (c) Liability for the payment of any amounts as a result of being party to any tax sharing agreement or as a result of any express or implied obligation to indemnify any other Person with respect to the payment of any amounts of the type described in clause (a) or (b).

“Tax Return” means all returns, requests for extensions of time, claims for refund, declarations of estimated Tax payments, reports, estimates, information returns and statements, filed or to be filed with any Taxing Authority in connection with the determination, assessment, collection or administration of any Taxes, including any amendments thereto as well as any related or supporting information with respect to any of the foregoing.

“Taxing Authority” means any federal, state, local or foreign government, any subdivision, agency, commission or authority thereof, or any quasi-governmental body exercising tax regulatory authority.

“Technology” means all inventions, works, discoveries, innovations, know-how, information (including ideas, research and development, formulas, algorithms, compositions, processes and techniques, data (including clinical data), designs, drawings, lab records and notebooks, specifications, graphics, documentation and manuals), equipment, and all other forms of technology, business materials, and embodiments of Intellectual Property Rights, embodied in any form, whether or not protected by patent, copyright, trade secret Law, or otherwise, and all documents and other materials recording any of the foregoing.

“Technology Transfer” has the meaning set forth in Section 5.4.

“Territory” means worldwide.

“Third Party” means any Person other than: (a) Seller or Buyer or (b) any Affiliates of Seller or Buyer.

“Third Party Claim” has the meaning set forth in Section 6.1(a).

“Trade Secrets” has the meaning set forth in the definition of Intellectual Property Rights.

“Transfer” has the meaning set forth in Section 5.10(a).

“Transfer Taxes” has the meaning set forth in Section 5.6(a).

“UPenn” means The Trustees of the University of Pennsylvania, a Pennsylvania nonprofit corporation.

“UPenn IND Payments” means those certain payments set forth on Schedule A to the Second UPenn Amendments that are listed on Annex 1.1(e).

“UPenn License” means that certain Research, Collaboration and License Agreement by and between Seller and UPenn, dated as of November 4, 2020 and amended by (a) the First Amendment to the Research, Collaboration and License Agreement dated November 1, 2021 and (b) the Second Amendment to the Research, Collaboration and License Agreement dated August 6, 2024 (the “Second UPenn Amendment”).

“US Territory” means the United States of America and its territories and possessions.

“Valid Claim” means a claim of any issued and unexpired Patent within the Seller Intellectual Property whose validity, enforceability or patentability has not been affected by any of the following: (a) irretrievable lapse, abandonment, revocation, dedication to the public or disclaimer or (b) a holding, finding or decision of invalidity, unenforceability or non-patentability by a court, governmental agency, national or regional patent office or other appropriate body that has competent jurisdiction, such holding, finding or decision being final and unappealable or not appealed within the time allowed for appeal.

“Voting Rights Agreement” has the meaning set forth in Section 2.12.

“VWAP” means, as of a specific date, the volume-weighted average price per Solid Share, as reported on Nasdaq, during the consecutive [**] trading days immediately preceding the specified date, as calculated by Bloomberg Financial LP under the function “VWAP”.

Section 1.2 Interpretation. When a reference is made in this Agreement to an Article, a Section, Exhibit, Schedule or Annex, such reference will be to an Article of, a Section of, or an Exhibit, Schedule or Annex to, this Agreement unless otherwise indicated. Any exception set forth in a section or subsection of any Annex or any of the Schedules will be deemed to be disclosed for purposes of, and will qualify, such section or subsection of this Agreement and any other section or subsection of this Agreement where it is reasonably apparent on the face of such exception that such exception would be applicable to such other section or subsection. The table of contents and headings contained in this Agreement, any Related Document or in any Exhibit, Schedule or Annex hereto are for reference purposes only and will not affect in any way the meaning or interpretation of this Agreement, such Related Document or such Exhibit, Schedule or Annex. Whenever the words “include”, “includes” or “including” are used in this Agreement or any Related Document, they will be deemed to be followed by the words “without limitation.” The word “or,” when used in this Agreement, has the inclusive meaning represented by the phrase “and/or.” The words “hereof”, “herein” and “hereunder” and words of similar import when used in this Agreement will refer to this Agreement as a whole and not to any particular provision of this Agreement. References to the “date hereof” refer to the date of this Agreement. “Extent” in the phrase “to the extent” means the degree to which a subject or other thing extends, and such phrase does not mean simply “if”. All terms defined in this Agreement will have the defined meanings when used in any certificate or other document made or delivered pursuant hereto unless otherwise defined therein. The definitions contained in this Agreement are applicable to the

singular as well as the plural forms of such terms and to the masculine as well as to the feminine and neuter genders of such term. Any Contract or statute defined or referred to herein or in any Contract that is referred to herein means (a) in the case of any statute, such statute and any comparable statute that from time to time replaces such statute by succession and any rules or regulations promulgated by an applicable Governmental Authority thereunder and (b) in the case of any Contract, such Contract and all amendments, modifications and attachments thereto and instruments incorporated therein. References to a Person are also to its permitted successors and assigns.

ARTICLE II

PURCHASE AND SALE

Section 2.1 Purchase and Sale of Purchased Assets. Upon and subject to the terms and conditions hereof, at the Closing, Buyer shall purchase from Seller, and Seller shall sell, convey, assign, transfer and deliver to Buyer, all of Seller's right, title and interest in and to all assets, properties, rights, titles and interests of every kind and nature owned, licensed or leased by Seller (including indirect and other forms of beneficial ownership) as of the Closing Date that are used (or held for use) in connection with, related to, useful or otherwise necessary for the conduct of the Business, whether tangible or intangible, real or personal and wherever located (the "Purchased Assets"), free and clear of all Liens, other than the Liens set forth on Annex 2.1 ("Permitted Liens"), and agrees to assume, satisfy and discharge when due all Assumed Liabilities. The purchase and sale of the Purchased Assets hereunder is referred to herein as the "Acquisition."

Section 2.2 Purchased Assets; Excluded Assets.

(a) Without limiting the generality of Section 2.1, the Purchased Assets include all of Seller's right, title and interest in and to the following assets:

- (i) all assets related to, or used in, the Business, including, but not limited to, the FA Asset;
 - (ii) all Seller Intellectual Property;
 - (iii) (A) the UPenn License and (B) all Contracts set forth on Annex 2.2(a)(iii)((A) and (B), together, the "Assigned Agreements");
 - (iv) all Product Inventory;
 - (v) all Books and Records; provided, that Seller may retain copies of the Books and Records to the extent necessary to comply with applicable Law or Seller's bona fide internal policies with respect to record-keeping obligations; and
 - (vi) all claims, counterclaims, credits, Actions, rights of recovery, and rights of indemnification or setoff against Third Parties and other claims arising out of or relating
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to the Purchased Assets and all other intangible property rights that relate to any Purchased Asset or any Assumed Liabilities.

(b) Other than the Purchased Assets, Buyer will not acquire any right, title or interest in or to any assets, properties, goodwill, and rights of Seller and its Affiliates, including the following assets (collectively, the “Excluded Assets”):

(i) any assets, properties, goodwill and rights of Seller and its Affiliates, in each case, that do not relate to the Business; and

(ii) all Contracts other than the Assigned Agreements.

Section 2.3Assumption of Certain Liabilities. Subject to the terms and conditions set forth herein, Buyer agrees, effective at and after the Closing, to assume and to timely satisfy and discharge all Liabilities:

(a) relating to the Purchased Assets, (including Liabilities under any Assigned Agreement), but only to the extent that such Liabilities (i) arise from any act or omission at or after the Closing, (ii) do not arise from any act or omission prior to the Closing, and (iii) with respect to any Assigned Agreement, such Assigned Agreement is assigned to Buyer or Buyer otherwise receives the rights and benefits of such Assigned Agreement pursuant to Section 2.2(a)(iii), and in each case specifically excluding any Liability or obligation arising from any act or omission prior to the Closing or relating to or arising out of the Purchased Assets as a result of: (A) any breach of an Assigned Agreement occurring prior to Closing; (B) any violation of law, breach of warranty, tort or infringement occurring prior to the Closing; or (C) any charge, complaint, action, suit, proceeding, hearing, investigation, claim or demand occurring prior to the Closing or relating to the facts or circumstances occurring prior to Closing;

(b) resulting from the ownership, use, operation or maintenance of the Purchased Assets and/or the Exploitation of Products by or on behalf of Buyer, in each case, only to the extent arising at or after the Closing Date; and

(c) set forth on Annex 2.3 hereto (such Liabilities set forth in the foregoing (a), (b) and (c), collectively, the “Assumed Liabilities”).

Section 2.4Excluded Liabilities.

(a) Buyer will not be the successor to Seller or any of its Affiliates and Buyer expressly does not assume and will not become liable to pay, perform or discharge, any Liability whatsoever of Seller or any of its Affiliates other than the Assumed Liabilities (collectively, the “Excluded Liabilities”). Notwithstanding anything to the contrary in this Agreement, Excluded Liabilities will include (i) any Liabilities for Taxes relating to, or arising out of or imposed on the Business or the Purchased Assets for any Pre-Closing Tax Period, (ii) any Liabilities for Taxes of Seller or any of its Affiliates for any taxable period, (iii) any Liabilities of Seller for the payment of any amounts of Tax as a result of being a member of an affiliated, consolidated, combined or

unitary group, as a result of any Tax sharing or Tax allocation agreement, arrangement or understanding, or as a result of being liable for another Person's Taxes as a transferee or successor, by Contract or otherwise, (iv) any Liabilities relating to, or arising out of the employment or engagement, or termination of the employment or engagement, of any employee or other service provider of Seller or any of its Affiliates at any time and (v) the UPenn IND Payments.

Section 2.5 Closing; Closing Deliverables.

(a) Closing. The closing of the Acquisition (the "Closing") will take place on the date hereof via an electronic exchange of documents (the "Closing Date").

(b) Seller Closing Deliverables. Prior to the Closing, Seller will deliver or cause to be delivered to Buyer or to Buyer's designee:

(i) the Bill of Sale, dated the Closing Date and duly executed by Seller;

(ii) a duly completed and executed IRS Form W-9 of Seller, or, if Seller is a disregarding entity for U.S. federal income tax purposes, a duly completed and executed IRS Form W-9 or IRS Form W-8 as appropriate of Seller's regarded owner;

(iii) Seller's Secretary's Certificate, dated the Closing Date;

(iv) the Member Approval;

(v) the assignments, consents, waivers, approvals and authorizations, in form and substance reasonably satisfactory to Buyer, relating to those items set forth on Annex 2.5(b)(v);

(vi) all bills of sale, instruments of assignment and other transfer documentation as reasonably requested by Buyer, in form and substance reasonably satisfactory to Buyer, pursuant to which all of Seller's right, title and interest in and to Seller Intellectual Property and other Purchased Assets are transferred to Buyer;

(vii) all tangible Purchased Assets in Seller's possession and control as of the Closing Date (if any); and

(viii) each of the items and materials listed on Section 2.5(b)(viii) of the Seller Disclosure Schedules.

(c) Buyer Closing Deliverables. At the Closing, Buyer will deliver or cause to be delivered to Seller the Bill of Sale.

(d) Payments by Buyer at Closing. In consideration of the sale, conveyance, delivery, transfer and assignment of the Purchased Assets to Buyer and Seller's other covenants and obligations hereunder, Buyer and its applicable Affiliates will pay, or cause to be paid, to Seller, by wire transfer of immediately available funds to the account or accounts specified by

Seller to Buyer, an amount equal to the Closing Purchase Price no later than [**] following the Closing Date; provided that such [**] period shall not commence until the date that Buyer has received all required IRS Form W-9s or IRS Form W-8s in order to process the payment of the Closing Purchase Price.

Section 2.6 Developmental and Sales Milestones.

(a) Subject to adjustment pursuant to this Section 2.6 and Section 6.5, Buyer will make the non-refundable cash payments or issuances of Solid Shares (or combination thereof, as applicable) described in Table 1 below (each, “Milestone Consideration”) following the first achievement by Buyer of the corresponding event (each a “Milestone Event”) described in the column to the left of such payment in the table below.

Table 1		
No.	Milestone Event	Milestone Consideration
1	First IND Clearance of a Product	At the election of Buyer, (a) either (i) a number of Solid Shares representing [**]% of the Outstanding Solid Shares or (ii) a number of Solid Shares equal to \$5,000,000 in value, whichever is valued higher at the time of achievement of Milestone Event No. 1 (provided, that in no event will any Solid Shares paid pursuant to the foregoing (i) or (ii) exceed a value of \$[**] or [**]% of the Outstanding Solid Shares, as applicable) (the “ <u>Milestone 1 Share Consideration</u> ”), (b) cash, in an amount equal to the consideration to be paid pursuant to the foregoing clause (a) in lieu of payment in Solid Shares (the “ <u>Milestone 1 Cash Consideration</u> ”), or (c) a combination of (a) and (b), in an amount equal to the consideration to be paid pursuant to the foregoing clause (a). If, as of the date Milestone Event No. 1 is achieved, Buyer is no longer a publicly traded company, Buyer will pay to Seller cash in the amount of \$5,000,000 in lieu of payment as described in the foregoing (a) - (c) (the “ <u>Milestone 1 Private Cash Consideration</u> ”).
2	[**]	At the election of Buyer, (a) either (i) a number of Solid Shares representing [**]% of the Outstanding Solid Shares or (ii) a number of Solid Shares equal to \$[**] in value, whichever is valued higher at the time of achievement of Milestone Event No. 2 (provided, that in no event will any Solid Shares paid pursuant to the foregoing (i) or (ii) exceed a value of \$[**] or [**]% of the Outstanding Solid Shares, as applicable) (the “ <u>Milestone 2 Share Consideration</u> ”), (b) cash, in an amount equal to the consideration to be paid pursuant to the foregoing clause (a), in lieu of payment in Solid Shares (the “ <u>Milestone 2 Cash Consideration</u> ”), or (c) a combination of (a) and (b), in an amount equal to the consideration to be paid pursuant to the foregoing clause (a). If, as of the date Milestone Event No. 2 is achieved,

Table 1		
No.	Milestone Event	Milestone Consideration
		Buyer is no longer a publicly traded company, Buyer will pay to Seller cash in the amount of \$[**] in lieu of payment as described in the foregoing (a) - (c) (the “ <u>Milestone 2 Private Cash Consideration</u> ”).
3	[**]	At the election of Buyer, (a) either (i) a number of Registrational Clinical Trial Solid Shares representing [**]% of the Outstanding Solid Shares or (ii) a number of Solid Shares equal to \$[**] in value, whichever is valued higher at the time of achievement of Milestone Event No. 3 (provided, that in no event will any Solid Shares paid pursuant to the foregoing (i) or (ii) exceed a value of \$[**] or [**]% of the Outstanding Solid Shares, as applicable) (the “ <u>Milestone 3 Share Consideration</u> ”), (b) cash, in an amount equal to the consideration to be paid pursuant to the foregoing clause (a), in lieu of payment in Solid Shares (the “ <u>Milestone 3 Cash Consideration</u> ”), or (c) a combination of (a) and (b), in an amount equal to the consideration to be paid pursuant to the foregoing clause (a). If, as of the date Milestone Event No. 3 is achieved, Buyer is no longer a publicly traded company, Buyer will pay to Seller cash in the amount of \$[**] in lieu of payment as described in the foregoing (a) - (c) above (the “ <u>Milestone 3 Private Cash Consideration</u> ”).
4	[**]	\$[**] in cash.
5	[**]	\$[**] in cash.
6	Annual Net Sales in the Territory are equal to or greater than \$[**] and less than or equal to \$[**]	\$[**] in cash.
7	Annual Net Sales in the Territory are greater than \$[**] and less than or equal to \$[**]	\$[**] in cash.
8	Annual Net Sales in the Territory are greater than \$[**]	\$[**] in cash.

