

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): September 30, 2022

Solid Biosciences Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38360
(Commission
File Number)

90-0943402
(IRS Employer
Identification No.)

**500 Rutherford Avenue, Third Floor
Charlestown, Massachusetts 02129**
(Address of Principal Executive Offices) (Zip Code)

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

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock \$0.001 par value per share	SLDB	The Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth 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.

Item 7.01. Regulation FD Disclosure.

As previously announced, on September 29, 2022, Solid Biosciences Inc. (the “Company”) entered into an Agreement and Plan of Merger (the “Merger Agreement”) by and among the Company, Greenland Merger Sub LLC, a Delaware limited liability corporation and a wholly owned subsidiary of the Company (“Transitory Subsidiary”), AavantiBio, Inc., a Delaware corporation (“AavantiBio”), and, solely in his capacity as equityholder representative, Doug Swirsky. The Merger Agreement provides for the acquisition of AavantiBio by the Company through the merger of Transitory Subsidiary into AavantiBio, with AavantiBio surviving as a wholly owned subsidiary of the Company (the “Merger”).

As previously announced, on September 29, 2022, the Company entered into securities purchase agreements with several accredited investors (the “Investors”), pursuant to which the Company agreed to issue and sell to the Investors in a private placement an aggregate of 159,574,463 shares of the Company’s common stock, at a price of \$0.47 per share (the “Private Placement”), which is expected to close immediately following the closing of the Merger, subject to the satisfaction of specified customary closing conditions, including approval from the stockholders of the Company, and contingent upon, among other things, the closing of the Merger.

On September 30, 2022, the Company and AavantiBio hosted a webcast presentation regarding the Merger between the Company and AavantiBio and the Private Placement (the “Presentation”). A transcript of the Presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference, and a copy of the investor presentation was previously furnished as Exhibit 99.2 to that certain Current Report on Form 8-K filed by the Company on September 30, 2022, and which is incorporated herein by reference.

Furnished as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference are social media posts posted by the Company on Twitter and LinkedIn on September 30, 2022 regarding the announcement of the Merger and the Private Placement.

The information furnished in this Item 7.01 and Exhibits 99.1 and 99.2 attached hereto shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of such section, nor shall such information be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation statements regarding: future expectations, plans and prospects for the Company, AavantiBio and the combined company following the anticipated consummation of the proposed Merger; the anticipated benefits of the Merger; the anticipated timing of the Merger and Private Placement; the anticipated milestones, business focus and pipeline of the combined company; the expected cash and cash investments of the combined company at closing of the transactions and the cash runway of the combined company; the expected management team and Board of the combined company; the Company’s SGT-003 program, including expectations for filing an investigational new drug application and initiating dosing; AavantiBio’s AVB-202 program and AVB-401 program, including expectations for filing an IND for AVB-202, and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” “working” and similar expressions. Any forward-looking statements are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in, or implied by, such forward-looking statements. These risks and uncertainties include, but are not limited to, risks and uncertainties associated with: completion of the proposed Merger and Private Placement in a timely manner or on the anticipated terms or at all; the satisfaction (or waiver) of closing conditions to the consummation of the merger and the private placement, including with respect to the approval of the Company’s stockholders; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the Merger Agreement or the Private Placement; the effect of the announcement or pendency of the Merger on the Company’s or AavantiBio’s business relationships, operating results and business generally; the ability to recognize the anticipated benefits of the Merger; the outcome of any legal proceedings that may be instituted against the Company or AavantiBio following any announcement of the Merger and related transactions; the ability to obtain or maintain the listing of the common stock of the combined company on the Nasdaq Stock Market following the Merger; risks related to the Company’s and AavantiBio’s ability to estimate their respective operating expenses and expenses associated with the transaction, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company’s cash resources; costs related to the Merger, including unexpected costs, charges or expenses resulting from the Merger; changes in applicable laws or regulation; the possibility that the Company or AavantiBio may be adversely affected by other economic, business and/or competitive factors; competitive responses to the Merger and Private Placement; risks related to the Company’s continued listing on the Nasdaq Global Select Market, including the Company’s ability to regain compliance with Nasdaq’s minimum bid price requirement; the Company’s ability to advance its SGT-003 program on the timelines expected or at all, obtain and maintain necessary

approvals from the U.S. Food and Drug Administration (“FDA”) and other regulatory authorities; following the Merger, the Company’s ability to advance the programs acquired from AavantiBio, including the AVB-202 and AVB-401 programs, on the timelines expected or at all, obtain and maintain necessary approvals from the FDA and other regulatory authorities; obtaining and maintaining the necessary approvals from investigational review boards at clinical trial sites and independent data safety monitoring board; replicating in clinical trials positive results found in preclinical studies and early-stage clinical trials of product candidates; whether the methodologies, assumptions and applications utilized to assess particular safety or efficacy parameters will yield meaningful statistical results; advancing the development of product candidates under the timelines it anticipates in current and future clinical trials; successfully transitioning, optimizing and scaling the Company’s manufacturing process; obtaining, maintaining or protecting intellectual property rights related to the Company’s and AavantiBio’s product candidates; competing successfully with other companies that are seeking to develop Duchenne treatments, Friedreich’s ataxia, BAG3 and other gene therapies; managing expenses; and raising the substantial additional capital needed, on the timeline necessary, to continue development of SGT-003, AVB-202, AVB-401 and other product candidates; achieving the Company’s other business objectives and continuing as a going concern. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company’s actual results to differ from those contained in the forward-looking statements, see the “Risk Factors” section, as well as discussions of potential risks, uncertainties and other important factors, in the Company’s most recent filings with the SEC. In addition, the forward-looking statements included in this Current Report on Form 8-K represent the Company’s views as of the date hereof and should not be relied upon as representing the Company’s views as of any date subsequent to the date hereof. The Company anticipates that subsequent events and developments will cause the Company’s views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so.

