Solid Biosciences Reports First Quarter 2026 Financial Results and Provides Business Updates

May 12, 2026

*- **Duchenne (SGT-003):** First participant dosed in the Phase 3 IMPACT DUCHENNE clinical trial, receipt of positive opinion on the Company's Pediatric Investigation Plan from the European Medicines Agency and Orphan drug designation from the European Commission mark important advancements in the program's global development -*

- Continued progress achieved across the SGT-003 development program, including dosing of 47 participants in Phase 1/2 INSPIRE DUCHENNE clinical trial, and ongoing engagement with the FDA for guidance on a potential accelerated approval pathway for SGT-003 -

*- **Friedreich's Ataxia (SGT-212):** Second participant dosed in the Phase 1b FALCON clinical trial; SGT-212 has been well tolerated with no serious adverse events observed -*

*- **CPVT (SGT-501):** Company anticipates dosing the first participant in the Phase 1b ARTEMIS clinical trial evaluating SGT-501 for the treatment of catecholaminergic polymorphic ventricular tachycardia (CPVT) in H2 2026 -*

*- **Capital Position:** Cash, cash equivalents and available-for-sale securities of $380.7 million at March 31, 2026; the Company's cash runway is anticipated to extend into H1 2028 -*

CHARLESTOWN, Mass., May 12, 2026 (GLOBE NEWSWIRE) -- Solid Biosciences Inc. (Nasdaq: SLDB) (the "Company" or "Solid"), a life sciences company developing precision genetic medicines for neuromuscular and cardiac diseases, today reported financial results for the first quarter ended March 31, 2026, and provided a business update.

Bo Cumbo, President and CEO of Solid Biosciences, stated: "The beginning of 2026 has seen Solid make meaningful strides as we continue to execute across our pipeline and platform development efforts. In Duchenne, we dosed the first participant in our Phase 3 IMPACT DUCHENNE clinical trial for SGT-003 and received Orphan drug designation from the European Commission, representing important milestones in the program's global advancement. We also continue to enroll and dose participants in the Phase 1/2 INSPIRE DUCHENNE clinical trial, which has maintained a consistent and encouraging safety and tolerability profile.

"As we progress through the year, we look forward to ongoing engagement with the FDA, focusing on our thoughtful approach to generating rigorous, well-controlled clinical data through our integrated, multi-country, multi-trial development program. We recognize the significant unmet need in Duchenne and see the potential for our novel therapy to offer a differentiated treatment option for families living with this unrelenting disease.

"In parallel, we are working closely with the UK Medicines and Healthcare products Regulatory Agency (MHRA) under our ILAP Innovation Passport and recently received a positive opinion from the European Medicines Agency (EMA) on our Pediatric Investigation Plan, reflecting our efforts to inform potential development and regulatory pathways outside of the United States. We continue to build the organizational and geographic foundations to support future global development and have made the decision to establish dedicated ex-U.S. leadership with the planned addition of a Head of Europe.

"Beyond Duchenne, we have now dosed two participants in the Phase 1b FALCON clinical trial of our Friedreich's ataxia gene therapy program, SGT-212, which has been well tolerated by both participants. While still early, we are encouraged by initial clinical observations and remain focused on advancing the program thoughtfully as data emerge. Across our company, we continue to execute our plan and advance our programs with the fiscal discipline and operational rapidity required to deliver meaningful outcomes to patients and our shareholders," Mr. Cumbo concluded.

Company Updates

Neuromuscular Pipeline
SGT-003 Next-Generation Duchenne Muscular Dystrophy (Duchenne) Program

- As announced on May 7, 2026, the Company reported that the first participant was dosed in IMPACT DUCHENNE, the Phase 3 multi-country, placebo-controlled, randomized, double-blind, clinical trial.
  - Solid has received a positive opinion from the European Medicines Agency's Paediatric Committee on its Pediatric Investigation Plan (PIP), establishing alignment on its pediatric development framework for SGT-003 in Europe.
- The Company announced on April 28, 2026, that SGT-003 had been granted Orphan drug designation by the European Commission (EC).
  - SGT-003 has received numerous regulatory designations from global health authorities, including the Innovation Passport designation under the new U.K. Innovation License and Access Pathway program and Fast Track, Orphan Drug and Rare Pediatric Disease designations from the U.S. Food and Drug Administration.

- SGT-003 continued to be generally well tolerated in the 47 participants dosed in the INSPIRE DUCHENNE trial as of May 11, 2026.
    - The 47th participant was dosed on May 8, 2026.
- The Company reported positive interim data from the ongoing Phase 1/2 INSPIRE DUCHENNE clinical trial on March 11, 2026, which continued to suggest differentiated clinical, safety and tolerability profiles.
- The Company announced on February 9, 2026, that it had reached alignment with the U.S. Food and Drug Administration (FDA) on the overall study design for IMPACT DUCHENNE.
- Solid expects to continue discussions with the FDA to receive guidance on a potential accelerated approval pathway for SGT-003 and expects to provide an update as discussions progress.