(b) Promptly upon the achievement of a Milestone Event, and in any event within [**], Buyer will notify Seller of the achievement of such Milestone Event. Promptly

following, and in any event within [**] following such notice from Buyer of the achievement of such Milestone Event, Seller will submit an invoice to Buyer for the amount of the corresponding Milestone Consideration (each, a “Milestone Invoice”), and Buyer will pay the applicable Milestone Consideration by wire transfer of immediately available funds or issuance of Solid Shares to Seller, or both, as applicable, no later than the date that is [**] after the date of such Milestone Invoice.

(c) For clarity, if any of the Milestone Event No. [**] has not been achieved at the time of the [**], then any such Milestone shall be deemed achieved and the corresponding Milestone Consideration shall become due and payable. Notwithstanding the foregoing, each Milestone Consideration payment is payable only once, upon the first achievement (or deemed achievement) of the applicable Milestone Event, regardless of any subsequent or repeated achievements of Milestone Events with respect to one or more of the same or different Products. For the avoidance of doubt, (i) the maximum aggregate value of Milestone Consideration payable with respect to Milestone Events No. [**] through No. [**] under this Agreement will be \$34,000,000 or [**]% of the Outstanding Solid Shares (which \$34,000,000 or [**]% represents the aggregate value or percentage of Outstanding Solid Shares measuring each issuance of such Milestone Shares in connection with the achievement of Milestone Events No. [**] through No. [**] as of the date such Milestones were achieved), as applicable, and (ii) the maximum aggregate payments of Milestone Consideration payable with respect to Milestone Events No. [**] through No. [**] under this Agreement will be \$21,000,000. In no event will the aggregate amount of Solid Shares issued as Milestone Consideration pursuant to this Agreement exceed 19.9% of all of the Solid Shares issued and outstanding as of the Closing Date (the “Share Issuance Cap”); provided, that if Buyer elects to issue an amount of Solid Shares as Milestone Consideration equal to the Share Issuance Cap, then, thereafter, any payment of Milestone Consideration or portion thereof payable to Seller will be paid in cash, subject and pursuant to this Section 2.6. For purposes of determining any Milestone Consideration payable pursuant to Section 2.6(a), so long as the Solid Shares are publicly traded on a U.S. national exchange, Solid Shares shall be valued at the VWAP for such Solid Shares as of the date such Milestone Event was achieved. For the avoidance of doubt:

(i) with respect to Milestone Event No. 1, Buyer will only be required to pay, and Seller will only be entitled to receive, one of the Milestone 1 Cash Consideration, the Milestone 1 Share Consideration or the Milestone 1 Private Cash Consideration. In no event will Buyer be required to pay, or will Seller be entitled to receive, more than one of the foregoing payments for achievement of Milestone Event No. 1;

(ii) with respect to Milestone Event No. 2, Buyer will only be required to pay, and Seller will only be entitled to receive, one of the Milestone 2 Cash Consideration, the Milestone 2 Share Consideration or the Milestone 2 Private Cash Consideration. In no event will Buyer be required to pay, or will Seller be entitled to receive, more than one of the foregoing payments for achievement of Milestone Event No. 2; and

(iii) with respect to Milestone Event No. Event No. 3, Buyer will only be required to pay, and Seller will only be entitled to receive, one of the Milestone 1 Cash Consideration, the Milestone 3 Share Consideration or the Milestone 3 Private Cash Consideration.

In no event will Buyer be required to pay, or will Seller be entitled to receive, more than one of the foregoing payments for achievement of Milestone Event No. 3.

(d) In the event that Buyer elects to pay any Milestone Consideration in the form of Solid Shares pursuant to Section 2.6(a):

(i) notwithstanding anything to the contrary herein, no fractional Solid Shares will be issued as Milestone Consideration and any portion of Solid Shares representing fractional shares that would otherwise be issued as Solid Shares will instead be rounded up to the nearest whole Solid Share prior to the issuance of such Solid Shares to Seller;

(ii) Seller acknowledges and understands that any Solid Shares issued to Seller as Milestone Consideration are issued to Seller pursuant to a “private placement” exemption or exemptions from registration under Section 4(a)(2) of the Securities Act and/or Regulation D promulgated under the Securities Act and an exemption from qualification under applicable state securities Laws. Such Solid Shares will be “restricted securities” under the United States federal and state securities Laws and cannot be offered or resold except pursuant to registration under the Securities Act and applicable state securities Laws or an available exemption from registration. Seller further acknowledges that if an exemption from registration or qualification is available with respect to the resale by it of the Solid Shares, it may be conditioned on compliance with applicable Laws, which may include the time and manner of sale and the holding period for the shares of Solid Shares;

(iii) prior to receipt of any such Solid Shares, Seller will execute a representation letter in substantially the form of Exhibit B-1 (the “Seller Representation Letter”) and Buyer will execute a representation letter in substantially the form of Exhibit B-2 (the “Buyer Representation Letter”);

(iv) Seller acknowledges that the certificates representing the Solid Shares will bear the following legends or legends substantially similar:

“the shares represented by this certificate have not been registered under the Securities Act of 1933 (the “Act”) and may not be offered, sold or otherwise transferred, assigned, pledged or hypothecated unless registered under the Act or unless an exemption from the registration requirements of the Act is available”; and

(v) Buyer shall file within [**] of the date of the achievement of Milestone Event No. 1, Milestone Event No. 2 and Milestone Event No. 3, with respect to any Solid Shares that Buyer determines to issue as Milestone Consideration, a registration statement on Form S-3 (or any successor form to Form S-3) registering the resale of such Solid Shares (the “Registrable Securities”) (or, in the event that (i) Form S-3 is not available for the registration of the resale of the Registrable Securities, another appropriate form reasonably acceptable to Seller or (ii) if available, include the Registrable Securities in a prospectus supplement under an already effective registration statement of Buyer) by Seller (a “Registration Statement”). Buyer shall use commercially reasonable efforts (a) to cause the Registration Statement to become effective as

promptly as practicable; and (b) to cause the Registration Statement to remain effective until the earlier of (i) the date on which Seller has disposed of all of the Registrable Securities and (ii) the date on which Rule 144 promulgated under the Securities Act is available for the disposition of such Registrable Securities without volume or manner-of-sale restrictions. Seller agrees to cooperate with Buyer as reasonably requested by Buyer in connection with the preparation and filing of the Registration Statement, including furnishing to Buyer such information regarding itself, the Solid Shares held by it and the intended method of disposition of the Registrable Securities as shall be reasonably required to effect the registration of such Registrable Securities. Buyer shall bear all expenses incurred in connection with the filing of the Registration Statement; provided, however, that Buyer shall have no obligation to pay for any commissions or transfer taxes of Seller.

(e) The Parties acknowledge that it is the intention of the Parties that the development, commercialization and other Exploitation of the Products will be exercised by Buyer and its Affiliates in accordance with its or their own business judgment and, subject to the requirements of this Agreement, in its or their reasonable business judgement.

(f) To the extent permitted by applicable Law, the Parties intend that the payment of the Milestone Consideration be treated as deferred contingent purchase price eligible for installment sale treatment under Section 453 of the Code (subject to imputation of interest under Section 483 or Section 1274 of the Code).

(g) The Parties acknowledge that the achievement of the Milestone Events is uncertain and that Buyer and its Affiliates may not achieve results requiring the payment of any Milestone Consideration at all, and it is therefore not assured that Buyer will be required to pay any Milestone Consideration.

(h) As between the Parties, other than as set forth in Section 5.1 and Section 5.2, Buyer and its Affiliates have no duty to develop, commercialize or otherwise Exploit the Products, to exert any level of efforts in developing, commercializing or Exploiting the Products or to achieve the Milestone Events.

(i) Subject to Buyer's obligations under Section 5.1, Buyer and its Affiliates are not prohibited from developing, manufacturing, marketing, selling, Exploiting or acquiring assets, businesses, or other products that may compete with the Products or any other products of Buyer, Seller or its or their Affiliates.

Section 2.7Royalties.

(a) On a Product-by-Product and country-by-country basis, during the Royalty Term for such Product, Buyer will pay a royalty to Seller on Annual Net Sales of such Product in the Territory as follows:

(i) **[**]**% of Annual Net Sales of such Product that are less than or equal to **[\$**]**; and

(ii) [**]% on Annual Net Sales of such Product that are greater than \$[**] (each of (Section 2.7(a)) and (Section 2.7(a)(i)), the “Royalties”).

(b) Buyer’s obligation to pay Royalties for a Product in a country in the Territory will begin upon the First Commercial Sale of such Product in such country and will expire upon the later of (x) the date that is [**] following the First Commercial Sale of such Product in such country, (y) the date on which the sale of such Product is not (or is no longer) Covered by a Valid Claim in such country and (z) expiration of all Regulatory Exclusivity, if any, for such Product in such country (the “Royalty Term”). Following the expiration of the Royalty Term for a Product in a given country, Annual Net Sales of such Product in such country will be excluded from Annual Net Sales for purposes of determining the Royalties due hereunder.

(c) Following the First Commercial Sale, for each calendar quarter until the expiration of the last to expire Royalty Term, Buyer will give Seller a written statement of the Royalties due with respect to a such calendar quarter within [**] after the end of such calendar quarter (each, a “Royalty Report”), which Royalty Report will include the Annual Net Sales of Products subject to Royalties sold by Buyer and its Affiliates and its and their licensees in the Territory during the reporting period and the Royalties payable on Annual Net Sales under this Agreement in accordance with this Section 2.7. Following receipt of such statement, Seller will promptly, but no more than [**] from receipt of the Royalty Report, submit an invoice to Buyer for the full amount of the corresponding Royalty payable under this Section 2.7, and Buyer will pay such amount no later than the date that is [**] after the receipt of such invoice.

Section 2.8Late Payments. In addition to any other remedies available to Seller, any failure by Buyer to make a payment within [**] after the date when due shall obligate Buyer to pay computed interest, the interest period commencing on the due date and ending on the actual payment date, to Seller at a per annum rate equal to the lower of (i) [**] percent ([**]%) or (ii) the Prime Rate, provided that such rate shall not in any event exceed the highest rate allowed by Law..

Section 2.9Accounting. Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with GAAP.

Section 2.10Records and Audit Rights. Buyer will and will cause its Affiliates and its and their licensees to, keep complete and accurate financial books and records pertaining to the Exploitation of Products hereunder (including Annual Net Sales of Products) to the extent required to calculate and verify all amounts payable hereunder. Buyer will, and will cause its Affiliates and its and their licensees to, retain such books and records for [**] after the end of the period to which such books and records pertain or for such longer period as may be required by applicable Law. Seller, at its own cost, through an independent auditor reasonably acceptable to Buyer (and who has executed an appropriate confidentiality agreement reasonably acceptable to Buyer that requires the auditor to keep any information learned by it confidential except as needed to report its audit conclusions to Seller), may inspect and audit the relevant records of Buyer pertaining to the calculation of any Milestone Consideration and Royalties due to Seller under this Agreement. Buyer will provide such auditors with access to the records during reasonable business hours. Such

access need not be given to any such set of records more often than [**] or more than [**] after the date of any report to be audited. Seller will provide Buyer with written notice of its election to inspect and audit the records related to the Milestone Consideration and Royalties due hereunder not less than [**] prior to the proposed date of review of Buyer's records by Seller's auditors. Should the auditor find any underpayment of Milestone Consideration or Royalties by Buyer to Seller, Buyer will (a) promptly pay Seller the amount of such underpayment; (b) if such underpayment equals or exceeds the higher of (i) [**] Dollars (\$[**]) or (ii) [**] percent ([**]%) of Milestone Consideration or Royalties paid during the time period audited, reimburse Seller for the cost of the audit; and (c) provide such auditors with an audit right exercisable within [**] after Seller receives the audit report. If the auditor finds an overpayment by Buyer, then Buyer will have the right to deduct the overpayment from any future Milestone Consideration or Royalties due to Seller by Buyer or, if no such future Milestone Consideration or Royalties are payable, then Seller will refund the overpayment to Buyer within [**] after Seller receives the audit report. Buyer may designate competitively sensitive information which such auditor may see and review but which it may not disclose to Seller; provided, however, that such designation will not restrict the auditor's investigation or conclusions.

Section 2.11Purchase Price Allocation. In accordance with Section 1060 of the Code and the methodology set forth on Schedule Section 2.11, Buyer will prepare an allocation of the purchase price (the "Purchase Price Allocation") and provide a draft IRS Form 8594 to Seller no later than [**] after the Closing Date. Seller shall review in good faith the Purchase Price Allocation and IRS Form 8594 prepared by Buyer and shall have the opportunity to provide reasonable comments to Buyer within [**] of receipt thereof. The Parties shall cooperate in good faith to resolve any disagreements regarding the Purchase Price Allocation or IRS Form 8594. Buyer and Seller will file all Tax Returns (including IRS Form 8594) in a manner consistent with the Purchase Price Allocation, as finally determined, unless otherwise required by applicable Law or a Taxing Authority. In the event that the Purchase Price Allocation is disputed by any Governmental Authority, the Party receiving notice of the dispute will promptly notify the other Party in writing of such notice and resolution of the dispute.

Section 2.12Voting Agreement. If, and only if, Buyer elects to pay any Milestone Consideration to Seller in the form of Solid Shares pursuant to Article II, then, prior to the first issuance of any Solid Shares as Milestone Consideration (the "First Stock Consideration Issuance"), Buyer and Seller will enter into a mutually agreeable voting rights agreement, in substantially the form attached hereto as Exhibit C (the "Voting Rights Agreement").