No Offer or Solicitation

This Current Report on Form 8-K is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the proposed business combination and shall not constitute an offer to sell or a solicitation of an offer to buy any securities nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

Important Additional Information Will Be Filed with the SEC

In connection with the Merger and the Private Placement, the Company intends to file with the SEC preliminary and definitive proxy statements relating to the Merger and the Private Placement and other relevant documents. The definitive proxy statement will be mailed to the Company’s stockholders as of a record date to be established for voting on the shares to be issued in the Merger and the Private Placement and any other matters to be voted on at the special meeting. **BEFORE MAKING ANY VOTING DECISION, INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE PRELIMINARY AND DEFINITIVE PROXY STATEMENTS, ANY AMENDMENTS OR SUPPLEMENTS THERETO AND ANY OTHER DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE MERGER OR THE PRIVATE PLACEMENT OR INCORPORATED BY REFERENCE IN THE PROXY STATEMENTS WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE COMPANY, AAVANTIBIO, THE MERGER AND THE PRIVATE PLACEMENT.** Investors and security holders may obtain free copies of these documents (when they become available) on the SEC’s website at www.sec.gov, on the Company’s website at www.solidbio.com or by contacting the Company’s Investor Relations via email at clowie@solidbio.com or by telephone at 607-423-3219.

Participants in the Solicitation

The Company, AavantiBio and their respective directors and executive officers may be deemed participants in the solicitation of proxies from the stockholders of the Company in connection with the issuance of shares in the Merger and Private Placement and any other matters to be voted on at the special meeting. Information about the Company’s directors and executive officers is included in the Company’s most recent definitive proxy statement filed with the SEC on April 28, 2022. Additional information regarding the names, affiliations and interests of the Company’s and AavantiBio’s directors and executive officers will be included in the preliminary and definitive proxy statements (when filed with the SEC).

These documents (when filed with the SEC) will be available free of charge as described above.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits*

Exhibit No.	Description
99.1	<u>Transcript of Webcast Presentation held by Solid Biosciences Inc. and AavantiBio, Inc. on September 30, 2022</u>
99.2	<u>Social Media Posts posted by Solid Biosciences Inc. on September 30, 2022</u>
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements 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 hereunto duly authorized.

SOLID BIOSCIENCES INC.

Date: September 30, 2022

By: /s/ Ilan Ganot

Name: Ilan Ganot

Title: Chief Executive Officer

**Solid Biosciences
Business Update Call
September 30, 2022**

Presenters

Caitlin Lowie - VP, Communications and IR, Solid Biosciences
Ilan Ganot - Co-Founder, President and CEO, Solid Biosciences
Bo Cumbo - President, Chief Executive Officer of AavantiBio
Carl Morris - Chief Financial Officer, Solid Biosciences
Jenny Marlow - Chief Scientific Officer, AavantiBio
Steve DiPalma - Interim Chief Financial Officer, Solid Biosciences

Q&A Participants

Unidentified Analyst - SVB Securities
Unidentified Analyst - Jefferies
Unidentified Analyst - Barclays
Allison Bratzel - Piper Sandler
Unidentified Analyst - J.P. Morgan
Unidentified Analyst - Chardan

Operator

Ladies and gentlemen, thank you for standing by and welcome to today's joint conference call with Solid Biosciences and AavantiBio to discuss their strategic business transaction. Please be advised that today's conference may be recorded.

I would now like to hand the conference over to Caitlin Lowie, Vice President of Communications and Investor Relations at Solid Biosciences. Ms. Lowie, you may begin.

Caitlin Lowie

Good morning, and thank you, operator. Before we begin, I would like to remind everyone that this discussion and the accompanying presentation will contain forward-looking statements based on the current expectations of Solid Biosciences and AavantiBio, including but not limited to statements regarding the expected timing, completion, effects, and potential benefits of the proposed merger and private placement of our future expectation plan and prospects for the combined company.

Such statements represent management's judgment and intention as of today, and involve assumptions, risks, and uncertainties. Actual results could differ material - materially from those discussed in these forward-looking statements due to a number of important factors, risks, and uncertainties, including those risks set forth on slide two of the accompanying presentation and other risks described in the risk factors section of our most recently filed annual report on Form 10-K and other periodic reports filed with the SEC. Solid and AavantiBio undertake no obligation to update any forward-looking statements after the date of this call.

Further, as indicated on slide three of the accompanying presentation, Solid Biosciences intends to file a preliminary and definitive proxy statement with the SEC relating to the proposed merger and private placement. Please be advised to read, when available, the preliminary and definitive proxy statements and the other relevant documents filed with the SEC, as these will contain important information about Solid, AavantiBio, and the transaction. Once available, these documents can be obtained free of charge from the SEC at SEC.gov or on the Solid Biosciences website.

With me on today on the call are Ilan Ganot, Co-Founder, President, and Chief Executive Officer of Solid Biosciences; Bo Cumbo, President and Chief Executive Officer of AavantiBio; Steve DiPalma, Solid's interim Chief Financial Officer; Dr. Carl Morris, Solid's Chief Financial Officer; and Dr. Jenny Marlow, Chief Scientific Officer for AavantiBio.

During today's call, we will share details of the strategic update the company announced this morning. Yesterday, Solid entered into a definitive merger agreement to acquire AavantiBio, a privately held gene therapy company. Solid also entered into a securities purchase agreement with a select group of healthcare and biotech investors for a \$75 million private placement that is expected to close concurrently with the closing of the merger.

We will begin with opening remarks from Ilan, who will share details of the planned acquisition of AavantiBio, followed by Bo, who will discuss Solid's strategic path forward. We will then open the call to questions. Before I turn the call over to Ilan, I want to acknowledge that the materials related to these transactions were filed with the SEC this morning.