SGT-212 for Friedreich's ataxia (FA)

- Two participants have been dosed in the Phase 1b FALCON clinical trial, and SGT-212 has been well tolerated as of May 11, 2026, with no serious adverse events observed.
- Participant dosing remains ongoing with initial data expected by year-end 2026, subject to participant enrollment.

Cardiac Pipeline
SGT-501 for catecholaminergic polymorphic ventricular tachycardia (CPVT)

- Clinical trial sites have been activated and participant screening is underway for the Phase 1b ARTEMIS trial.
- The first participant is anticipated to be dosed in the second half of 2026, with initial safety data anticipated in the first half of 2027, subject to participant enrollment.

Platform Technologies – Capsids

- In March 2026, AAV-SLB101, the Company's next-generation, muscle-tropic capsid used in SGT-003, was renamed POLARIS-101™.
- Solid has executed more than 50 agreements, including licenses, with corporations, institutions and academic labs for the use of POLARIS-101™.

First Quarter 2026 Financial Highlights

- **Cash Position:** Solid had $380.7 million in cash, cash equivalents, and available-for-sale securities as of March 31, 2026, compared to $187.9 million as of December 31, 2025. The Company expects that its existing cash, cash equivalents, and available-for-sale securities will be sufficient to fund its operational runway into the first half of 2028.

- **Research and Development (R&D) Expenses:** R&D expenses for the first quarter of 2026 were $46.1 million, compared to $30.9 million for the first quarter of 2025. The increase of $15.2 million in research and development expenses was primarily due to a $13.6 million increase in costs for SGT-003 primarily related to manufacturing and clinical costs, a $3.3 million increase in personnel related expenses, a $2.5 million increase in costs for SGT-212 primarily related to clinical costs and license and milestone payments, and a $0.4 million increase in external expenses primarily related to consulting and professional services, partially offset by a $3.1 million decrease in costs for SGT-501 primarily related to lower manufacturing and research costs, and a $1.7 million decrease in costs for SGT-601 related to lower manufacturing and research costs.

- **General and Administrative (G&A) Expenses**: G&A expenses for the first quarter of 2026

were $11.2 million, compared to $9.1 million for the first quarter of 2025. The increase of $2.0 million was primarily related to a $1.5 million increase in personnel related costs, a $0.5 million increase in consulting services, and a $0.4 million increase in equipment costs, partially offset by a $0.5 million decrease in legal fees.

- **Net Loss:** Net loss for the first quarter of 2026 was $56.7 million, compared to a net loss of $39.3 million for the first quarter of 2025.

About SGT-003
SGT-003 is an investigational gene therapy containing a novel microdystrophin construct and a proprietary, next-generation capsid, POLARIS-101™ (formerly known as AAV-SLB101), which was rationally designed to target integrin receptors, and has shown enhanced cardiac and skeletal muscle transduction with decreased liver targeting in data from the Phase 1/2 INSPIRE DUCHENNE clinical trial and in nonclinical studies. SGT-003's microdystrophin construct uniquely includes the R16/17 domains, which localize nNOS to the muscle. Nonclinical studies have shown that nNOS can improve blood flow to the muscle thereby reducing muscle breakdown from ischemia and muscle fatigue. Together, these design features suggest that SGT-003 could be a potential best-in-class investigational gene therapy for the treatment of Duchenne.

About the SGT-003 Development Program
The SGT-003 clinical development program consists of two multinational clinical trials – the Phase 1/2 INSPIRE DUCHENNE trial and the Phase 3 IMPACT DUCHENNE trial – which together were designed to generate a comprehensive data package to support potential global regulatory authorizations.

INSPIRE DUCHENNE is a first-in-human, open-label, single-dose, multicenter Phase 1/2 clinical trial evaluating the safety, tolerability and efficacy of a single dose of SGT-003 in pediatric participants with a genetically confirmed Duchenne diagnosis. The trial is being conducted at clinical sites in the United States, Canada, the United Kingdom and Italy.

IMPACT DUCHENNE is a Phase 3 placebo-controlled, randomized, double-blind clinical trial evaluating the efficacy of a single dose of SGT-003 in ambulatory participants with a genetically confirmed Duchenne diagnosis. Clinical trial sites are currently active in Australia and Canada and additional clinical site activations in the UK and US are expected in the second half of 2026, with sites in the EU anticipated to follow, subject to regulatory clearances.

About SGT-212
SGT-212 is a recombinant AAV-based gene replacement therapy for Friedreich's ataxia (FA) designed to deliver full-length human frataxin (FXN) via a dual route of administration: intradentate nucleus (IDN) infusion, using an FDA-approved neurosurgical device in a stereotactic, precision MRI-guided technique, followed by an intravenous (IV) infusion, with the intent to increase therapeutic FXN levels in the cerebellar dentate nuclei, cardiomyocytes and other systemic tissues. Targeted delivery to the dentate nuclei will be confirmed in real time via MRI. Restoration of FXN levels is expected to repair the underlying mitochondrial dysfunction in neurons and cardiomyocytes to address neurologic, cardiac and systemic manifestations of the disease.