ARTICLE III

REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the Seller Disclosure Schedules, Seller represents and warrants to Buyer as of the date hereof (or, if applicable, as of such earlier date as may be set forth in any representation and warranty in this Article III) as follows:

Section 3.1 Organization, Standing and Power. Seller is a limited liability company, duly organized, and validly existing, under the Laws of the State of Delaware, and has all requisite power and authority to own, lease or otherwise hold and operate its properties and other assets and to carry on its business as presently conducted. Seller is duly qualified or licensed to do business and is in good standing (in jurisdictions that recognize the concept of good standing) in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification or licensing necessary. Seller has made available to Buyer, prior to the execution of this Agreement, complete and accurate copies of Seller's Certificate of Formation, dated September 9, 2020 ("Seller's Certificate of Formation") and its Amended and Restated Limited Liability Company Agreement, dated [**] ("Seller's Operating Agreement"), in each case as amended as of the date hereof. Seller is not in violation of any of the provisions of Seller's Certificate of Formation or Seller's Operating Agreement. Seller's Certificate of Formation and Seller's Operating Agreement have not been amended or modified. Seller does not have, and has never had, any Subsidiaries, and none of its Affiliates holds any properties, interests, assets or rights that are used or held for use in, or necessary for the conduct of the Business or the Purchased Assets, including the Exploitation of the Products.

Section 3.2 Authority; Noncontravention.

(a) Seller has all requisite power and authority to execute and deliver this Agreement and the Related Documents and to consummate the Contemplated Transactions. The execution and delivery of this Agreement and the Related Documents by Seller and the consummation by Seller of the Contemplated Transactions have been duly authorized by all necessary action on the part of Seller and no other proceedings on the part of Seller are necessary to authorize this Agreement, the Related Documents or to consummate the Contemplated Transactions. Each of this Agreement and the Related Documents has been duly executed and delivered by Seller and, assuming the due authorization, execution and delivery by Buyer, constitutes a legal, valid and binding obligation of Seller, Enforceable against Seller in accordance with its terms.

(b) The board of managers of Seller, by unanimous written consent, duly adopted resolutions: (i) approving and declaring advisable this Agreement, the other Related Documents and the Contemplated Transactions, (ii) declaring that it is in the best interests of the members of Seller that Seller enter into this Agreement and the Related Documents and consummate the Contemplated Transactions on the terms and subject to the conditions set forth in this Agreement or such Related Documents, (iii) authorizing Seller to enter into this Agreement and to consummate the Contemplated Transactions, on the terms and subject to the conditions set forth in this Agreement and the Related Documents, (iv) directing that this Agreement and the other Related Documents be submitted to the members of Seller at a meeting or by written consent in lieu of a meeting for a vote for adopting this Agreement and the Related Documents and approving the Contemplated Transactions, and (v) recommending that the members of Seller vote to approve and adopt this Agreement and the Related Documents and approve the Contemplated Transactions, which resolutions have not been subsequently rescinded, modified or withdrawn in any way.

(c) The only votes or consent of holders of any class or series of membership units necessary to approve and adopt this Agreement, the Related Documents and the Contemplated Transactions pursuant to the provisions of Seller's Certificate of Formation, Seller's Operating Agreement and applicable Law are the affirmative votes or consent of the Requisite Preferred Members (as defined in Seller's Operating Agreement) (the "Member Approval"). On the date hereof, Seller has obtained the Member Approval and delivered to Buyer a copy of such Member Approval dated on the date hereof. No other member approval is required on behalf of Seller for the execution, delivery or performance of this Agreement, the other Related Documents and the Contemplated Transactions.

(d) The execution and delivery of this Agreement and the Related Documents by Seller do not, and the consummation of the Contemplated Transactions and compliance by Seller with the provisions of this Agreement and the Related Documents will not, conflict with, or result in any violation or breach of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of, or result in, termination, cancellation or acceleration of any obligation or to the loss of a benefit under, or result in the creation of any Lien (other than a Permitted Lien) in or upon the Purchased Assets under, or give rise to any payment under or any increased, additional, accelerated or guaranteed rights or entitlements under, or require any action by or notice to any Person under, (i) Seller's Certificate of Formation or Seller's Operating Agreement, (ii) any Contract to which Seller is a party or any of its properties or other assets is subject or (iii) any Law or Order applicable to Seller, the Business or the Purchased Assets.

(e) No consent, approval, Order or authorization of, action by or in respect of, or registration, declaration or filing with, any Governmental Authority is required by or with respect to Seller, the Business or the Purchased Assets for, or in connection with, (i) the execution and delivery of this Agreement by Seller, (ii) the transfer of the Purchased Assets to Buyer or (iii) the consummation of the Contemplated Transactions.

Section 3.3No Undisclosed Liabilities; Debt. There are no Liabilities of Seller arising out of or related to the Business or the Purchased Assets of any kind whatsoever, whether accrued, fixed, absolute, contingent, known, unknown, determined, determinable or otherwise. Seller does not have any Liability in respect of a guarantee of any debt or other Liability of any other Person or entity related to the Purchased Assets.

Section 3.4Good Title; Sufficiency of Assets.

(a) Seller has sole and exclusive, good and marketable title to, or, in the case of property held under a lease or other Contract, an Enforceable leasehold interest in, or adequate rights to use, all of the Purchased Assets free and clear of all Liens, other than Permitted Liens. Seller has the power and right to sell, assign, transfer and deliver to Buyer, as applicable, all of Seller's right, title and interest in and to the Purchased Assets. To Seller's Knowledge, there are no adverse claims of ownership to the Owned Intellectual Property and Seller has not received written notice that any Person has asserted a claim of ownership in or to any of the Owned Intellectual Property. At the Closing, Buyer will acquire from Seller sole and exclusive, good and marketable title to, or, in the case of property held under a lease or other Contract, an Enforceable

leasehold interest in, or adequate rights to use, all of the Purchased Assets, free and clear of all Liens, other than Permitted Liens. Seller does not own, nor has ever owned any, real property. This Section 3.4(a) is not, and shall not be construed as, a representation or warranty regarding non-infringement or misappropriation by the Seller of the Intellectual Property Rights of any other Persons (which representation and warranty is provided in Section 3.6(d)).

(b) The Purchased Assets constitute all properties, interests, assets and rights of Seller used or held for use in connection with, and that are necessary for the conduct of, the Business as currently conducted by Seller (other than the Excluded Assets). None of the Excluded Assets are used or held for use in connection with the Business. Without limiting the foregoing, the Assigned Agreements are all Contracts used or held for use by Seller or any Affiliate in connection with the Exploitation of any Product. This Section 3.4(b) is not, and shall not be construed as, a representation or warranty regarding non-infringement or misappropriation by Seller of the Intellectual Property Rights of any other Persons (which representation and warranty is provided in Section 3.6(d)).

Section 3.5Books and Records. Annex 1.1(a) describes, as of the date hereof, a complete and accurate list of all material Books and Records.

Section 3.6Intellectual Property.

(a) To Seller's Knowledge, Annex 1.1(c) sets forth, as of the date hereof, a complete and accurate list of all Seller Intellectual Property, including, where applicable, the registration number, expiration date, country or territory, registrant and owner of record in respect of each such item of Seller Intellectual Property, other than the Excluded Assets.

(b) Seller owns all rights, title and interests in and to, or has and has had a valid written license to use all Seller Intellectual Property (including the right to make, have made, sell and have sold all Products), and has the right to transfer to Buyer or its Affiliates under the terms of this Agreement, all of Seller's right, title and interest in and to the Seller Intellectual Property free and clear of all Liens, other than Permitted Liens. Other than the Excluded Assets, immediately following the Closing, Buyer will have the same rights, interest, and title in and to each item of Seller Intellectual Property as held by Seller immediately prior to the Closing, in each case, without the payment of any additional amounts or consideration other than fees, royalties or payments which Seller would otherwise have been required to pay had the Contemplated Transactions not occurred, which right, interest and title in and to any Seller Intellectual Property other than Owned Intellectual Property, is on the terms, and subject to the conditions set forth in the applicable Assigned Agreement governing such Seller Intellectual Property. To Seller's Knowledge, Seller Intellectual Property includes all of the Intellectual Property Rights and Technology, respectively, that is owned or Controlled by Seller and used in the Business.

(c) Seller is in compliance with and has not breached, violated or defaulted under, or received written notice that it has breached, violated or defaulted under, any of the terms or conditions of any license, sublicense or other Assigned Agreement to which Seller is a party or is otherwise bound relating to any of Seller Intellectual Property (including any prior or

unamended versions of such Assigned Agreement), nor has there been or is there any event or occurrence that would constitute such a breach, violation or default (with or without the lapse of time, giving of notice or both).

(d) To Seller's Knowledge, Seller, in the conduct of the Business, has not infringed, diluted, misappropriated or otherwise violated and is not infringing, diluting, misappropriating or otherwise violating (including with respect to the development, marketing, license, manufacture, distribution, advertising, use, sale, maintenance, support or other Exploitation by Seller of the Products or its Intellectual Property Rights) the Intellectual Property Rights of any other Person. To Seller's Knowledge, no Person or Persons has infringed, diluted, misappropriated or otherwise violated or is or are infringing, diluting, misappropriating or otherwise violating Seller Intellectual Property. Seller has not agreed to indemnify any Person for or against any interference, infringement, misappropriation or other conflict with respect to the Intellectual Property Rights of any other Person in connection with the Products or the conduct of the Business.

(e) No claims have been asserted or threatened by any Person against Seller in writing, and nor to Seller's Knowledge, does there exist any valid basis for such a claim, with respect to: (i) challenging the ownership, licensing or use of any Seller Intellectual Property; (ii) any actual or potential infringement, dilution, misappropriation or unauthorized use of Seller Intellectual Property by Seller; (iii) any actual or potential infringement, dilution, misappropriation or unauthorized use of any Third Party's Intellectual Property Rights with respect to any Seller Intellectual Property or the Products; (iv) the validity or enforceability of any Seller Intellectual Property; or (v) asserting that the operation of the Business, including the development, marketing, license, manufacture, distribution, advertising, use, sale, maintenance, support or other Exploitation of the Products by Seller prior to the Closing infringes, dilutes, misappropriates or otherwise violated any Intellectual Property Right of any Person.

(f) To Seller's Knowledge, the registered Seller Intellectual Property is subsisting, valid and enforceable, and have been duly registered or filed with or issued by each appropriate Governmental Authority. To Seller's Knowledge, all necessary filing, examination, registration, maintenance and renewal fees currently due in connection with such registered Seller Intellectual Property have been made, and all necessary documents, proofs of working or use, recordations, affidavits, and certificates in connection with such registered Seller Intellectual Property have been timely filed with the relevant authorities in the United States or applicable foreign jurisdictions, as the case may be, for the purposes of prosecuting, registering or maintaining such registered Seller Intellectual Property. To Seller's Knowledge, the registered Seller Intellectual Property has not expired or been declared invalid, in whole or in part, by any Governmental Authority, and is not subject to any interference, opposition, reissue, reexamination, cancellation or other similar proceeding which challenge the validity or ownership of such registered Seller Intellectual Property. There are no pending or published Patents within the Owned Intellectual Property.

(g) To Seller's Knowledge, no current or former employee or consultant of Seller owns any rights, title or interests in or to any Owned Intellectual Property or the Products. All current and former employees and consultants of Seller and its Affiliates who contributed to

the discovery, creation or development of any Seller Intellectual Property or Products have executed a valid and enforceable written Contract which assigned to Seller all of his or her rights in or to the relevant Seller Intellectual Property or Products and agreed to confidentiality restrictions restricting such Person's right to use or disclose proprietary information of Seller.

(h) Seller has used commercially reasonable efforts and taken commercially necessary steps to protect its rights in Seller Intellectual Property and to maintain its Trade Secrets constituting the Owned Intellectual Property in confidence, including requiring all employees, consultants or contractors of Seller to execute confidentiality agreements with respect to intellectual property developed for or obtained from Seller. Seller has not made any of its Trade Secrets or other confidential or proprietary information available to any other Person except pursuant to written agreements requiring such Person to maintain the confidentiality of such information.

(i) Other than UPenn, no college, university or other educational or research institution or agency, Governmental Authority or other organization has sponsored research or development conducted by Seller or has any claim of right or license to, or ownership of, or other Lien, other than Permitted Liens, upon any Owned Intellectual Property.

(j) The Products have not been offered for sale or sold to any Person. To Seller's Knowledge, no inventions disclosed or claimed in any Owned Intellectual Property have been offered for sale or sold to any Person.

(k) To Seller's Knowledge, other than the UPenn License, no license or right to any Intellectual Property Right of any Third Party is necessary for to Exploit the FA Asset.

Section 3.7 Compliance with Law; Regulatory Approvals.

(a) To Seller's Knowledge, the Business and the Purchased Assets have been and are conducted, used and developed in all material respects in compliance with all applicable Law. Seller has not received any notice from any Governmental Authority or other Person in writing to the effect that Seller or any of the Purchased Assets is not, or may not be, in compliance with any Law.

(b) Seller is and has at all times been in possession of, and in material compliance with, all Regulatory Approvals required for the conduct of the Business as of the Closing Date. Each such Regulatory Approval is valid and in full force and effect, and Seller has not received any notice of and, to Seller's Knowledge, there is not pending or threatened any suspension, cancellation, modification, termination, revocation, or nonrenewal of any Regulatory Approval. There has occurred no material default (by Seller) under, or violation (by Seller) of, any Regulatory Approval.

Section 3.8 Litigation. There is no Action to which Seller (or members or managers, directors, officers, employees or agents of Seller in its, his, or her capacity as such and to the extent such Actions relate to Seller) is a party (either as plaintiff or defendant) or to which its Purchased

Assets are or may be subject that is pending, or, to Seller's Knowledge, threatened, that affects or, if successful, could reasonably be expected to be adverse to Seller, the Business, the Products, the Purchased Assets or the Assumed Liabilities or that, if successful, could reasonably be expected to result in restraining, enjoining or otherwise preventing the completion by Seller of the Contemplated Transactions, nor are there, to Seller's Knowledge, any facts, circumstances or conditions on which any such Action could be brought in the future. There is no Action in respect of Seller that (a) resulted in an Order of any Governmental Authority against or settlement by Seller (whether or not such Order or settlement was paid, in whole or in part, by an insurer of Seller or other Third Party) or (b) resulted in any equitable relief or (c) relates to the Contemplated Transactions. There is no Action which Seller presently intends to initiate.

Section 3.9 Taxes.