I'd like to turn the call over to Solid's CEO, Ilan Ganot. Ilan?

Ilan Ganot

Thanks, Caitlin, and thank you all for joining us this morning. When we founded Solid nearly 10 years ago, we wanted to identify a meaningful treatment—meaningful treatment options for the boys and families who live with the devastating consequences of Duchenne muscular dystrophy. Over that time, Solid has experienced many ups and downs, but our commitment to patients and our mission has remained our guide.

I personally have had the privilege of watching great science be conducted by our team, and the lives of boys who have been treated with our product candidate in clinical trials be improved. As the leadership team, the board and I have discussed how to position Solid for success in the future and ensure that our treatment can reach patients.

We recognized a number of challenges that we were continually facing. One, manufacturing is a critical factor in the development process. Two, a single disease focus with a single asset exposed us to greater market volatility and risk. Three, Solid has produced some interesting and innovative technologies, but was not able to explore their potential with patients.

In April, we began to address the first challenge when we announced our intention to focus our manufacturing on a single manufacturing methodology, transient transfection, because we believed it would improve our consistency of supply as well as potentially improve the quality of the product candidate. That decision has thus far proven to be a positive one.

Today's announcement of the proposed merger and private placement I believe will help address the last two challenges. We believe that diversifying Solid's business into more disease areas will allow us to open doors to new investment and create a more stable business model to move our Duchenne program to patients. AavantiBio emerged as an ideal partner, and a group of healthcare and biotech investors agreed to commit \$75 million in a PIPE that was announced alongside the acquisition of AavantiBio.

First, a bit about the transactions before I hand it over to Bo Cumbo, who will assume the role of President and CEO of Solid upon the closing of the transactions. The acquisition of AavantiBio is expected to strengthen and expand Solid's pipeline and add organizational capacity to help advance our programs into and through commercialization, and hopefully ultimately to patients.

AavantiBio has been developing a gene transfer product candidate for Friedreich's ataxia, or FA, another neuromuscular disease, as well as a product--as well as product candidates for cardiac indications, including BAG3-mediated dilated cardiomyopathy. Together, we believe that Solid has the potential to become a leader in gene therapy for neuromuscular and cardiac diseases.

When discussions began to with Bo and the AavantiBio team, it was clear on that their--it was clear that--sorry, it was clear early on that there were some natural synergies. First, AavantiBio has some great talent that would complement the leadership team we have here Solid. As you will see, the new team has strong leaders in all areas of the organization.

Second, the companies have similar pipelines. Obviously, Solid is focused on Duchenne, a neuromuscular disorder that has cardiac manifestations. There are many similarities between Duchenne, Friedreich's ataxia, and the cardiac programs that AavantiBio is developing. We're also both working to identify promising next generation novel capsids.

Finally, both companies have found themselves in a similar place with manufacturing. Just as we have begun to focus on transient transfection-based manufacturing in our manufacturing platform, AavantiBio has made a similar decision to switch from HSV to transient transfection. We believe we can drive consistent drug product with desired quality attributes by having a single specialized CMC team working across these programs. All of these activities will support our goal of having multiple programs in the clinic in the coming years, leading with SGT-003 for Duchenne.

Now, few details on the transactions we announced in the press release earlier this morning. Solid signed a definitive agreement to acquire AavantiBio concurrently with a \$75 million private placement in Solid. The private placement will add to the combination of existing cash from both Solid and Aavanti.

The merger is an all stock transaction where, upon closing, AavantiBio shareholders will own approximately 15% of the combined company. Upon the closing, the combined company will operate as Solid Biosciences under the ticker SLDB, and AavantiBio will become a wholly-owned subsidiary of Solid.

The merger has been approved by the boards of Solid and AavantiBio, as well as stockholders of AavantiBio. We expect the merger to close by the end of this year, subject to approval of Solid stockholders and other customary closing conditions.

The \$75 million PIPE will close concurrently with the acquisition of AavantiBio. In the PIPE, we agreed to sell approximately 159 million shares of common stock at \$0.47 per share. Our lead investors in the PIPE are Perceptive Advisors, RA Capital Management, and Bain Capital Life Sciences. Other new and existing investors include CaaS Capital Management, Invus, Laurion Capital Management, and Pura Vida Investments.

Finally, we expect the combined company to have cash and investments of approximately \$215 million at close, which we expect will be sufficient to fund operations and capital expenditures into 2025 and through important milestones for the lead programs.

With that, I am going to hand it over to Bo Cumbo. I have known Bo for nearly 10 years now. I've also worked closely with Bo recently as we have discussed how to bring these two organizations together. Through that process, we discussed the future leadership of the company as I was thinking about my next phase.

Bo has significant experience bringing products through development and commercialization, and I believe he is a strong leader for this next phase of Solid. I look forward to working with Bo in the future, both as a member of Solid's Board of Directors and as a strategic business advisor during this transition period.

Bo Cumbo

Thanks, Ian. I'm really glad to join you today. While I've been out of DMD for multiple years and had not anticipated coming back into the Duchenne space, I'm truly excited to help the children, young men, and their extended families suffering from the consequences of Duchenne. I care deeply for this patient community, and I hope that Solid, as well as the entire industry trying to make advancements in care for patients suffering from DMD, find success and change the course of this disease.

With that said, I have a vision of building a company that will tackle additional severe genetic diseases, and we hope to be a leader in developing novel therapies in both the neuromuscular and cardiac spaces. Over the next few slides, I will walk you through what we envision the future of the company will become and what we expect to happen in the next couple years.

As Ilan mentioned, the core of the company will be built upon three pillars; people, pipeline, and process. And I'm going to walk through each of those, but first a bit about the combined company. We will be headquartered in Charlestown, Massachusetts under Solid's roof. They have great R&D and analytical and process development labs. We also will leverage Aavanti's Vector Core, located in North Carolina, that can produce material for small-scale studies while our PD teams can stay very focused on our lead programs. We value AavantiBio's current relationship with the University of Florida, and we intend to maintain a research presence in Gainesville.