About the FALCON Clinical Trial
FALCON is a first-in-human, open-label, multi-center Phase 1b clinical trial designed to evaluate the safety and tolerability of SGT-212 in participants aged 18-40 who have been diagnosed with FA. FALCON is being conducted in the United States.

About Solid Biosciences
Solid Biosciences is a precision genetic medicine company focused on advancing a portfolio of gene therapy candidates targeting rare neuromuscular and cardiac diseases, including SGT-003 for Duchenne muscular dystrophy (Duchenne), SGT-212 for Friedreich's ataxia (FA), SGT-501 for catecholaminergic polymorphic ventricular tachycardia (CPVT), SGT-601 for TNNT2-mediated dilated cardiomyopathy and additional fatal, genetic cardiac diseases. The Company is also focused on developing innovative libraries of genetic regulators and other enabling technologies with promising potential to significantly impact gene therapy delivery cross-industry. Solid is advancing its diverse pipeline and delivery platform in the pursuit of uniting experts in science, technology, disease management, and care. Patient-focused and founded by those directly impacted by Duchenne, Solid's mission is to improve the daily lives of patients living with devastating rare diseases. For more information, please visit www.solidbio.com.

Cautionary Note Regarding Forward-Looking Statements
This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements regarding future expectations, plans and prospects for the company; the ability to successfully achieve and execute on the company's goals; anticipated benefits of SGT-003, SGT-212, SGT-501and other pre-clinical programs and technologies; strategies and expectations for the company's SGT-003, SGT-212, SGT-501, SGT-601 and other pre-clinical programs and technologies; expectations for planned site activation, planned enrollment, planned regulatory interactions and the potential approval pathways for SGT-003, SGT-212 and SGT-501; the cash runway of the company and the sufficiency of the Company's cash, cash equivalents, and available-for-sale securities to fund its operations; 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 associated with the company's ability to advance SGT-003, SGT-212, SGT-501, SGT-601 and other preclinical programs, capsid libraries and other enabling technologies on the timelines expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; replicate in clinical trials positive results found in preclinical studies and early-stage clinical trials of the company's product candidates; manufacture sufficient quantities of our drug product in a timely manner and maintain adequate supply to support our clinical development and potential commercialization; obtain, maintain or protect intellectual property rights related to its product candidates; replicate preliminary or interim data from clinicals trials in the final data of such trials; compete successfully with other companies that are seeking to develop Duchenne, FA, CPVT and other neuromuscular and cardiac treatments and gene therapies; manage expenses; and raise the substantial additional capital needed, on the timeline necessary, to continue development of SGT-003, SGT-212, SGT-501, SGT-601 and other candidates; achieve its other business objectives and continue 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 Securities and Exchange Commission. In addition, the forward-looking statements included in this press release 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.

Solid Biosciences Investor Contact:
Nicole Anderson
Senior Director, Investor Relations and Corporate Communications
Solid Biosciences Inc.
investors@solidbio.com

SOLID BIOSCIENCES INC.
SELECTED FINANCIAL INFORMATION (UNAUDITED)

CONDENSED CONSOLIDATED BALANCE SHEETS **(in thousands, except share data)**	**March 31, 2026**	**December 31, 2025**
Cash and cash equivalents	$ 297,099	$ 59,900
Available-for-sale securities	83,581	127,950
Prepaid expenses and other current assets	15,470	16,384
Restricted cash, current	638	1,222
Operating lease, right-of-use assets	21,300	21,924
Property and equipment, net	3,914	4,169
Other non-current assets	183	223
Restricted cash, net of current portion	708	768
Total assets	$ 422,893	$ 232,540
Accounts payable	$ 5,563	$ 3,224
Accrued expenses and other current liabilities	19,182	18,945
Operating lease liabilities, current	2,188	2,103
Derivative liabilities	3,350	9,200
Operating lease liabilities, net of current portion	18,478	19,058
Total stockholders' equity	374,132	180,010
Total liabilities and stockholders' equity	$ 422,893	$ 232,540
Common stock outstanding	98,394,720	78,967,888

CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS **(in thousands, except per share data)**	**Three Months Ended March 31,** **2026**	**2025**
Operating expenses:		
Research and development	$ 46,140	$ 30,914
General and administrative	11,168	9,138
Total operating expenses	57,308	40,052
Loss from operations	(57,308)	(40,052)
Other income, net:		
Interest income	2,064	2,300
Interest expense	—	(68)
Change in fair value of derivative liabilities	(1,650)	(1,650)
Other income, net	157	188
Total other income, net	571	770
Net loss	$ (56,737)	$ (39,282)
Net loss per share, basic and diluted	$ (0.52)	$ (0.59)
Weighted average shares of common stock outstanding, basic and diluted	109,811,461	66,341,305

Source: Solid Biosciences Inc.