(a) Seller has timely and properly filed all income and other material Tax Returns with respect to the Business and the Purchased Assets that are required to be filed and timely and properly paid all Taxes due and payable with respect to the Business and the Purchased Assets (whether or not shown as due and owing on such Tax Returns). All such Tax Returns are true, complete, and accurate in all material respects and prepared in accordance with applicable Law.

(b) There are no liens for Taxes upon any of the Purchased Assets other than liens for Taxes not yet due and payable.

(c) As of the date of this Agreement, Seller is not the subject of an audit, investigation, or other proceeding relating to the payment of or failure to pay any amount of Taxes with respect to the Business or the Purchased Assets, and Seller has not received written notice from any Taxing Authority that such an audit, investigation, or other proceeding will be initiated in the future. No private letter rulings, technical advice memoranda, or similar agreement or rulings relating to Taxes have been requested, entered into or issued by any Taxing Authority with or in respect of Seller.

(d) Seller has not entered into an agreement or waiver extending any statute of limitations relating to the assessment, payment or collection of a material amount of Taxes that that is currently in effect.

(e) All Taxes required to be deducted or withheld and paid in connection with amounts paid or owing to any current or former employee, independent contractor, partner, member, manager, creditor, equity holder or other Person or by Seller have been so deducted or withheld and timely paid over to the appropriate Taxing Authority, and all associated reporting and recordkeeping requirements have been complied with in all material respects.

(f) No claim has been made to Seller by any Taxing Authority in a jurisdiction where Seller does not file Tax Returns that Seller is subject to taxation by or required to file Tax Returns in that jurisdiction.

(g) Seller has not been a member of an “affiliated group” within the meaning of Section 1504(a) of the Code filing a consolidated federal income Tax Return or any other group filing or required to file Tax Returns on a combined, consolidated or unitary basis. Seller is not party to any Contract relating to Tax sharing or Tax allocation. Seller has no Liability for the Taxes of any Person under Treasury Regulation 1.1502-6 (or any similar provision of state, local or foreign Law), as a transferee or successor, by Contract or otherwise.

(h) Seller has not received any prepaid amount that has been deferred pursuant to Section 451(c) of the Code, Revenue Procedure 2004-34, 2004-22 I.R.B. 991 or otherwise.

(i) Seller has not been a party to a transaction that is or is substantially similar to a “listed transaction” as defined in Treasury Regulation Section 1.6011-4(b).

(j) No closing agreements, private letter rulings, technical advice memoranda or similar agreements or rulings related to Taxes have been entered into, issued by or requested from any Taxing Authority with or in respect of the Business or the Purchased Assets.

(k) Neither the execution and delivery of this Agreement by Seller nor the consummation of the Contemplated Transactions (alone or together with any other event) will give rise to any payments or benefits that would be nondeductible by the payor under Section 280G of the Code.

Section 3.10 FDA Regulatory Matters.

(a) To Seller’s Knowledge, Seller has conducted all Exploitation of Products in material compliance with applicable Laws, including, as applicable, the FDCA, the PHSA, good laboratory practices, good clinical practices, and good manufacturing practices, and all similar applicable Laws of any jurisdiction (collectively, “FDA Laws”).

(b) To Seller’s Knowledge, all ongoing and completed preclinical studies of any Product and Clinical Trials conducted by Seller have been conducted in all material respects in accordance with all FDA Laws and preclinical study and Clinical Trial protocols. No Clinical Trial conducted by or on behalf of Seller has been placed on full or partial clinical hold or terminated or suspended prior to completion. Seller has not received any notice that any Governmental Authority, investigator, or any review board has, in each case with respect to any Product: (a) refused to approve any preclinical study or Clinical Trial or any substantial amendment to a protocol for any preclinical study or Clinical Trial conducted or proposed to be conducted by Seller; (b) initiated, or threatened to initiate, any action to suspend any preclinical study or Clinical Trial conducted by or on behalf of Seller, or suspend or terminate any application for any Regulatory Approval, or otherwise restrict or delay the preclinical study; or (c) alleged that any preclinical study or Clinical Trial conducted Seller is in violation of FDA Laws.

(c) Seller has not received any notice or other correspondence from any Governmental Authority of any pending or threatened claim, suit, proceeding, hearing, enforcement, audit, investigation, or arbitration alleging potential or actual noncompliance by or liability of Seller under any FDA Laws or threatening to withdraw or suspend any Regulatory

Approval or IND Clearance. Seller has not received any notices or other correspondence from any Governmental Authority or review board with respect to the Exploitation of any Product which could prevent Seller from conducting such activities substantially in the manner presently performed or contemplated by Seller and, to Seller's Knowledge, no Governmental Authority, review board or similar body has threatened any such action.

(d) Seller has filed, maintained, and furnished all material reports, documents, registrations, applications, filings, authorizations, claims, and notices required to be filed, maintained, or furnished to FDA or any other Regulatory Authority.

(e) Seller has not received from any Governmental Authority any warning letter, untitled letter, FDA Form 483, prohibition notice, recall notice or equivalent in any jurisdiction with respect to any Product, or any written notice of any pending or threatened civil, criminal, administrative or regulatory claim, suit, proceeding, hearing, enforcement, audit, investigation, arbitration, inquiry, search warrant, subpoena (other than those related to actions against third parties), and there is not pending any allegation that any operation or activity performed by of Seller is in violation of any FDA Laws.

(f) To Seller's Knowledge, Seller has not made any untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to any Product, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority with respect to any Product, or committed an act, made a statement, or failed to make a statement with respect to any Product that could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities," set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous applicable Laws.

(g) Seller is not debarred, has not been convicted, and is not subject to debarment or conviction pursuant to Section 306 of the FDCA or any similar Law. Seller has not used in connection with the Exploitation of any Product, any employee, agent, or independent contractor who has been debarred, or, to Seller's Knowledge, has been convicted or is the subject of debarment proceedings pursuant to Section 306 of the FDCA or any similar Laws.

(h) Notwithstanding the foregoing, Seller expressly disclaims, and makes no representation with respect to, any actions taken by or on behalf of UPenn.

Section 3.11 Product Inventory.

(a) Annex 1.1(b) sets forth, as of the date hereof, a list of all Product Inventory.

(b) To Seller's Knowledge, the Product Inventory was manufactured in accordance with the applicable specifications and all applicable Laws, including current good manufacturing practices.

Section 3.12Brokers and Other Advisors. No broker, investment banker, financial advisor or other Person is entitled to any broker's, finder's, financial advisor's or other similar fee or commission in connection with the Contemplated Transactions based upon arrangements made by or on behalf of Seller.

Section 3.13Solvency. Seller (a) is able to pay its debts as they become due, (b) is solvent and will be solvent immediately following the Closing, (c) immediately following the Closing, will possess sufficient assets to discharge its Liabilities, and (d) will, prior to any distribution to members, discharge such Liabilities. Seller is not engaged in business or a transaction, and it is not about to engage in business or a transaction, for which its remaining assets and capital are or will be insufficient to discharge such Liabilities. Seller does not intend to incur, or believe that it will incur, Liabilities that would be beyond its ability to pay as such Liabilities matured. Seller has not entered into this Agreement for the purpose of hindering, delaying or defrauding its creditors.

Section 3.14Contracts.

(a) As to Seller, and, to Seller's Knowledge, as to any third party, as of the date of this Agreement, each Assigned Agreement is Enforceable in accordance with its terms against Seller and will be Enforceable on identical terms as of immediately following the consummation of the Contemplated Transactions.

(b) A true, correct and complete copy of each Assigned Agreement has been made available to Buyer and its Representatives. There is no violation, breach, default or delay under any Assigned Agreement by Seller or, to Seller's Knowledge, by any other party thereto, and no event has occurred or condition exists that with the lapse of time or the giving of notice or both would constitute a default thereunder by Seller or, to Seller's Knowledge, any other party thereto, and Seller has not received or given notice of any default or claimed or purported or alleged default or state of facts which, with notice or lapse of time or both, would constitute a default on the part of any party in the performance or payment of any Assigned Agreement. No notice, waiver, consent or approval is required (or the lack of which would give rise to a right of termination, cancellation or acceleration of, or entitle any party to accelerate, whether after the giving of notice or lapse of time or both, any obligation under any Assigned Agreement) under or relating to any Assigned Agreement in connection with the execution, delivery and performance of this Agreement or the consummation of the Contemplated Transactions. Each Assigned Agreement was entered, and performance under each Assigned Agreement has been, in compliance with all applicable Law, and there is no Action with respect to the entry or performance under any Assigned Agreement, nor is there, to Seller's Knowledge, any fact, circumstance or condition on the basis of which any such Action could be brought in the future.

Section 3.15Affiliate Transactions. No manager, member, officer, director, employee, equity holder or other Affiliate of Seller, or any individual related by blood, marriage or adoption to any such Person or entity, or to Seller's Knowledge, any entity in which any such Person or entity owns any beneficial interest, is a party to any Contract or transaction relating to the Purchased Assets.

Section 3.16No Other Representations or Warranties. THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS ARTICLE III (AS MODIFIED BY THE SELLER DISCLOSURE LETTER OR ANY ANNEX), IN ANY RELATED DOCUMENT TO WHICH SELLER IS A PARTY OR IN ANY CERTIFICATE DELIVERED HERETO OR THERETO, CONSTITUTE THE EXCLUSIVE REPRESENTATIONS AND WARRANTIES OF SELLER IN CONNECTION WITH, ARISING OUT OF, OR WITH RESPECT TO, THE CONTEMPLATED TRANSACTIONS.

Section 3.17Non-Reliance. SELLER HEREBY ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES CONTAINED IN ARTICLE IV OF THIS AGREEMENT, THE OTHER RELATED DOCUMENTS TO WHICH BUYER IS A PARTY AND EACH BUYER REPRESENTATION LETTER (IN EACH CASE, OR IN ANY CERTIFICATE DELIVERED THERETO), NEITHER BUYER NOR ANY OTHER PERSON ON BEHALF OF BUYER MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WITH RESPECT TO BUYER, AND (SUBJECT TO THE EXPRESS REPRESENTATIONS AND WARRANTIES OF BUYER SET FORTH IN ARTICLE IV OF THIS AGREEMENT, THE OTHER RELATED DOCUMENTS TO WHICH BUYER IS A PARTY AND EACH BUYER REPRESENTATION LETTER (IN EACH CASE, OR IN ANY CERTIFICATE DELIVERED THERETO), IN EACH CASE, AS QUALIFIED AND LIMITED BY THE BUYER DISCLOSURE SCHEDULES, SELLER HAS NOT RELIED ON ANY SUCH INFORMATION (INCLUDING THE ACCURACY OR COMPLETENESS THEREOF). NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT, INCLUDING IN THIS SECTION 3.17, SHALL LIMIT THE RIGHTS OF SELLER TO BRING A CLAIM FOR FRAUD.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller as follows:

Section 4.1Organization, Standing and Power. Buyer is a corporation duly organized and validly existing under the Laws of the State of Delaware and has all requisite corporate power and authority to carry on its business as now being conducted, except where the failure to have such power or authority or possess such governmental licenses, permits, authorizations or approvals, individually or in the aggregate, has not been and would not reasonably be expected to be material to Buyer, taken as a whole. Buyer is duly qualified or licensed to do business and is in good standing (in jurisdictions that recognize the concept of good standing) in each jurisdiction in which the nature of its business or the ownership, leasing or operation of its properties makes such qualification or licensing necessary, other than in such jurisdictions where the failure to be so qualified or licensed or to be in good standing individually or in the aggregate has not been and would not reasonably be expected to be material to Buyer.

Section 4.2Authority; Noncontravention.

(a) Buyer has all requisite corporate power and authority to execute and deliver this Agreement and the Related Documents and to consummate the Contemplated Transactions. The execution and delivery of this Agreement and the Related Documents by Buyer and the consummation by Buyer of the Contemplated Transactions have been duly authorized by all necessary corporate action on the part of Buyer and no other corporate proceedings on the part of Buyer are necessary to authorize this Agreement, the Related Documents or to consummate the Contemplated Transactions. Each of this Agreement and the Related Documents has been duly executed and delivered by Buyer and, assuming the due authorization, execution and delivery by Seller, constitutes an Enforceable obligation of Buyer in accordance with its terms.

(b) The execution and delivery of this Agreement and the Related Documents by Buyer do not, and the consummation of the Contemplated Transactions and compliance by Buyer with the provisions of this Agreement and the Related Documents will not, conflict with, or result in any violation or breach of, or default (with or without notice or lapse of time, or both) under, or give rise to a right of, or result in, termination, cancellation or acceleration of any obligation or to the loss of a benefit under, or result in the creation of any Lien in or upon any of the properties or other assets of Buyer under (i) the certificate of incorporation or bylaws of Buyer, (ii) any Contract to which Buyer is a party or any of its respective properties or other assets is subject or (iii) any Law or Order, except in the cases of clauses (ii) and (iii), where the conflict, violation, breach, default, termination, cancellation, acceleration or creation of a Lien, individually or in the aggregate, would prevent, materially impede or materially delay the consummation by Buyer of the Contemplated Transactions (including the payments required to be made pursuant to Article II).

(c) No consent, approval, Order or authorization of, action by or in respect of, or registration, declaration or filing with, any Governmental Authority is required by or with respect to Buyer in connection with the execution and delivery of this Agreement by Buyer or the consummation by Buyer of the Contemplated Transactions.

Section 4.3 Buyer Capitalization; Valid Issuance.

(a) The authorized capital stock of Buyer consists of 120,000,000 shares of Solid Shares and 10,000,000 shares of Solid Preferred Stock. Buyer's disclosure of its issued and outstanding capital stock in its most recent SEC Filing containing such disclosure was accurate in all material respects as of the date indicated in such SEC Filing.

(b) All of the outstanding shares of Solid Capital Stock have been duly authorized and validly issued and are fully paid, non-assessable; none of such shares were issued in violation of any preemptive rights or similar rights; and such shares were issued in compliance in all material respects with applicable state and federal securities laws and any rights of third parties. Except for (a) stock options and restricted stock units approved pursuant to Buyer stock-based compensation plans described in the SEC Filings and (b) warrants disclosed in the SEC Filings, there are no outstanding warrants, options, convertible securities or other rights, agreements or arrangements of any character under which Buyer is or may be obligated to issue any equity securities of any kind, except as contemplated by this Agreement.

Section 4.4Financing. Buyer has, and at the Closing shall have, sufficient funds, funding options and/or existing liquidity facilities to permit Buyer to consummate the Contemplated Transactions, and with respect to the payment of Royalties and Milestone Consideration, as of the date hereof, Buyer has sufficient funds, funding options and existing liquidity facilities to permit Buyer to pay each Royalty and Milestone Consideration if, as and when payable.