As Ilan noted, this merger would significantly diversify Solid's pipeline. All of the programs in the combined company's pipeline focus on rare diseases that are estimated to have greater than 5,000 treatable patients in the United States alone. As we look out over the next few years of the combined company, we have some key anticipated milestones we aim to achieve.

First, we expect to close the transaction by the end of this year following a Solid shareholder vote. In mid-2023, we anticipate an IND submission for SGT-003. You probably saw in the press release that SGT-003 has been prioritized over Solid's first generation program, SGT-001, which will be paused.

We will get into that in a minute, but after having lengthy discussion with Solid's leadership team these past few weeks, I'm very supportive of their decision to make SGT-003 the primary focus of the company's Duchenne efforts moving forward.

In addition, in the second half of 2024, we anticipate submitting an IND for our other lead program, AVB-202, for the treatment of Friedreich's ataxia. This is a neuromuscular disorder that has neurological as well as cardiac manifestations affecting muscle control and coordination, with possible loss of vision, hearing, and slurred speech.

We also plan to initiate IND enabling activities for AVB-401 for the treatment of BAG3-mediated dilated cardiomyopathy, or BAG3, in 2024. BAG3 is a devastating disease that can ultimately lead to halt—heart failure. We also plan to continue our effort to develop novel AV cardiac directed capsids for our emerging cardiac pipeline.

We're excited to highlight the executive team post merger. This group has extensive experience in genetic medicine and will be a major asset to the combined company as we move forward. After the closing of the merger, I will assume the role as the president and CEO. I've been in the industry for 28 years in specialty or rare disease companies.

For the past two years, I've been solely focused on building AavantiBio, and am extremely proud of the exciting work we have done. Before Aavanti, I was at Sarepta Therapeutics for eight years, where I served as the Executive Vice President and Chief Commercial Officer. Prior to that, I worked at both Vertex and Gilead.

The scientific foundation of the combined company is on the call today, Dr. Morris and Dr. Marlowe. Carl will be our Chief Scientific Officer for neuromuscular programs. He is a muscle biologist by training and has been in the industry for very long time. Prior to Solid, Carl worked at Pfizer. Carl is well known in the neuromuscular space, and I've known him for an extended period of time. I'm very grateful that Carl and I get to work together.

Jenny is currently the scientific officer—Chief Scientific Officer at Aavanti. She will be the CSO responsible for our Friedreich's ataxia and cardiac programs. Prior to joining Aavanti, Jenny was the vice president of preclinical and translational development for bluebird bio. Jenny also spent 11 years in the Novartis' preclinical safety group and is a molecular toxicologist by training.

So, we have a muscle biologist and a toxicologist, which will really sync up nicely for the work we need to accomplish. Carl and Jenny will combine efforts and continue the work on our capsid libraries for both skeletal and cardiac tissues.

It is important to have regulatory expertise on the executive team, and we will have one of the best in the industry with Dr. Jessie Hanrahan. Jessie is well known globally and has worked with EMA, OTAT, and others. Jessie came to Aavanti from bluebird, where she was the vice president of regulatory. She's also been with Boston Scientific as well as Genzyme. Jessie had--also has an incredible team with experience in both regulatory strategy and CMC regulatory within gene and cell therapies. This team will help support all our efforts going forward.

Paul Herzich will be the Chief Technology Officer. Paul has decades of experience right where you want it, in gene therapy and biologics. Prior to Aavanti, Paul was the Vice President of CMC at BridgeBio. Prior to this, he was also at Novartis, LogicBio, Bamboo, etc., so he has deep gene therapy experience and is very well known within the CMC community.

Dr. Roxana Dreghici will be the head of clinical development. Roxana is a specialist within Duchenne and spinal muscular atrophy, and is very well known within the industry and Duchenne community. She was at Roche prior to Solid, and I'm very excited to have her--have the opportunity to work with Roxana.

Steve DiPalma, who's on the call today, has extensive experience as a CFO in the biotech and pharma space, and has been the interim CFO at Solid for the past couple years. He will stay with us while we recruit an experienced CFO in the Boston area.

Ty Howton rounds out the team as the Chief Administrative Officer. Ty currently serves as AavantiBio's Chief Operating Officer and will oversee legal, HR, and program management, among other functions. Ty has been on the executive teams of Vertex, Sarepta, and Aavanti. His background is in law. And while he will head--be the head of legal, he also brings the experiences he's gained in 20 plus years at companies like Aavanti, Sarepta, Vertex, and Genentech in areas including regulatory, preclinical, CMC, government affairs, and patient advocacy.

This merger will also bring together all the pieces you need to be a leading genetic medicine company. We have the vector core up and running, as well as animal models and supporting natural history studies in place within the key diseases, and great scientists able to develop novel capsids, regulatory elements, and promoters.

The merger is also expected to bring together a network of research partners globally that will help support our ongoing research efforts for our pipeline programs. We believe this merger will put all the critical pieces together to create a leading gene therapy company, and our goal is to have multiple INDs in the coming years, leading with our next generation microdystrophin program, SGT-003, followed by AVB-202 for FA.

This will be the company—combined company's initial pipeline, bringing together gene therapy candidates from Solid and Aavanti. I'm very excited about the combined pipeline. As you can see, we are targeting an IND submission for our lead program, SGT-003, in mid 2023, with patient dosing starting in late 2023, pending IND acceptance.

AVB-202 for FA will follow that, with an anticipated IND submission in the second half of '24. AVB-401 for BAG3 is currently in preclinical development, and hopefully in the future we will be in a position to share details on our undisclosed cardiac targets.