Section 4.5Litigation. As of the date of this Agreement, there is no Action pending (or, to the knowledge of Buyer, threatened in writing) against Buyer that would, or would be reasonably likely to materially delay, restrain, prevent, enjoin or otherwise prohibit the execution, delivery and performance by Buyer of this Agreement and the Contemplated Transactions.

Section 4.6No Buyer Vote Required. No vote or action of the stockholders of Buyer is required by applicable Law, the Buyer Charter or otherwise, in order for Buyer to consummate the Contemplated Transactions, including the payment or issuance of the Milestone Consideration or payment of Royalties, if and when payable or issuable in accordance with and subject to Section 2.6 and Section 2.7, respectively.

Section 4.7Issuance of Solid Shares. The issuance and delivery of Solid Shares in accordance with this Agreement has been, or will be prior to such issuance, duly authorized by all necessary corporate action on the part of Buyer and, when issued as contemplated hereby, such Solid Shares shall be duly and validly issued, fully paid and nonassessable. Such Solid Shares when so issued and delivered in accordance with the provisions of this Agreement, shall be free and clear of all Liens, other than restrictions on transfer created by applicable securities Laws or the terms of this Agreement and will not have been issued in violation of applicable Laws, applicable Nasdaq rules or regulations, or any preemptive rights or rights of first refusal or similar rights.

Section 4.8Financial Statements. The financial statements included in each SEC Filing filed prior to the date hereof comply in all material respects with applicable accounting requirements and the rules and regulations of the SEC with respect thereto as in effect at the time of filing (or to the extent corrected by a subsequent restatement) and present fairly, in all material respects, the consolidated financial position of Buyer as of the dates shown and its consolidated results of operations and cash flows for the periods shown, subject in the case of unaudited financial statements to normal, immaterial year-end audit adjustments, and such consolidated financial statements have been prepared in conformity with GAAP (except as may be disclosed therein or in the notes thereto, and except that the unaudited financial statements may not contain

all footnotes required by GAAP, and, in the case of quarterly financial statements, except as permitted by Form 10-Q under the Exchange Act). Except as set forth in the financial statements of Buyer included in the SEC Filings filed prior to the date hereof, Buyer has not incurred any liabilities, contingent or otherwise, except those incurred in the ordinary course of business, consistent (as to amount and nature) with past practices since the date of such financial statements.

Section 4.9Compliance with Nasdaq Continued Listing Requirements. Buyer is in compliance with all applicable Nasdaq continued listing requirements as of the date hereof.

Section 4.10SEC Filings; Securities Law and Other Matters.

(a) Buyer has filed or furnished, as applicable, on a timely basis, all reports, schedules, forms, statements and other documents required to be filed by Buyer under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the three-year period preceding the date hereof (collectively, the “SEC Filings”). At the time of filing thereof, the SEC Filings complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the SEC thereunder, and none of the SEC Filings, when filed or furnished, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading.

(b) Buyer is eligible to register securities on Form S-3 under the Securities Act.

(c) The Solid Shares are registered pursuant to Section 12(b) of the Exchange Act and are listed on Nasdaq and Buyer has taken no action designed to, and will not take any action to, terminate the registration of the Solid Shares under the Exchange Act or delisting the Solid Shares from Nasdaq in a manner intended to deprive Seller of any consideration payable to Seller in respect of such shares, nor has Buyer received any notification that the SEC or Nasdaq is contemplating terminating such registration or listing.

Section 4.11No Other Representations or Warranties. THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS ARTICLE IV (AS MODIFIED BY THE BUYER DISCLOSURE LETTER OR ANY ANNEX), IN ANY RELATED DOCUMENT TO WHICH BUYER IS A PARTY OR IN ANY CERTIFICATE DELIVERED HERETO OR THERETO, CONSTITUTE THE EXCLUSIVE REPRESENTATIONS AND WARRANTIES OF BUYER IN CONNECTION WITH, ARISING OUT OF, OR WITH RESPECT TO, THE CONTEMPLATED TRANSACTIONS.

Section 4.12Non-Reliance. BUYER HEREBY ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES CONTAINED IN ARTICLE III OF THIS AGREEMENT, THE OTHER RELATED DOCUMENTS TO WHICH SELLER IS A PARTY AND EACH SELLER REPRESENTATION LETTER (IN EACH CASE, OR IN ANY CERTIFICATE DELIVERED THERETO), NEITHER SELLER NOR ANY OTHER PERSON ON BEHALF OF SELLER MAKES ANY EXPRESS OR IMPLIED REPRESENTATION OR WARRANTY WITH RESPECT TO SELLER, AND (SUBJECT TO THE EXPRESS REPRESENTATIONS AND WARRANTIES OF SELLER SET FORTH IN ARTICLE III OF THIS AGREEMENT, THE OTHER RELATED DOCUMENTS TO WHICH SELLER IS A PARTY AND EACH SELLER REPRESENTATION LETTER (IN EACH CASE, OR IN ANY CERTIFICATE DELIVERED THERETO), IN EACH CASE, AS QUALIFIED AND LIMITED BY THE SELLER DISCLOSURE SCHEDULES, BUYER HAS NOT RELIED

ON ANY SUCH INFORMATION (INCLUDING THE ACCURACY OR COMPLETENESS THEREOF). NOTWITHSTANDING THE FOREGOING, NOTHING IN THIS AGREEMENT, INCLUDING IN THIS SECTION 4.12, SHALL LIMIT THE RIGHTS OF BUYER TO BRING A CLAIM FOR FRAUD.

ARTICLE V

ADDITIONAL AGREEMENTS

Section 5.1 Diligence Efforts. Buyer, itself or through its Affiliates or licensees, will use Commercially Reasonable Efforts to develop and seek Regulatory Approval for at least one Product in the Field in each of the US Territory and the European Territory and, to the extent that Regulatory Approval is received in the US Territory or the European Territory, to commercialize such Product in the Field in such territory. Buyer shall not knowingly take any action (or fail to take any action) for the primary purpose of avoiding (a) the achievement of any of the Milestone Event or (b) payment of any Milestone Consideration.

Section 5.2 Anti-Shelving. In the event Buyer and its Affiliates cease all research, development, and commercialization activities and other Exploitation with respect to any Product for a period of at least **[**]**, and such cessation is not due to a fact, circumstance or requirement outside of Buyer's reasonable control, including a requirement of a Regulatory Authority, such cessation shall be deemed a material breach of Section 5.1, and Seller shall have the right to exercise the Reversion Rights provided in Section 5.11.

Section 5.3 Joint Steering Committee.

(a) Establishment and Responsibilities. The Parties will establish a joint steering committee ("JSC") within **[**]** following the Closing Date. The JSC will (i) serve as a forum for the exchange of information regarding the development of the FA Asset and Products, and (ii) oversee the conduct of the Technology Transfer.

(b) Membership. The JSC will consist of an equal number of representatives for each Party, with at least **[**]** representatives appointed by each Party. A Party may change any of its representatives on the JSC at any time with a new person (with appropriate expertise to replace the outgoing member) by giving written notice to the other Party. One member of the JSC will serve as secretary of the JSC at each JSC meeting, and the secretary will alternate from meeting to meeting between a Seller member and a Buyer JSC member.

(c) Meetings. Once established, the JSC will meet as frequently as Seller and Buyer mutually agree upon as appropriate, but no less than **[**]** per calendar year. Meetings of the JSC will be effective only if at least one (1) representative of each Party is present or participating. The JSC may meet either (i) in person at either Party's facilities (alternating between the facilities of Seller and Buyer) or at such locations as the Parties may otherwise agree or (ii) by audio or video teleconference. Other representatives of each Party may attend meetings as non-voting participants, subject to the confidentiality provisions set forth in Section 5.5.

(d) Authority; Decision-Making. The JSC will serve as a forum for exchange of information relating to the development of the FA Asset and Products, and will have no decision-making authority. The JSC will not have any power to (i) modify or amend the terms and conditions of this Agreement, (ii) waive either Party's compliance with, or determine that either Party has or has not fulfilled, the terms and conditions of this Agreement, or (iii) determine any issue in a manner that would conflict with, expand, or reduce the express terms and conditions of this Agreement. Buyer shall consider any comments and recommendations from Seller's members of the JSC in good faith.

(e) Exchange of Information. Buyer will keep Seller reasonably informed as to its progress and activities in material aspects relating to the development of the Product in the Territory, by way of updates to JSC at their meetings. In connection therewith, Buyer will provide to Seller high-level progress reports in the form and containing the same substance as provided to UPenn under the UPenn License (with the same frequency as provided thereto), within [**] following the provision of such reports to UPenn.

(f) Discontinuation. The JSC will disband and will have no further authority hereunder upon the completion of the [**].

(g) Expenses. Each Party will be responsible for all of its own expenses incurred in connection with participating in the JSC meetings.

Section 5.4 Technology Transfer and Assistance.

(a) Technology Transfer. Seller will transfer or make available to (or will use commercially reasonable efforts to cause its vendors and contractors to transfer or make available to, as applicable), Buyer or its designee (i) all Books and Records described on Annex 1.1(a), (ii) all Product Inventory set forth on Annex 1.1(b), (iii) all tangible embodiments of the Seller Intellectual Property set forth on Annex 1.1(c) and (iv) the FA Asset sequence set forth on Annex 1.1(d), in each case, to the extent within Seller's possession and control, promptly following the Closing Date, and in no event more than [**] after the receipt of the consideration set forth in Section 2.5(d) (the "Technology Transfer"). Seller will effect the Technology Transfer to Buyer (or its applicable designee(s)), through the method of delivery reasonably agreed upon by Seller and Buyer in advance of the Closing, which shall be through (x) electronic delivery or (y) access to Seller's "data room" or other cloud-based storage software (in the case of (x) and (y), all electronically stored files within Seller's possession and control must be able to be downloaded by Buyer, and any documents that may require edits or modifications upon transfer to Buyer shall be provided in Microsoft Word format).

(b) Assistance. From the Closing Date until the later of (i) the date of IND Clearance for the first Product by the FDA or (ii) the date that is [**] following the Closing Date, Seller will make available to Buyer or its designees such personnel of Seller as may reasonably be requested by Buyer to assist Buyer in connection with understanding the content, or implementing or using the content, of the Technology Transfer. In addition, at the request of Buyer, Seller will use reasonable efforts to facilitate the (i) cooperation of any Seller vendor or contractor in

connection with providing such assistance and (ii) UPenn's [**], in the case of clause (ii), to the extent not completed prior to the Closing Date.

Section 5.5 Confidentiality; Non-Solicitation.

(a) Confidentiality.

(i) Each of Buyer and Seller acknowledges that the information provided to them in connection with this Agreement and the consummation of the Contemplated Transactions is subject to the terms of the Confidentiality Agreement. Effective upon, and only upon, the Closing, the Confidentiality Agreement will terminate with respect to information included in or related to the Purchased Assets, and such information will be deemed to have been provided under this Agreement and subject to this Section 5.5.

(ii) For purposes of this Agreement, "Confidential Information" will include any and all confidential or proprietary information, whether or not patentable and in any form (written, oral, photographic, electronic, magnetic, or otherwise), including information of Third Parties, that a Party (or an Affiliate or representative of such Party) discloses or otherwise makes available to the other Party (or to an Affiliate or representative of such Party) in connection with this Agreement. Notwithstanding the foregoing, any information, knowledge and data contained or included in the Purchased Assets or related to the Business, including Seller Intellectual Property, will be the Confidential Information of Buyer, regardless of which Party is the disclosing Party with respect to such information, knowledge or data. The terms and conditions of this Agreement will be the Confidential Information of both Parties.

(iii) Each Party agrees that, for a period of [**] following receipt of Confidential Information, it will keep confidential and will not publish or otherwise disclose and will not use for any purpose other than as provided for in this Agreement or any Reversion Agreement (including for the exercise of the rights granted to such Party hereunder) any Confidential Information of the other Party, except to the extent expressly agreed in writing by the other Party. The foregoing confidentiality and non-use obligations will not apply with respect to any information that the receiving Party can demonstrate by competent written proof:

(A) was in the lawful knowledge and possession of the receiving Party prior to the time it was disclosed by the disclosing Party to the receiving Party, or was otherwise developed independently by or for the receiving Party without use of or reference to the disclosing Party's Confidential Information, as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by the receiving Party;

(B) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party;

(C) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; or

(D) was disclosed to the receiving Party, other than under an obligation of confidentiality, by a Third Party who, to the knowledge of the receiving Party, had no obligation to the disclosing Party not to disclose such information to others.

(iv) If a Party is required by applicable Law or judicial or administrative process to disclose Confidential Information that is subject to the non-disclosure provisions of this Section 5.5(a), such Party may disclose such Confidential Information as so required; provided, that such Party will to the extent reasonably practicable inform the other Party of the disclosure that is being sought in order to provide such other Party an opportunity to challenge or limit the disclosure obligations, and, if requested by the other Party, cooperate in all reasonable respects with the other Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure. Confidential Information that is disclosed as required by applicable Law or by judicial or administrative process will remain otherwise subject to the confidentiality and non-use provisions of this Section 5.5(a), and the Party so disclosing Confidential Information will (A) take all steps reasonably necessary to endeavor to ensure the continued confidential treatment of such Confidential Information and (B) disclose such Confidential Information only to the extent required by such applicable Law or judicial or administrative process.

(v) Notwithstanding anything to the contrary in this Section 5.5(a), the receiving Party may disclose the disclosing Party's Confidential Information if and to the extent such disclosure is reasonably necessary in the following instances: (A) to its actual or potential acquirors, investors, lenders or other similar sources of financing solely for the purpose of evaluating or carrying out an actual or potential investment, loan, financing or acquisition; (B) to its Affiliates, employees, consultants, agents, and, in the case of Buyer, actual or potential licensees or contractors to exercise its rights or perform its obligations in accordance with the terms of this Agreement; and (C) to its external attorneys, independent accountants or financial advisors solely for the purpose of enabling such attorneys, independent accountants or financial advisors to provide advice to it with respect to this Agreement or the activities contemplated hereunder; provided, that in each case ((A) through (C)) such Person is subject to a written agreement containing obligations of confidentiality and non-use at least as stringent as those herein (or without such agreement for recipients that are financial or legal advisors under a professional code of conduct giving rise to an expectation of confidentiality and non-use at least as restrictive as those set forth in this Agreement), and where the applicable disclosure is of the terms of this Agreement, each Party will redact confidential or commercially sensitive information or other information that is not relevant to the purpose of the applicable disclosure.