I think everyone on this call knows Duchenne and how devastating this disease is and can be to patients and families. You also know that Solid has potentially the best in class microdystrophin construct containing the nNOS binding domain. I will spend a few moments on the announcement that Solid made this morning regarding SGT-003, notably to pause SGT-001 and prioritize SGT-003 as the lead Duchenne program.

This slide shows the evolution of Solid's microdystrophin programs, starting with SGT-001, which was used in the IGNITE DMD study, to the second-generation SGT-001 manufactured using a triple transfection process, and finally Solid's next generation program on the right-hand side, SGT-003, which will be the leading—lead going forward.

As you know, SGT-003 delivers Solid's nNOS microdystrophin protein with a novel capsid. Using a reporter transgene, this capsid has shown a 10 times improvement in transgene expression compared to AAV9, a two times increase in muscle distribution compared to AAV9, and it's liver de-targeting, showing less than half the biodistribution to the liver compared to AAV9.

We believe that SGT-003 could be best in class and offer improved microdystrophin expression at lower viral loads. Solid has been delivering SGT-003 since the program was publicly launched in May of last year, including conducting nonhuman primate study, scale-up activities at the CDMO partner, and several confirmatory nonclinical studies.

This slide shows some of the data that Solid has previously shared that demonstrated the benefit of novel capsid. Ultimately, the team decided that SGT-003 now deserves the focus of Solid's Duchenne efforts in order to achieve the timeline we have set, and anticipate IND submission in mid 2023 and subject to IND clearance, patient dosing, and anticipated in late 2023.

Over the next few months, we will complete current ongoing preclinical and manufacturing activities for SGT-001. This will allow us to pause SGT-001 when it's ready for IND filing. I'm spending time on this because I know many people have asked the Solid team about the two DMD programs and at what point they would go to a single program. I fully support the decision management made--has made to prioritize and progress SG--and progress SGT-003.

As we've mentioned a few times, we expect to bring SGT-003 to patients in a clinical setting next year, pending an IND acceptance. Our immediate focus in the coming months will be able to complete our manufacturing and regulatory engagement activities to support our anticipated IND submission next year.

Now, our second program is going to be AVB-202 for the treatment of Friedreich's ataxia. FA is similar to Duchenne in that it's caused by a lack of a protein, frataxin. It's a multisystem disease that has both neurological and cardiac manifestations that can be severe. We plan to address the cardiac and neuromuscular manifestations, administering AVB-202 via both intrathecal and intravenous routes.

What is important about FA is that it's not just the amount of frataxin that is required, but it's the distribution of frataxin to the targeted locations throughout the relevant target tissues of the central nervous system as well as the heart. Aavanti's frataxin transgene fits very nicely within the capsid.

It is full-length human frataxin with the addition of regulatory elements that are naturally occurring in the 3' UTR region. We are using the CBA promoter as well as AV9, and I will show you the iterations on how our program has evolved to what we believe has the potential to be the best in class gene therapy for the treatment of FA.

Similar to what Solid did, we took multiple iterations and reviewed every aspect of our product candidate to make a potentially best in class program, AVB-202. Whether it was codon optimizing the gene, the manufacturing platform in which we moved away from HSV to transient transfection, adding in regulatory elements, and then AV9 with a plasma design that is optimized for yield and productivity, we have ended up with an optimized construct and delivery, which is shown on this right-hand side slide. We will use this construct to advance IND enabling activities and manufacturing scale-up using a transient transfection process to support an anticipated IND submission in the second half of 2024.

Here is some of the preclinical data for AVB-202 we have collected. This model is a frataxin deficient knockout mouse model. We've performed experiments in this mouse model in both pre- and post-symptomatic contexts to understand whether we could change the course of the disease after symptom onset or before, and we're very pleased with the results in both models, in which we observed that AVB-202 extended survival and improved cardiac function.

We also understand from the preclinical studies that frataxin is functional in the dosed mouse mitochondria, because you can look at the health of the mitochondria through the surrogate marker called succinate dehydrogenase, which we see return to normal levels post-dose.

Now, our third program is going to be AVB-401 for the treatment of BAG3-mediated dilated cardiomyopathy, or BAG3. The BAG3 gene codes for this BCL-2-associated athanogene 3 protein, or BAG3. If you don't have BAG3 protein or a reduction in the BAG3 protein, you are likely to end up with dilated cardiomyopathy and ultimately heart failure. If you have this disease, you are likely going to seek treatment because your daily activities are severely impaired.

We are using rh74 to deliver an optimized BAG3 transgene with a specific cardiac promoter, and we are piggybacking off FA and Duchenne with transient transfection manufacturing process.

Now, there are a lot of synergies we expect to come together with this transaction, including the next generation capsid libraries the two companies are independently developing. Aavanti was working on discovering next generation highly complex cardiac capsid libraries generated through a combination of rational design and random mutagenesis, screened via directed evolution and nonhuman primates using an RNA-based readout for positive selection from cardiac tissues and DNA for negative selection from liver tissue.

Meanwhile, Carl and the team at Solid were working on a ground-up rational design approach to optimize capsids and drive expression to skeletal muscle while lowering transduction to the liver. We expect the combination of the two developed programs to create large tissue specific capsid libraries that we believe we can leverage for our own internal R&D programs as well as potentially to out-license for non-core disease areas. Of note, on the bottom right of this slide, you can see the results from SLB101, the capsid used in SGT-003.

Now, we believe that CMC is the foundation of the drug, and we will focus our efforts on having the best in class CMC for all our programs. As I mentioned earlier, we have full teams, QA, QC, PD, AD, and great labs. We will also have CMC regulatory teams integrated in each one of our programs right from the beginning, so we always have an eye on CMC.