(b) Non-Solicitation. Seller agrees that for a period of **[**]** commencing upon the Closing Date, Seller will not, directly or indirectly, recruit or otherwise solicit any employee of Buyer or any of its Affiliates (each, a "Business Partner") to terminate or diminish its employment relationship with Buyer or any of its Affiliates after the Closing; provided, (i) nothing herein shall prohibit Seller from hiring, retaining, employing or otherwise engaging, or attempting to hire, retain, employ or engage, any Business Partner who was terminated by Buyer or its Affiliates at least **[**]** prior to Seller's initial contact with such Business Partner for the purpose of attempting to hire, retain, employ or otherwise engage such Business Partner, and (ii) placing a

general solicitation, advertisement or posting not targeting the employees, independent contractors or consultants of Buyer or its Affiliates.

(c) Injunctive Relief. Each Party understands that a breach of this Section 5.4 by the other Party may cause irreparable harm which may not be adequately compensated by money damages. Accordingly, in the event of a breach or threatened breach by either Party of this Section 5.4, the non-breaching Party or, as applicable, any of its Affiliates will be entitled to seek injunctive or other equitable relief to enforce the provisions hereof (without need to post bond), in addition to and not in the alternative to such other remedies to which such Party or its Affiliates may be entitled, including the recovery of money damages.

Section 5.6Certain Tax Matters.

(a) Transfer Taxes. All recordation, transfer, documentary, sales, value added, use, stamp, conveyance or other similar Taxes, duties or governmental charges, and all recording or filing fees or similar costs, imposed or levied by reason of, in connection with or attributable to this Agreement or the Acquisition (collectively, "Transfer Taxes") will be borne equally between Seller and Buyer. Transfer Taxes will be timely paid, and all applicable filings, reports and returns will be filed, as provided by applicable Law. The paying Party (if not specified as the responsible Party therefor) will be entitled to reimbursement from the non-paying Party in accordance with this Section 5.6(a).

(b) Proration of Taxes. All real and personal property Taxes, and other *ad valorem* Taxes with respect to the Purchased Assets for a taxable period that includes (but does not end on) the Closing Date will be prorated on a *per diem* basis between Seller and Buyer on the Closing Date.

(c) Tax Withholding. Buyer and any other applicable withholding agent will be entitled to deduct and withhold, or cause to be deducted and withheld, from any amounts payable pursuant to or as contemplated by this Agreement or any Related Document any Taxes or other amounts required under the Code or any applicable Law to be deducted and withheld. To the extent that any such amounts are so deducted or withheld and properly remitted to the appropriate Taxing Authority, such amounts will be treated for all purposes of this Agreement and any Related Document as having been paid to the Person in respect of which such deduction and withholding was made. Notwithstanding anything to the contrary in this Agreement, any compensatory amounts payable pursuant to or as contemplated by this Agreement will be remitted by the applicable payer to the applicable employer for payment through such employer's payroll procedure in accordance with applicable Law.

(d) Cooperation and Exchange of Information. To the extent relevant to the Business or the Purchased Assets, each of Seller and Buyer will (i) provide the other with such assistance as may reasonably be requested by the other Party in connection with the preparation of any Tax Return, audit or other examination by any Taxing Authority or Action relating to liability for Taxes in connection with the Business or the Purchased Assets, (ii) retain (for a period of [**] after the Closing) and provide the other with any records or other information that may be relevant

to such Tax Return, audit or examination, Action or determination and (iii) provide the other with any final determination of any such audit or examination, Action or determination that affects any amount required to be shown on any Tax Return of the other for any period.

Section 5.7Public Announcements. Seller and its Affiliates will not issue any press release or otherwise make any public statement with respect to the provisions of this Agreement or the Contemplated Transactions without the prior written consent of Buyer. Buyer or its Affiliates may issue a press release or otherwise make any public statement with respect to the provisions of this Agreement or the Contemplated Transactions without the prior written consent of Seller, as long as Buyer provides Seller with (i) a copy of such press release or public statement prior to the issuance thereof and (ii) a reasonable opportunity to comment thereon, which comments Buyer will consider in good faith. Notwithstanding anything to the contrary in this Agreement or any Related Document, either Party may issue a press release or make a public statement with respect to the Contemplated Transactions as may be required by Law or any listing agreement with any applicable securities exchange or market, in which case such Party shall use reasonable best efforts to consult with the other Party regarding the contents thereof prior to issuing any such press release or making any such public statement or public announcement and shall consider in good faith any comments proposed by such other Party. The foregoing will not limit any non-public equity holder communication of either Party or any disclosure made in connection with a court pleading.

Section 5.8Expenses; UPenn IND Payment.

(a) Except as expressly set forth herein, each of Seller and Buyer will bear its own costs and expenses incurred in connection with this Agreement and the Contemplated Transactions.

(b) Following a UPenn IND Payment becoming due pursuant to the Second UPenn Amendment, Buyer will provide an invoice to Seller and Seller will promptly, but in any event within [**] of receipt of such invoice or notice, pay such UPenn IND Payment directly to UPenn by wire transfer of immediately available funds.

Section 5.9Further Assurances and Approvals.

(a) Seller will at any time and from time to time after the Closing Date and for no further consideration, upon the request of Buyer, execute, acknowledge, deliver and file, or cause to be done, executed, acknowledged, delivered or filed, all such further acts, deeds, transfers, conveyances, assignments or assurances as may be reasonably required for the better transferring, conveying, assigning, assuring and vesting to and in Buyer, or for the aiding and assisting in the reducing to possession by Buyer of, Seller's right, title and interest in and to any of the Purchased Assets or Assumed Liabilities, or as may otherwise be necessary to carry out the purposes of this Agreement and the Related Documents and the consummation of the Contemplated Transactions (including transferring (or upon Buyer's request, providing Buyer or its Affiliates with access to the premises or systems of Seller to so transfer), at no additional cost to Buyer, Seller's right, title

and interest in and to any Purchased Asset or Assumed Liability contemplated by this Agreement to be transferred to Buyer at the Closing and that was not so transferred at the Closing).

(b) If, after the Closing, Buyer or any of its Affiliates possesses any Excluded Asset, Buyer will, or will cause its Affiliates to, transfer such asset to Seller at no cost to Seller. If, after the Closing, Seller or any of its Affiliates possesses any Purchased Asset, Seller will, or will cause its Affiliates to, transfer such asset to Buyer at no cost to Buyer.

(c) From and after the Closing, Seller will refer all inquiries and other communications (whether written or oral) in respect of the Business to Buyer, and will promptly inform Buyer of such inquiries and communications. At Buyer's request, Seller will reasonably cooperate with Buyer to facilitate Buyer's communication with such Person's inquiry or other communication in respect of the Business.

Section 5.10 Lock-Up.

(a) During each period commencing on the date on which Buyer has received all of the following from Seller: (i) a Milestone Invoice, (ii) all necessary documentation from Seller reasonably required by Buyer to issue the Solid Shares (including, without limitation, "live validation" and all account and other similar information required by Buyer to transfer the Solid Shares to Seller) and (iii) in the case of the First Stock Consideration Issuance, Seller's delivery of a signature page to the Voting Rights Agreement; and ending on the earlier of (A) the date that is **[**]** following such date or (B) the date upon which Buyer files for, or becomes subject to a proceeding for, bankruptcy, reorganization, liquidation, dissolution or similar process (each, a "Lock-Up Period"), Seller will not directly or indirectly, in any single transaction or series of related transactions, sell, assign, pledge, hypothecate or otherwise transfer (or enter into an obligation or agreement regarding the future sale, assignment, pledge or transfer of) (a "Transfer") (I) more than **[**]** of the aggregate Solid Shares then held by Seller during the first **[**]** of the Lock-Up Period, or (II) more than **[**]** of the remaining aggregate Solid Shares then held by Seller during any subsequent **[**]** period of the Lock-Up Period, in either case ((I) or (II)), other than (1) any Transfer of Solid Shares by Seller to an Affiliate of Seller, (2) any Transfer required by Law or (3) any Transfer that has been approved in advance by the Board of Directors of Buyer or a duly authorized committee thereof. Any attempted Transfer in violation of this Section 5.10 will be of no effect and null and void, regardless of whether the purported transferee has any actual or constructive knowledge of the Transfer restrictions set forth herein. For the avoidance of doubt, a new Lock-Up Period with respect to the Solid Shares held by Seller will commence after any payment by Buyer to Seller of Milestone Shares as Milestone Consideration pursuant to Section 2.6.

(b) Following the Lock-Up Period, Seller will be entitled to Transfer any Solid Shares in its sole discretion, provided that Seller will not directly or indirectly, in any single transaction or series of related transactions, Transfer any Solid Shares:

(i) other than in accordance with all applicable Laws and the other terms and conditions of this Agreement; or

(ii) to a Person who has filed or is party of a “group” (as defined in Section 13(d) of the Exchange Act) that has filed a Schedule 13D with the SEC in respect of Solid Shares; provided, that such restriction will not apply to Transfers (A) into the public market pursuant to a bona fide, broadly distributed public offering, in each case made pursuant to the registration rights herein, (B) through a bona fide sale into the public market without registration effectuated pursuant to Rule 144 under the Securities Act or (C) in connection with a merger, tender offer or exchange offer or other business combination, acquisition of assets or similar transaction or any change of control transaction involving Buyer (which such transaction has been approved by the Board of Directors of Buyer).

Section 5.11 Reversion Rights.

(a) In the event of Buyer’s (i) material breach of its diligence obligations under Section 5.1 that remains uncured [**] after Buyer’s receipt of notice of such breach from Seller, (ii) public announcement that it intends to terminate all Exploitation of Products or (iii) written notice to Seller that it intends to terminate all Exploitation of Products, then Seller may in Seller’s sole discretion, upon written notice to Buyer (a “Reversion Notice”), elect to exercise the reversion rights set forth in this Section 5.11 (the “Reversion Rights”), effective as of the date Seller delivers the Reversion Notice to Buyer. In such event:

(i) The Parties will promptly, for a period not to exceed [**] following Buyer’s receipt of a Reversion Notice, provided that such period shall be automatically extended for an additional [**] so long as the Parties continue to negotiate in good faith (such period, the “Negotiation Period”), negotiate in good faith a written agreement (the “Reversion Agreement”) pursuant to which: (A) Buyer would transfer and assign to Seller (I) all of Buyer’s right, title and interest in and to the Purchased Assets (including the UPenn License and the Technology licensed pursuant thereto) and (II) all Regulatory Documentation and Regulatory Approvals relating to any Reversion Product(s); (B) at Seller’s election and request, Buyer would grant to Seller and its Affiliates a license under the Grant-Back Intellectual Property solely to the extent necessary for Seller and its Affiliates to Exploit any Reversion Product in the Field in the Territory, (C) Buyer would orderly wind-down or transfer, at Seller’s election, the conduct of any ongoing Clinical Trials for any Product(s), in accordance with applicable Law and taking into account patient safety matters, and (D) Buyer would transfer to Seller any Product Inventory transferred to Buyer pursuant to Section 5.4 that (I) has not been used in [**] or (II) has been used only for [**]. Without limiting the foregoing, the license grant set forth in the foregoing clause (B) will be royalty-bearing, and the Parties will negotiate in good faith a reasonable royalty on Annual Net Sales (as such term applies to the sale of Reversion Products that use or incorporate Grant-Back Intellectual Property by or on behalf of Seller or any of its Affiliates or licensees or sublicensees, *mutatis mutandis*) of such Reversion Products by or on behalf of Seller or any of its Affiliates or licensees or sublicensees in the Territory.

(ii) If Seller exercises the Reversion Right prior to the achievement of Milestone Event No. 1, Buyer will promptly pay Seller the prorated costs of any Product Inventory transferred to Buyer pursuant to clause (D) of Section 5.11(a)(i) that is not in usable condition at the time of transfer to Seller due to Buyer’s (or its Affiliates’, Subsidiaries or their respective

vendors') failure to use, store, handle, or transport such Product Inventory in accordance with applicable Law.

(iii) Notwithstanding anything to the contrary in this Section 5.11, at the request of any Third Party licensee of Buyer under the Purchased Assets, Seller will grant to such former licensee a direct license on the same terms granted to such licensee by Buyer, taking into account any difference in license scope, territory and duration of sublicense grant, provided, that (i) such former licensee is not then in default of its license agreement, (ii) agrees in writing to comply with the terms of such new license agreement and (iii) such license agreement with any such former licensee was in effect prior to the date of the Reversion Notice and was entered into on commercially reasonable terms and negotiated on an arm's length basis.

(iv) Subject to the Reversion Agreement (including any obligation set forth in the Reversion Agreement for Buyer to transfer, rather than wind-down, any ongoing Clinical Trials), Buyer will be responsible for the prompt wind-down of Buyer's, its Affiliates' and its and their licensees' Exploitation of any Reversion Product(s) in compliance with applicable Law; provided, that during the [**] period following the effective date of termination, Buyer and its Affiliates and its and their licensees will have the right to sell or otherwise dispose of all any Reversion Product(s) then in its or their respective inventory and any in-progress inventory, provided, further, that Buyer will continue to make payments to Seller on Annual Net Sales of such Reversion Product(s) in accordance with Section 2.6 and Section 2.7.

(v) Notwithstanding anything to the contrary in Section 5.11(a), if Buyer disputes in good faith the existence or materiality of a breach specified in a Reversion Notice, and Buyer provides Seller notice of such dispute within [**], then Seller will not have the Reversion Rights set forth in Section 5.11(a) unless and until it is determined in accordance with Section 7.8 that Buyer has materially breached its diligence obligations under Section 5.1 of this Agreement and has failed to cure such breach within [**] from the date of the Reversion Notice.

(b) If Seller delivers a Reversion Notice to Buyer, then Seller agrees that the Reversion Right shall be its sole and exclusive remedy for such material breach, announcement or notice, provided that the Parties enter into a Reversion Agreement as provided by Section 5.11(a) within the Negotiation Period. In the event Parties are unable to enter into a Reversion Agreement within the Negotiation Period, the delivery of a Reversion Notice to Buyer shall have no impact on, and the rights set forth in this Section 5.11 shall be in addition to any other rights or remedies to which Seller is entitled at law or in equity (including the Seller's ability to receive legal damages or equitable relief, with respect to any material breach of this Agreement).

ARTICLE VI

INDEMNIFICATION

Section 6.1 Indemnification of Buyer.