This slide helps to illustrate why CMC is so important. I want you to look at just the first two columns because there is only one thing that has changed from column one to column two. It's not the dose. It's not the capsid. It's not the transgene. It's the manufacturing process. Switching from an HSV to a transient transfection process increased the microdystrophin expression by approximately 1.5 fold.

Now, this is when column three comes into play. SGT-003, using the novel capsid, showed nearly a two times increase in microdystrophin expression when compared to SGT-001 when both product candidates are manufactured using transient transfection. The only thing that changed between column two and three is using AAV-SLB101 capsid instead of AAV9. In summary, they observed two to three times better expression with SGT-003 using triple transfection compared to SGT-001 using the HSV process.

Aavanti and Solid's respective manufacturing partners are currently in place for FA and Duchenne. And as I mentioned before, Aavanti's vector core is able to support smaller scale needs for BAG3 and the other cardiac programs.

Before we turn to questions, I want to review some of the combined company key milestones we discussed during today's call. First, we expect to close the merger by the end of the year, following a solid shareholder vote, including a \$75 million financing in connection with the business combination, providing a total cash position at the close of the transactions of approximately \$215 million, which is expected to extend our runway into 2025 and through important key milestones for our lead programs.

Next, we plan to report new data from the IGNITE DMD phase 1/2 clinical trial of our first generation program, SGT-001, in the--early 2023. This will include the study's preliminary report of all patients to the primary endpoint of one year, as well as three year longitudinal data for the first three patients treated in the high-dose cohort. Again, we anticipate submitting an IND submission for SGT-003 mid next year. And pending IND acceptance, we expect the dosing in late 2023.

Finally, we currently expect to submit an IND for our FA program in the second half of 2024, which is subject to an IND clearance, will lead then to first patient dosing. In addition, we plan to move our BAG3 program into IND enabling studies, advance our early stage cardiac programs, and continue development work on our capsids.

As you can see, I'm very excited about the opportunities in front of us and hope to build a leading gene therapy company in both neuromuscular and cardiac space. We have a talented team, a diversified pipeline we believe potentially could be best in class, and a strategic focus on a single manufacturing methodology. We also expect to have a strong cash position that will--we expect will be sufficient to achieve the milestones just discussed.

And with that, I'll turn it over to Ilan to close.

Ilan Ganot

Thank you, Bo, and I also want to thank all the Solid and AavantiBio employees for their tireless efforts. You've all done important work for patients, and I look forward to seeing what these two teams can achieve together.

Thank you all for dialing in. We can take some questions now.

Operator

Thank you. If you'd like to be placed in the question queue, please press star-one on your telephone keypad. A confirmation tone will indicate your line is in the question queue. You may press star-two if you'd like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing star-one. One moment, please, while we poll for questions.

Our first question today is coming from Joe Schwartz from SVB Securities. Your line is now live.

Unidentified Analyst

Hi. This is Beth on for Joe Schwartz. Congrats, everyone, on this exciting advancement, and thanks for taking our question today. I was just curious if you could talk a little more about your decision to bring SGT-003 forward as your lead pipeline candidate. Specifically curious how you're thinking about the opportunity for 003 in light of Sarepta's recent accelerated approval filing for their microdystrophin gene therapy, and, you know, any sort of learnings you can take from 001 as you move 003 into clinical development.

Carl Morris

Yeah. Hi. Thanks. This is Carl Morris. Yeah, we--we've been going through de-risking of 003 all the way through, and so it got to a point where we were quite confident in where it's at. Also, we received some guidance from the FDA recently around SGT-001 that sort of brought the timelines a little bit closer together, and really made the strategic decision to move forward with our next gen program, 003.

We've gone through our pre-IND--we've gone through the pre-IND meeting. We also have scale up activities with--at our CDMO partner, Forge. So, we're in a good place to move forward with SGT-003 at this point in time, and really made that decision. And I'll pass over to Bo to talk a little bit about the Sarepta.

Bo Cumbo

Yeah. They've--you know, just regarding Sarepta, I think they've--one, they've made tremendous progress over the last couple years. And I think it's not only great for the industry, but also great for the children suffering from DMD. We'll continue to--you know, they've laid out a very clear path, and we should try to follow it. And we'll--you know, we'll move with lightning speed to try to get there with 003.

Ilan Ganot

Yeah. I'd just add that, you know, we've always had this in mind because the protein is the same protein between 001 and 003. And we believe that everything we're seeing in 001 should give us a lot of confidence to move 003 aggressively forward. Thank you for the question.

Unidentified Analyst

Great. Thanks.

Operator

Thank you. Our next question is coming from Maury Raycroft from Jeffries. Your line is now live.

Unidentified Analyst

Hi. Good morning. This is Farsid [ph] on for Maury. Congrats on the update and thanks for taking our question. To clarify, for 202 for FA, is there preclinical data in the slide deck? I'm guessing that only they have been IV injected. Can you clarify that? And then can you also talk about what you're seeing in the NHP data and more on how the dual IV/IT dosing would work?

Bo Cumbo

Yeah. I think what I'm going to do is I'm going to turn it over to Jenny in a second. We're--you know, we--I think we--you saw the preclinical data that--the cardiac mouse model, and, you know, continuing to do additional work for IND enabling studies.

The non-human primate data--this is for FA, right? Yeah. For nonhuman primate data, it's continuing and ongoing. We're going to have to do additional studies. As I mentioned, we are switching over from HSV manufacturing platform to triple transfection manufacturing platform, and there will be compatibility studies that we'll have to complete as well.

Jenny?

Jenny Marlow

Yeah. Thank you for your question. To answer directly the question around IV administration, yes, in that particular model we dosed IV only. In our nonhuman primate model, we are dosing by the dual route of administration, both intravenous and by IT.

Unidentified Analyst

Got it. And then for the 202 optimization and plasmid design, how do you see a differentiation versus other competitors in development?