(a) Subject to the limitations set forth in this Article VI, from and after the Closing, Seller will indemnify and hold harmless each of Buyer and its Affiliates and each of their

respective officers, directors, employees, equity holders, agents, Affiliates and Representatives (each, a “Buyer Indemnified Party”) from and against, and compensate and reimburse each Buyer Indemnified Party for, the aggregate amount of any Losses incurred by such Buyer Indemnified Party, whether or not arising from, relating to or otherwise in connection with a claim of a Third Party (each, a “Third Party Claim”), as a result of, arising out of or from, directly or indirectly:

(i) any breach of or inaccuracy in any representation or warranty set forth in Article III (other than Fundamental Representations) or in any Seller Representation Letter as such representation or warranty would read had all references to “material,” “materiality,” “substantial compliance” or any similar materiality qualifications, been deleted therefrom;

(ii) any breach by Seller of any Fundamental Representation;

(iii) any breach or violation of, or failure to perform by Seller of any covenant or agreement of Seller contained in this Agreement or any Related Document or Seller Representation Letter;

(iv) any claim of Fraud committed by Seller solely in respect of (A) a breach of the representations and warranties set forth in Article III or (B) the negotiation, execution, delivery, or performance of this Agreement;

(v) any Excluded Liabilities or Excluded Assets; and

(vi) the portion of any Transfer Taxes and prorated Taxes allocated to Seller pursuant to Section 5.6.

(b) Notwithstanding anything to the contrary contained herein:

(i) no Buyer Indemnified Party will be entitled to be indemnified pursuant to Section 6.1(a)(i) unless and until the aggregate of all Losses for which the Buyer Indemnified Parties would, but for this Section 6.1(b), be entitled to indemnification hereunder exceeds on a cumulative basis \$[**] (the “Seller Indemnity Threshold”), at which time the Buyer Indemnified Parties will be entitled to be indemnified and held harmless by Seller for and against the full amount of such aggregate Losses, including the amount of the Seller Indemnity Threshold; provided, however, that the foregoing Seller Indemnity Threshold of this Section 6.1(b) will not apply to Losses for which the Buyer Indemnified Parties may be entitled pursuant to Section 6.1(a)(ii) or Section 6.1(a)(iv); and

(ii) other than Losses for which the Buyer Indemnified Parties may be entitled pursuant to Section 6.1(a)(iv) in no event will the aggregate amount of Losses for which the Buyer Indemnified Parties will be indemnified and held harmless and entitled to recover (i) under Section 6.1(a)(i) exceed [**] percent ([**]%) of the Indemnity Liability Cap; (ii) pursuant to Section 6.1(a)(ii), exceed the Indemnity Liability Cap; or (iii) under Section 6.1(a)(iii) exceed an amount equal to the Greater Liability Cap.

Section 6.2 Indemnification of Seller Indemnified Parties.

(a) Subject to the limitations set forth in this Article VI, from and after the Closing, Buyer will indemnify Seller and its Affiliates and each of their respective officers, managers, directors, employees, equity holders, agents, Affiliates and Representatives (each a “Seller Indemnified Party”) from and against, and compensate and reimburse each Seller Indemnified Party for, any Losses incurred by such Seller Indemnified Party, whether or not arising from, relating to or otherwise in connection with a Third Party Claim, as a result of, arising out of or from, directly or indirectly:

(i) any breach of or inaccuracy in any representation or warranty set forth in Article IV or in any Buyer Representation Letter, as such representation or warranty would read had all references to “material,” “materiality,” “substantial compliance” or any similar materiality qualifications, been deleted therefrom;

(ii) any breach or violation of, or failure to perform by Buyer of any covenant or agreement of Buyer contained in this Agreement or any Related Document;

(iii) any claim of Fraud committed by Buyer solely in respect of (A) a breach of the representations and warranties set forth in Article IV or (B) the negotiation, execution, delivery, or performance of this Agreement;

(iv) the portion of any Transfer Taxes and prorated Taxes allocated to Buyer pursuant to Section 5.6; and

(v) any Assumed Liabilities.

(b) Notwithstanding anything to the contrary contained herein:

(i) no Seller Indemnified Party will be entitled to be indemnified pursuant to Section 6.2(a)(i) unless and until the aggregate amount of all Losses for which Seller Indemnified Parties would, but for this Section 6.2(b)(i), be entitled to indemnification hereunder exceeds on a cumulative basis \$[**] (the “Buyer Indemnity Threshold”), at which point the Seller Indemnified Parties will be entitled to be indemnified and held harmless by Buyer for and against the full amount of such Losses, including the amount of the Buyer Indemnity Threshold; provided, however, that the foregoing Buyer Indemnity Threshold of this Section 6.2(b)(i) will not apply to Losses for which the Seller Indemnified Parties may be entitled pursuant to Section 6.2(a)(iii); and

(ii) other than Losses for which the Seller Indemnified Parties may be entitled pursuant to Section 6.2(a)(iii) in no event will the aggregate amount for which Seller Indemnified Parties will be indemnified and held harmless and entitled to recover (i) under Section 6.2(a)(i) exceed the Indemnity Liability Cap; or (ii) under Section 6.2(a)(ii), exceed an amount equal to the Greater Liability Cap. For clarity, the Greater Liability Cap will not be construed hereunder as a limitation on any payment obligation otherwise due and payable by Buyer pursuant to Section 2.6 (with respect to an achieved Milestone Event) or Section 2.7 (with respect to earned Royalties).

Section 6.3 Indemnification Claims.

(a) In order for a Buyer Indemnified Party or a Seller Indemnified Party (an “Indemnified Party”) to be entitled to any indemnification provided for under Section 6.1 or Section 6.2 in respect of, arising out of or involving a Third Party Claim, such Indemnified Party must notify, with respect to a claim for indemnification pursuant to Section 6.1, Seller, or, with respect to a claim for indemnification pursuant to Section 6.2, Buyer (each, an “Indemnifying Party”) in writing of the Third Party Claim (including in such notice a brief description of the applicable claim(s), including damages sought or estimated, to the extent actually known by such Indemnified Party) within [**] after receipt by such Indemnified Party of actual notice of the Third Party Claim; provided, however, that failure to give such notification or any deficiency in such notification will not affect the indemnification provided under Section 6.1 or Section 6.2 except to the extent that the Indemnifying Party has been actually prejudiced as a result of such failure or deficiency. The Indemnifying Party will have the right to undertake the defense or opposition to such Third Party Claim (at the Indemnifying Party’s expense) with counsel selected by it and reasonably satisfactory to the Indemnified Party so long as (i) the Indemnifying Party gives written notice to the Indemnified Party within [**] after it has been notified of the Third Party Claim that it will defend the Indemnified Party against such Third Party Claim and the Indemnifying Party acknowledges its obligation to indemnify the Indemnified Party for all Losses related to such Third Party Claim, (ii) the Third Party Claim involves only money damages and does not seek an injunction or other equitable relief against the Indemnified Party, (iii) the Third Party Claim does not relate to or arise in connection with Taxes, any purported class action, or any criminal or regulatory enforcement Action, (iv) the amount claimed in such Third Party Claim, taken together with the reasonably estimated costs of defense thereof and the claimed amount with respect to any unresolved claims for indemnification under this Article VI then pending, is (A) greater than the Seller Indemnity Threshold (if Seller is the Indemnifying Party) or the Buyer Indemnity Threshold (if Buyer is the Indemnifying Party) and (B) if applicable, less than the Indemnity Liability Cap, (v) the Indemnified Party has not been advised in writing by outside counsel that a legal conflict exists between the Indemnified Party and the Indemnifying Party in connection with conducting the defense of the Third Party Claim, (vi) the Third Party Claim does not allege the infringement of the Intellectual Property Rights of any Person by the Indemnified Party, (vii) settlement of, an adverse Order with respect to, or conduct of the defense of the Third Party Claim by the Indemnifying Party is not, in the good faith judgment of the Indemnified Party, likely to be materially adverse to the Indemnified Party’s or its Affiliates’ reputation or continuing business interests (including its relationships with current or potential customers, licensors, distributors, suppliers or other parties material to the conduct of its business) and (viii) the Indemnifying Party diligently and vigorously and in good faith conducts the defense of the Third Party Claim. The Indemnifying Party may not settle any Third Party Claim without the prior written consent of the Indemnified Party unless (1) the claimant in such Third Party Claim provides to the Buyer Indemnified Parties or Seller Indemnified Parties, as applicable, a full, general and unqualified release from all liability in respect of such Third Party Claim, (2) such settlement does not involve any injunctive relief, (3) such settlement does not create a Lien on any of the assets of the applicable Indemnified Parties or impose any restriction or condition that would apply to or materially affect the applicable Indemnified Parties or the conduct of the applicable Indemnified Parties’ businesses and (4) such settlement does not involve any finding or admission of liability or wrongdoing.

(b) In order for an Indemnified Party to be entitled to any indemnification provided for under this Agreement other than in respect of, arising out of or involving a Third Party Claim, such Indemnified Party will deliver notice of such claim to the Indemnifying Party (including in such notice a brief description of the applicable claim(s), including damages sought or estimated, to the extent actually known by such Indemnified Party); provided, however, that failure to give such notification or any deficiency in such notification will not affect the indemnification provided under Section 6.1 or Section 6.2 except to the extent that the Indemnifying Party has been actually prejudiced as a result of such failure or deficiency. If the Indemnifying Party does not notify the Indemnified Party within [**] following its receipt of such notice that the Indemnifying Party disputes the indemnity claimed by the Indemnified Party under Section 6.1 or Section 6.2, such indemnity claim specified by the Indemnified Party in such notice will be conclusively deemed a liability to be indemnified under Section 6.1 or Section 6.2 and the Indemnified Party will be indemnified for the amount of the Losses stated in such notice to the Indemnified Party on demand or, in the case of any notice in which the Losses (or any portion thereof) are estimated, on such later date when the amount of such Losses (or such portion thereof) becomes finally determined, but in all cases subject to the Seller Indemnity Threshold, the Buyer Indemnity Threshold, and the Indemnity Liability Cap, to the extent applicable. If the Indemnifying Party objects in writing to such claim, then the Indemnifying Party and Indemnified Party shall attempt in good faith to agree upon the rights of the respective parties with respect to any such claims within [**] after such objection. If the Indemnifying Party and the Indemnified Party should so agree on a claim during such [**] period, a written memorandum setting forth such agreement with respect to the Losses sought shall be prepared and signed by such parties. If no agreement can be reached after good faith negotiation between the Indemnifying Party and Indemnified Party pursuant to this Section 6.3(b), then applicable Indemnified Party shall each have the right to submit such dispute to a court of competent jurisdiction in accordance with the provisions of Section 7.8.

(c) The agreed or finally determined amount of Losses for which an Indemnified Party is responsible pursuant to this Section 6.3 shall be deemed the “Owed Damages.”

Section 6.4 Termination of Indemnification Obligations.

(a) The obligations to indemnify and hold harmless an Indemnified Party hereto (i) pursuant to Section 6.1(a)(i) (excluding with respect to the representations and warranties set forth in Section 3.6 (Intellectual Property)) and Section 6.2(a)(i) will terminate when the applicable representation or warranty terminates pursuant to Section 6.4(b), (ii) pursuant to Section 6.1(a)(i) with respect to the representations and warranties set forth in Section 3.6 (Intellectual Property), will terminate when the applicable representation or warranty terminates pursuant to Section 6.4(b), (iii) pursuant to Section 6.1(a)(ii) will terminate when the applicable representation or warranty terminates pursuant to Section 6.4(b), and (iv) pursuant to the other clauses of Section 6.1(a) and Section 6.2(a) will not terminate; provided, however, that as to clauses (i)-(iv) above such obligation to indemnify and hold harmless will not terminate with respect to any claims as to which the Indemnified Party will have, before the expiration of the applicable period, previously delivered a notice of such claim to the Indemnifying Party.

(b) All representations and warranties contained in this Agreement will survive the Closing; provided, however, that except in the case of Fraud (to the extent a Party may claim indemnification pursuant to Section 6.1(a)(iv) or Section 6.2(a)(iii), as applicable, with respect to such Fraud), (i) the Fundamental Representations will terminate on the date that is **[**]** after the expiration of the applicable statute of limitation (taking into account any tolling periods and other extensions) and (ii) the representations and warranties contained in this Agreement (other than the Fundamental Representations) will terminate on the date that is **[**]** following the Closing Date. Notwithstanding the foregoing, all representations and warranties contained in a Buyer Representation Letter or a Seller Representation Letter, as applicable, will terminate on the date that is **[**]** following the date thereof.

(c) The Parties acknowledge and agree that the time periods set forth in this Section 6.4 for the assertion of claims under this Agreement are the result of arms'-length negotiation among the Parties and that they intend for the time periods to be enforced as agreed by the Parties.

Section 6.5 Damages; Remedies.

(a) Except for any claims involving Fraud against any Person who has committed such Fraud, from and after the Closing Date, the rights set forth in this Article VI and Section 5.11 (Reversion Rights) shall be the sole and exclusive remedy of the Indemnified Parties with respect to a breach of a representation or warranty, covenant or obligation set forth in this Agreement. For clarity, the Greater Liability Cap (as applied under Article VI) will not be construed hereunder as a limitation on any payment obligation otherwise due and payable by Buyer pursuant to Section 2.6 (with respect to an achieved Milestone Event) or Section 2.7 (with respect to earned Royalties).

(b) For purposes of this Agreement, all Losses shall be calculated after giving effect to any amounts actually recovered from third parties, including amounts recovered under insurance policies (for the avoidance of doubt, excluding any self-insurance program or similar arrangement) with respect to such Losses, and net of any costs to recover such amounts. Any Losses for which indemnification is sought under this Agreement shall be determined without duplication of recovery due to the facts giving rise to such Losses forming a basis for a claim for recovery under multiple provisions of this Article VI or a breach of more than one representation, warranty, covenant or agreement.

(c) Except as otherwise set forth herein, the rights of each Indemnified Party under this Article VI are cumulative, and each Indemnified Party will have the right in any particular circumstance, in its sole discretion, to enforce any provision of this Article VI without regard to the availability of a remedy under any other provision of this Article VI.

(d) The right of any Indemnified Party to indemnification pursuant to this Article VI will not be affected by any investigation conducted or knowledge acquired (or capable of being acquired) at any time, whether before or after the execution and delivery of this Agreement or the Closing, with respect to the accuracy of any representation or warranty, or

performance of or compliance with any covenant or agreement. The waiver of any condition contained in this Agreement based on the breach of any such representation or warranty, or on the performance of or compliance with any such covenant or agreement, will not affect the right of any Indemnified Party to indemnification pursuant to this Article VI based on such representation, warranty, covenant or agreement.