Bo Cumbo

For 202, you know, I only know of really one company that is--that's in--you know, that's done preclinical work and made it all the way to IND, and that's Lexeo. So, I'm not exactly sure their construct design compared to ours. But we've, you know, done a lot of work, as we mentioned on the slide, looking at codon optimization, adding in regulatory elements, moving to triple transfection. So, you know, I think it's a little too early to compare.

But we're very confident in our program. We've done a lot of work over the last couple years, and we're going to continue to do some more animal work. So, we're very--and we understand exactly how this drug should react when we get to the IND.

Unidentified Analyst

Got it. Thank you so much.

Operator

Thank you. Our next question is coming from Gina Wang from Barclays. Your line is now live.

Unidentified Analyst

This is Sheldon on for Gina. Thanks for taking our question. So, maybe first question is, could you remind us what are the remaining steps for the IND filing for SGT-003? And second question is I think you mentioned switching from HSV to the triple transfection was intended for when you initiate dosing with 001. So, could you give us some color on whether that switching on the solid part right now is already--is it already completed, and how would you coordinate the transition from HSV to transient for both organizations? Thanks.

Ilan Ganot

I'll start just by saying that, you know, Carl's going to mention some of the additional steps for the IND submission for 003. But as far as 001 goes, you know, we have nine patients who have been treated. We really like the data, and it continues to get collected on annual visits. We're expecting three year functional outcomes coming soon.

We're very excited about the durability profile of the treatment, and so we will definitely expect to see that and more from 003. And as Carl mentioned, this was sort of like a process of--an ongoing process of de-risking, you know, potentially the relapses coming to clinic. But as we learned more about 003, we learned more about the novel capsid. You know, we went from in vitro to in vivo, and then in vivo in HP data, all in order to get comfortable for that to turn into our lead, effectively, today. But Carl can talk more about the specifics.

Carl Morris

Yeah. Just on the 001 program, we are continuing with some of the nonclinical work as well as some manufacturing work on the 001 program. So, if something does delay or stop the 003 program, we will have that ready to go. So, we are continuing getting into a good pausing point.

For the SGT-003 program, we've completed it. We sort of have guidance from the FDA via the pre-IND meeting. We are sort of in the midst of sort of working through the IND enabling nonclinical work, and we have scaled up the manufacturing to a place where we can actually--to a scale that can supply the clinical study. So, we're in the process of getting to the GMP and finalizing all the study reports so we can submit the IND as soon as possible.

Unidentified Analyst

Thank you so much.

Operator

Thank you. Our next question is coming from Allison Bratzel from Piper Sandler. Your line is now live.

Allison Bratzel

Hi. Good morning. Congrats on all the updates, and thanks for holding this call and for taking my question. Could you just walk us through what assumptions are included in your 2025 cash run rate guidance in some more detail, and also just walk us through the expected cadence of value inflection points you're anticipating for SGT-003 and the AVB-202 through 2025? Does that contemplate clinical data is available for both assets by that 2025 timeframe? Thanks.

Bo Cumbo

Yeah. Let's kick it over to Steve for the financial update.

Steve DiPalma

Yeah. So, the runway would encompass important milestones in both programs. We do expect to have clinical readouts on 003, and also, you know, likely on 002 and FA as well into early 2025.

Bo Cumbo

Yeah. I think just answer your question, I mean, we're going to--you know, some of the milestones that we'll have from inflection points in the next couple of years, we'll obviously close the merger at the end of this year. As I mentioned before, we'll have an IND submission for the next generation SGT-003 mid next year. We intend to dose patients in that 003 program at the end of next year as well.

We will, you know, start having patient data expected from that same program, 003, in 2024. And the IND from FA would take hold late '24, and then we would start dosing patients, you know, soon after, whether it's through the runway or not. So--and then BAG3 will continue to move forward with IND enabling studies. Our other two cardiac programs will continue to move forward. And our capsid libraries both on the skeletal side as well as the cardiac side will have nonhuman primate data readouts early 2024, and that we can look to utilize those capsids for whether it's our cardiac--internal cardiac programs or out-license for non-dilutive financing. Thank you.

Operator

Thank you. Our next question is coming from Anupam Rama from J.P. Morgan. Your line is now live.

Unidentified Analyst

Hi. Thank you. This is actually Malcolm in for Anupam. Congrats on the updates today, and thank you for taking the question, just one quick one. What's kind of the [inaudible] in terms of target IND submission for 003? Thank you.

Carl Morris

Sorry, you broke up a little bit.

Bo Cumbo

We couldn't hear the question. You broke up. Could you repeat it?

Unidentified Analyst

Sure. What are the gating factors that we should be mindful of in terms of thinking about target IND submission for 003?

Carl Morris

Really, it's just the completion and the readouts from the IND enabling nonclinical work. We have--we know what we need to do. We've been told what the FDA is expecting, so we're just going through the execution of those studies right now. And the--additionally, we just have to ensure that we can release our material, our GMP material.

And that's really it. We have sort of a protocol outline, and we're looking at start up--starting up the sites. So, I think everything's in place and on track for a mid-2023 IND.

Unidentified Analyst

Excellent. Thank you.

Operator

Thank you. As a reminder, that star-one to be placed in the question queue. Our next question is coming from Geulah Livshits from Chardan. Your line is now live.

Unidentified Analyst

Hi. Good morning. This is Chloe for Geulah. So, thanks for taking the question and congratulations on the transaction. So, our question is you had guided to a sort of cadence of news coming from the 001 program for later this year. And you were going to update on--have a one year update on patients seven to nine and a potentially longer term update on the patients treated with 001 later this year. We're wondering if that was still going to be the case. And a second question on enrollment in the IGNITE DMD study. Based on conversations with regulators so far, what is your idea of how many more patients you'll need to dose before having a productive conversation with the FDA on any of this?

Carl Morris

So, for the first part, yes, we will be communicating the primary endpoint data, the 12 month endpoint data from the IGNITE DMD study, as well as three year data from a subset. And that should come out, you know, to the--later this year or early next year, Q1 next year, as we had guided to. So, that hasn't changed.

We are—we're sort of communicating now that we're pausing the 001 program. And given that we needed to file a new IND for the 001, it's unlikely we'll be sort of continuing with the dosing with 001 at this point.

Unidentified Analyst

All right. Thank you.

Operator

Thank you. We have reached the end of our question and answer session. And ladies and gentlemen, that does conclude today's teleconference and webcast. You may disconnect your lines at this time and have a wonderful day. We thank you for your participation today.

END

Forward-Looking Statements

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(the “Company”), AavantiBio and the combined company following the anticipated consummation of the proposed merger; the anticipated benefits of the merger; the anticipated timing of the merger and private placement; the anticipated milestones, business focus and pipeline of the combined company; the expected cash and cash investments of the combined company at closing of the transactions and the cash runway of the combined company; the expected management team and board of directors of the combined company; the Company’s SGT-003 program, including expectations for filing an investigational new drug application (“IND”) and initiating dosing; AavantiBio’s AVB-202 program and AVB-401 program, including expectations for filing an IND for AVB-202, and other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would,” “working” and similar expressions. 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These risks and uncertainties include, but are not limited to, risks and uncertainties associated with: completion of the proposed merger and private placement in a timely manner or on the anticipated terms or at all; the satisfaction (or waiver) of closing conditions to the consummation of the merger and the private placement, including with respect to the approval of the Company’s stockholders; the occurrence of any event, change or other circumstance or condition that could give rise to the termination of the merger agreement or the private placement; the effect of the announcement or pendency of the merger on the Company’s or AavantiBio’s business relationships, operating results and business generally; the ability to recognize the anticipated benefits of the merger; the outcome of any legal proceedings that may be instituted against the Company or AavantiBio following any announcement of the merger and related transactions; the ability to obtain or maintain the listing of the common stock of the combined company on the Nasdaq Stock Market following the merger; risks related to the Company’s and AavantiBio’s ability to estimate their respective operating expenses and expenses associated with the transaction, as well as uncertainties regarding the impact any delay in the closing would have on the anticipated cash resources of the combined company upon closing and other events and unanticipated spending and costs that could reduce the combined company’s cash resources; costs related to the merger, including unexpected costs, charges or expenses resulting from the merger; changes in applicable laws or regulation; the possibility that the Company or AavantiBio may be adversely affected by other economic, business and/or competitive factors; competitive responses to the merger and private placement; risks related to the Company’s continued listing on the Nasdaq Global Select Market, including the Company’s ability to regain compliance with Nasdaq’s minimum bid price requirement; the Company’s ability to advance its SGT-003 program on the timelines expected or at all, obtain and maintain necessary approvals from the U.S. Food and Drug Administration (“FDA”) and other regulatory authorities; following the merger, the Company’s ability to advance the programs acquired from AavantiBio, including the AVB-202 and AVB-401 programs, on the timelines expected or at all, obtain and maintain necessary approvals from the FDA and other regulatory authorities; obtaining and maintaining the necessary approvals from investigational review boards at clinical trial sites and independent data safety monitoring board; replicating in clinical trials positive results found in preclinical studies and early-stage clinical trials of product candidates; whether the methodologies, assumptions and applications utilized to assess particular safety or efficacy parameters will yield meaningful statistical results; advancing the development of product candidates under the timelines it anticipates in current and future clinical trials; successfully transitioning, optimizing and scaling the Company’s manufacturing process; obtaining, maintaining or protecting intellectual property rights related to the Company’s and AavantiBio’s product candidates; competing successfully with other companies that are seeking to develop Duchenne treatments, Friedreich’s ataxia, BAG3 and other gene therapies; managing expenses; and raising the substantial additional capital needed, on the timeline necessary, to continue development of SGT-003, AVB-202, AVB-401 and other product candidates; achieving the Company’s other business objectives and continuing as a going concern. 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This communication is not a proxy statement or solicitation of a proxy, consent or authorization with respect to any securities or in respect of the proposed business combination and shall not constitute an offer to sell or a solicitation of an offer to buy any securities nor shall there be any sale of securities in any state or jurisdiction in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such state or jurisdiction.

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Participants in the Solicitation

The Company, AavantiBio and their respective directors and executive officers may be deemed participants in the solicitation of proxies from the stockholders of the Company in connection with the issuance of the shares in the merger and the private placement and any other matters to be voted on at the special meeting. Information about the Company's directors and executive officers is included in the Company's most recent definitive proxy statement filed with the SEC on April 28, 2022. Additional information regarding the names, affiliations and interests of the Company's and AavantiBio's directors and executive officers will be included in the preliminary and definitive proxy statements (when filed with the SEC).

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On September 30, 2022, Solid Biosciences Inc. published the following post on LinkedIn:

Today, Solid announced it has entered into a definitive merger agreement to acquire AavantiBio, Inc. and a securities purchase agreement for a concurrent \$75 million private placement. See our press release for more info [[Link to Press Release on Solid's Website](#)]

"I created Solid with my wife, Annie, and our co-founders nearly ten years ago to bring meaningful treatment options to patients and families who, like ours, live with the devastating consequences of Duchenne muscular dystrophy. This acquisition provides exciting opportunities to bring our potentially best-in-class Duchenne gene transfer candidate, SGT-003, to patients and to expand our portfolio with innovative gene therapies designed to address significant unmet need in additional, adjacent rare disease indications."



ILAN GANOT

President, Chief Executive Officer
and Co-Founder of Solid Biosciences



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Solid Biosciences
@SolidBioDMD



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ILAN GANOT

President, Chief Executive Officer
and Co-Founder of Solid Biosciences



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