Section 6.6 Right of Set-off

(a) If Buyer is entitled to indemnification for Owed Damages pursuant to Section 6.3, subject to the limitations contained in Section 6.1(b) and this Section 6.6, Buyer shall be and hereby is expressly entitled to set off and withhold the amount of any outstanding or unsatisfied indemnity claim made by a Buyer Indemnified Party or payable by Seller hereunder pursuant to this Article VI, against any payments that are or may become payable by Buyer either at the time of such setoff or at any future time to Seller pursuant to this Agreement, including any Milestone Consideration or Royalties, subject to the requirements of this Section 6.6 (which set off shall be allocated and applied against the next Milestone Consideration or the next Royalty, that is or becomes payable to Seller hereunder (if any), and if such Milestone Consideration or Royalty is insufficient to cover the full amount of Owed Damages, then Buyer shall offset such amount against each subsequent Milestone Consideration, that is or becomes payable to Seller hereunder, if any, until such Owed Damages are satisfied in full and if such Milestone Consideration is insufficient to cover the full amount of Owed Damages, then Buyer shall offset such amount against any Royalties that is or become available in the order in which such Milestone Consideration or Royalty becomes payable to Seller pursuant to the terms hereof); provided that the foregoing shall not in any manner limit the right to recover or method of recovery by Buyer of Losses hereunder.

(b) Notwithstanding anything to the contrary, Buyer must seek to recover Owed Damages as follows: (i) first, the Seller shall pay to an account designated by Buyer or the applicable Buyer Indemnified Party, an amount in cash and/or a number of Solid Shares (which Solid Shares will be valued at the VWAP (with the date of measurement being the date that the applicable Milestone Shares were issued pursuant to Section 2.6), equal to the Owed Damages, and (ii) second, if Seller fails to pay, in the aggregate, an amount in cash and/or a number of Solid Shares (which Solid Shares will be valued at the VWAP (with the date of measurement being the date that the applicable Milestone Shares were issued pursuant to Section 2.6), equal to the Owed Damages within [**], then Buyer may offset the Owed Damages from any Milestone Consideration or Royalties that become due and payable to Seller pursuant to this Agreement for the unpaid portion of the Owed Damages.

(c) If Buyer exercises its right of setoff under this Section 6.6, then Buyer will provide written notice to Seller thereof (including in such notice a summary of the applicable claim(s), including Owed Damages subject to such offset to the extent actually known by Buyer); provided, however, that failure to give such notification or any deficiency in such notification will not affect Buyer's rights under this Section 6.6. Seller must notify Buyer within [**] following its receipt of such notice that Seller disputes Buyer's right of set-off under this Section 6.6, and such amount claimed by Buyer will be held by Buyer, to be released to Buyer or Seller, as applicable,

after such dispute is finally determined in accordance with the dispute resolution procedures set forth herein. In the case of the exercise of the right to setoff against the payment of any Milestone Shares hereunder, the amount of Owed Damages which may be offset against such payment of Milestone Shares shall be determined as such number of Solid Shares equal to the applicable amount of Owed Damages divided by the VWAP for the Solid Shares (with the date of measurement being the date that the applicable claim for indemnification was made).

Section 6.7Purchase Price Adjustments. To the extent permitted by applicable Law, any amounts payable under Article VI will be treated by Buyer and Seller as an adjustment to the purchase price for United States federal income Tax purposes.

Section 6.8Indemnity Payments. In the event that an Indemnifying Party agrees to or is determined to have an obligation to reimburse an Indemnified Party for Losses as provided in this Article VI, except as otherwise set forth in Section 6.6, the Indemnifying Party will promptly pay such amount to the Indemnified Party in Dollars by wire transfer of immediately available funds to the accounts specified in writing by the Indemnified Party.

ARTICLE VII

GENERAL PROVISIONS

Section 7.1Rules of Construction. The Parties agree that they have been represented by counsel during the negotiation and execution of this Agreement and have together drafted this Agreement and, therefore, waive the application of any Law, regulation, holding or rule of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document.

Section 7.2Notices. All notices, requests, claims, demands and other communications hereunder will be given (and will be deemed to have been duly given upon receipt) (a) by hand delivery, (b) by prepaid overnight courier (providing written proof of delivery), (c) by certified or registered mail (return receipt requested and first class postage prepaid), addressed as follows (or at such other address for a Party as will be specified by like notice), or (d) by electronic mail (followed by confirmation via one of the methods set forth in the foregoing (a) - (c)):

if to Buyer, to:

Solid Biosciences Inc.
500 Rutherford Ave, 3rd Floor
Charlestown, MA 02129
Attention: General Counsel
Email: [**]

and

Ropes & Gray LLP
Prudential Tower

800 Boylston Street
Boston, Massachusetts 02199
Attention: Abigail Gregor
Email: Abigail.Gregor@ropesgray.com

if to Seller, to:

FA212 LLC
Attn: Thomas E. Hamilton
[**]

with a copy (which will not constitute notice) to:

Goodwin Procter LLP
One Commerce Square
2005 Market Street, 32nd Floor
Philadelphia, PA 19103
Attention: Rachael M. Bushey; Allison P. Nicklin
Email: RBushey@goodwinlaw.com; ANicklin@goodwinlaw.com

provided that any notice received at the addressee's location (or, if sent by electronic mail, to the appropriate email addresses set forth in this Section 7.2) on any Business Day after 5:00 p.m. (addressee's local time) will be deemed to have been received at 9:00 a.m. (addressee's local time) on the next Business Day.

Section 7.3Consents and Approvals. For any matter under this Agreement requiring the consent or approval of either Party to be valid and binding on the Party, such consent or approval must be in writing.

Section 7.4Counterparts. This Agreement may be executed in one or more counterparts (including by facsimile .pdf or other electronically transmitted signatures), all of which will be considered one and the same agreement and will become effective when one or more counterparts have been signed by each of the Parties and delivered to the other Party.

Section 7.5Entire Agreement; No Third-Party Beneficiaries. This Agreement, the Confidentiality Agreement and the other Related Documents (a) constitute the entire agreement, and supersede all prior agreements and understandings, both written and oral, among the Parties with respect to the subject matter of this Agreement, the Related Documents, and the Confidentiality Agreement and (b) other than in respect of any Indemnified Party pursuant to the terms of Article VI, are not intended to and do not confer upon any Person other than the Parties any legal or equitable rights or remedies.

Section 7.6Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder will be assigned, in whole or in part, by operation of Law or otherwise by either of the Parties without the prior written consent of the other Party, and any assignment without such consent will be null and void, except that (a) either Party may assigns any of or all

its rights, interests and obligations under this Agreement to one or more of its Affiliates or to a successor in interest in connection with a merger, acquisition, sale of all or substantially all of the assets of such party or other similar transaction, and (b) Seller may assign may assign to a Third Party its right to receive the Milestone Consideration under Section 2.6 or the Royalties under Section 2.7, provided, that the Third Party to which the right to receive payments is assigned is subject to confidentiality obligations and non-use restrictions that are substantially similar to the obligations of confidentiality and non-use set forth in Section 5.5. Subject to the preceding sentences, this Agreement will be binding upon, inure to the benefit of, and be Enforceable by, the Parties and their respective successors and assigns.

Section 7.7GOVERNING LAW. THIS AGREEMENT WILL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, REGARDLESS OF THE LAWS THAT MIGHT OTHERWISE GOVERN UNDER APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS THEREOF.

Section 7.8Dispute Resolution; Enforcement; Waiver of Jury Trial.

(a) Each Party irrevocably submits to the exclusive jurisdiction of (i) the courts of the State of New York located in New York, NY, and (ii) the United States District Court for the Southern District of New York, for the purposes of any suit, Action or other proceeding arising out of this Agreement or the Contemplated Transactions. Each Party agrees to commence any such Action, suit or proceeding either in the United States District Court for the Southern District of New York or if such Action may not be brought in such court for jurisdictional reasons, in the courts of the State of New York located in New York, NY. Each Party further agrees that service of any process, summons, notice or document by the United States registered mail to such Party's respective address set forth above in Section 7.2 will be effective service of process for any Action, suit or proceeding in New York with respect to any matters to which it has submitted to jurisdiction in this Section 7.8(a). Each Party irrevocably and unconditionally waives any objection to the laying of venue of any Action, suit or proceeding arising out of this Agreement or the Contemplated Transactions in (x) the courts of the State of New York located in New York, NY, and (y) the United States District Court for the Southern District of New York, and hereby and thereby further irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such Action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

(b) EACH PARTY WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY. Each Party (i) certifies that no Representative, agent or attorney of the other Party has represented, expressly or otherwise, that such Party would not, in the event of any Action, suit or proceeding, seek to enforce the foregoing waiver and (ii) acknowledges that it and the other Party has been induced to enter into this Agreement, by, among other things, the mutual waiver and certifications in this Section 7.8(b).

Section 7.9Specific Enforcement. The Parties agree that irreparable damage may occur and that the Parties may not have any adequate remedy at law if any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise

breached. Notwithstanding anything to the contrary herein, it is accordingly agreed that the Parties will be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in the state courts of New York located in New York, NY, and the United States District Court for the Southern District of New York, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby covenants and agrees not to raise, and irrevocably waives, any objections to the availability of such relief that a remedy at law would be adequate and that a bond or other security will be required.

Section 7.10Severability. If any term or other provision of this Agreement or any Related Document is invalid, illegal or incapable of being enforced by any rule of Law or public policy, all other conditions and provisions of this Agreement or such Related Document will nevertheless remain in full force and effect. Upon such determination that any term or other provision is invalid, illegal or incapable of being enforced, the Parties will negotiate in good faith to modify this Agreement or such Related Document so as to effect the original intent of the Parties as closely as possible to the fullest extent permitted by applicable Law in an acceptable manner to the end that the Contemplated Transactions are fulfilled to the extent possible.

Section 7.11Amendment. This Agreement may be amended by the Parties at any time by an instrument in writing signed on behalf of each of the Parties.

Section 7.12Release. Effective as of the Closing, each of Seller and Buyer, on behalf of itself and their respective Affiliates, successors and assigns (collectively, as applicable to Seller and Buyer, the “Releasors”), hereby release, acquit and forever discharge, to the fullest extent permitted by Law, the other Party and its Affiliates (each, a “Releasee”) of, from and against any and all Actions, causes of Action, claims, demands, damages, judgments, debts, dues and suits of every kind, nature and description whatsoever, in law or in equity, which such Releasor ever had, now has or may in the future have on or by reason of any matter, cause or thing whatsoever related to the Business and the Purchased Assets. Each Releasor covenants and agrees not to assert any claim released hereby against any Releasee. Notwithstanding anything contained in this Section 7.12 to the contrary, the release set forth in this Section 7.12 will not affect or release the obligations of the Parties under this Agreement or the Related Documents.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have caused this Asset Purchase Agreement to be signed by their respective officers hereunto duly authorized, all as of the date first written above.

SELLER:

FA212 LLC

By: /s/ Thomas E. Hamilton
Name: Thomas E. Hamilton
Title: Manager

[Signature Page to Asset Purchase Agreement]

IN WITNESS WHEREOF, the Parties have caused this Asset Purchase Agreement to be signed by their respective officers hereunto duly authorized, all as of the date first written above.

BUYER:

SOLID BIOSCIENCES INC.

By: /s/ Bo Cumbo
Name: Bo Cumbo
Title: President and CEO

[Signature Page to Asset Purchase Agreement]

AMENDMENT TO ASSET PURCHASE AGREEMENT

This Amendment (this “Amendment”), entered into as of October 31, 2025 (the “Amendment Effective Date”), amends the Asset Purchase Agreement dated as of September 19, 2024 (the “Agreement”), by and between Solid Biosciences Inc. (the “Buyer”) and FA212 LLC (the “Seller”). Each of the Buyer and the Seller shall be considered individually as a “Party” and collectively as the “Parties”. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, the Parties desire to amend the Agreement as set forth herein.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Amendment.** The first sentence of Section 2.6(d)(v) of the Agreement is hereby deleted in its entirety and the following is inserted in lieu thereof:

“If Solid Shares are issued as Milestone Consideration to Seller, then Buyer shall file a registration statement on Form S-3 (or any successor form to Form S-3) (or, (i) in the event that Form S-3 is not available for the registration of the resale of the Registrable Securities, another appropriate form reasonably acceptable to Seller or (ii) if available, include the Registrable Securities in a prospectus supplement under an already effective registration statement of Buyer) registering the resale of such Solid Shares (the “Registrable Securities”) by Seller (a “Registration Statement”) no later than one (1) Business Day after Buyer files its Annual Report on Form 10-K or Quarterly Report on Form 10-Q, as applicable, for the fiscal quarter in which such Solid Shares were issued (Buyer’s fourth fiscal quarter in the case of the Annual Report on Form 10-K).”

2. **Miscellaneous.**

2.1 The Parties hereby confirm and agree that, as amended hereby, the Agreement remains in full force and effect and is a binding obligation of the Parties.

2.2 This Amendment may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.

2.3 THIS AMENDMENT WILL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAWS OF THE STATE OF NEW YORK, REGARDLESS OF THE LAWS THAT MIGHT OTHERWISE GOVERN UNDER APPLICABLE PRINCIPLES OF CONFLICTS OF LAWS THEREOF.

IN WITNESS WHEREOF, the parties have caused this Amendment to be executed by their duly authorized representatives.

SOLID BIOSCIENCES INC.

FA212 LLC

By: /s/ Bo Cumbo

By: /s/ Thomas E. Hamilton

Name: Bo Cumbo

Name: Thomas E. Hamilton

Title: President and Chief Executive Officer

Title: Co-Founder

Subsidiaries of Solid Biosciences Inc.

<u>Name of Subsidiary</u>	<u>Jurisdiction of Organization</u>
AavantiBio, Inc.	Delaware
Solid Biosciences Securities Corporation	Massachusetts

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-287325, 333-285613, 333-285611, 333-277871, 333-276764, 333-269424, 333-254310 and 333-233594) and Form S-8 (Nos. 333-288022, 333-285603, 333-280116, 333-277869, 333-272456, 333-270765, 333-269162, 333-268643, 333-265351, 333-258856, 333-241370 and 333-222763) of Solid Biosciences Inc. of our report dated March 19, 2026, relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Boston, Massachusetts
March 19, 2026

**CERTIFICATION OF PERIODIC REPORT UNDER SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002**

I, Alexander Cumbo, certify that:

1. I have reviewed this Annual Report on Form 10-K of Solid Biosciences Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 19, 2026

By: /s/ Alexander Cumbo
Alexander Cumbo
President and Chief Executive Officer
(Principal Executive Officer)

1. I have reviewed this Annual Report on Form 10-K of Solid Biosciences Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

By: /s/ Kevin Tan
Kevin Tan
Chief Financial Officer
(Principal Financial and Accounting Officer)

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Alexander Cumbo
Alexander Cumbo
President and Chief Executive Officer
(Principal Executive Officer)

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Kevin Tan
Kevin Tan
Chief Financial Officer
(Principal Financial and Accounting Officer)

