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): March 19, 2023

Solid Biosciences Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-38360**	**90-0943402**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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.

On March 19, 2023, Solid Biosciences Inc. (the "Company") presented one-year post-treatment data relating to safety, efficacy and microdystrophin expression in muscle biopsies for patients enrolled in the Company's IGNITE DMD Phase I/II dose-ascending clinical trial evaluating SGT-001 in a poster presentation at the Muscular Dystrophy Association Clinical and Scientific Conference. Other than the required ongoing observation of patients in IGNITE DMD and the completion of already in process preclinical experiments, the SGT-001 program has concluded.

A copy of the Company's poster presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information provided under Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

By providing the information in Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1), the Company is not making an admission as to the materiality of any information herein. The information contained in this Current Report on Form 8-K is intended to be considered in the context of more complete information included in the Company's filings with the SEC and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Solid Biosciences Inc. Poster Presentation March 19, 2023
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: March 20, 2023

By: /s/ Alexander Cumbo
Name: Alexander Cumbo
Title: Chief Executive Officer

IGNITE DMD Phase I/II Study of SGT-001 Microdystrophin Gene Therapy for Duchenne Muscular Dystrophy

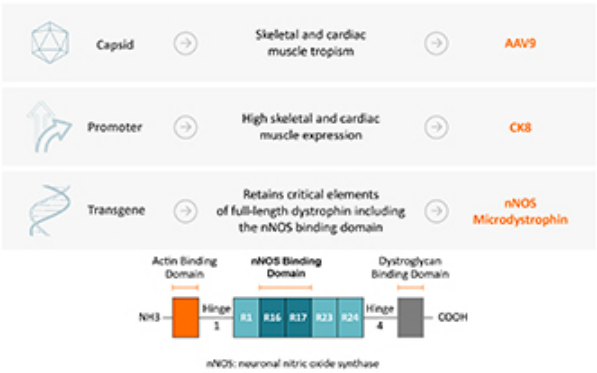
Roxana Donisa Dreghici[1], J. Patrick Gonzalez[1], Kristy J. Brown[1], Carl A. Morris[1], Perry Shieh[2], Barry Byrne[3]
[1] Solid Biosciences, Charlestown, MA; [2]University of California at Los Angeles, Los Angeles, CA;
[3]University of Florida, Gainesville, FL

Introduction / Objective

Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a fatal neuromuscular disease caused by mutations in the *DMD* gene that lead to the absence of functional dystrophin protein

SGT-001



nNOS: neuronal nitric oxide synthase

SGT-001 is an AAV microdystrophin gene transfer therapy evaluated for the safety, tolerability and efficacy in adolescents and children with DMD. SGT-001 was designed to deliver a unique, rationally designed dystrophin surrogate to replace absent protein in skeletal and cardiac muscles throughout the body

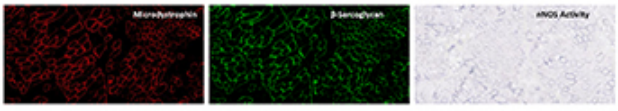
Methods

IGNITE DMD Phase I/II clinical trial to assess the safety and efficacy of SGT-001 (NCT03368742)

- Cohorts
  - n=3 control subjects analyzed
  - n=3 subjects at 5E13 vg/kg (Patients 1-3)
  - n=6 subjects at 2E14 vg/kg (Patients 4-9)
- Safety Assessments
  - Incidence of adverse events
- Biopsy Assessments
  - Microdystrophin expression in muscle biopsies (2E14 vg/kg cohort)
- Clinical Assessments
  - NSAA, 6MWT, FVC % Predicted, FEV1 % Predicted, PODCI
- Results presented as mean ± standard deviation for all control and treated subjects unless otherwise noted
- Enrollment in the study is complete and long term follow up to 5 years post-dosing continues

Results: Biopsy Analysis

Microdystrophin Expression and Protein Function in 3-Month and 12-Month Muscle Biopsies†



Biopsy from Pt. 5 at 18 months

Biopsy Results (2E14 vg/kg Cohort)	3 months (Mean % - Pts. 4-9)	12 months (Mean % - Pts. 6-9)	18 months (Pt. 5) †	24 months (Pt. 4) †
% Normal Dystrophin (Western Blot)	6.6%	7.0%	69.8%	BLQ*
% Positive Fibers (Immunofluorescence)				
Manual Assessment	31%	22%	85%	10%
Automated Assessment	40%	30%	84%	32%

*BLQ: Below the 5% limit of quantification by Western blot (BLQ values assigned 0.5*LLOQ for Mean calculations (=2.5%)

†12-month biopsies for Pts. 4 and 5 collected at 24 months and 18 months, respectively, due to COVID-19.

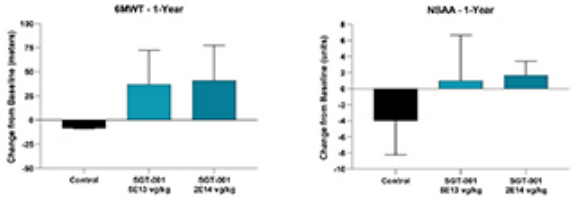
Results: 1-Year Assessments

Cumulative Summary Tabulations of Safety Findings

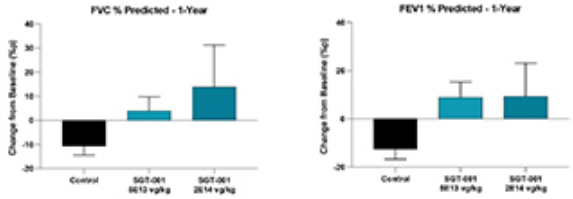
Serious Adverse Events (SAEs)	All SGT-001 (n=9)	Related to SGT-001
Thrombocytopenia	1/9	Yes
Hepatotoxicity	1/9	Yes
Systemic Inflammatory Response Syndrome	2/9	Yes
Giardiasis	1/9	No

Most Common Treatment-Emergent Adverse Events (TEAEs)	All SGT-001 (n=9)
Nausea	9/9
Vomiting	9/9
Pyrexia	8/9
Thrombocytopenia	7/9
Headache	4/9
Viral Upper Respiratory Tract Infection	4/9

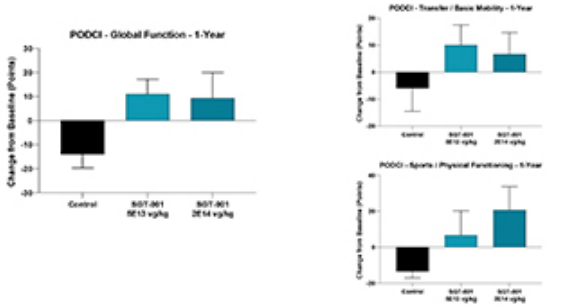
Motor Function Evaluated by 6-Minute Walk Test (6MWT) and North Star Ambulatory Assessment (NSAA)



Pulmonary Function Tests Performed by Spirometry to Evaluate Forced Vital Capacity (FVC) and Forced Expiratory Volume in 1 Second (FEV1)



Patient Reported Outcome Measures Evaluated by the Pediatric Outcomes Data Collection Instrument (PODCI)



Conclusions

- All subjects in IGNITE DMD have reached the 1-year study time point
- Results show positive changes from baseline to 1-year for motor function, pulmonary function, and patient reported outcome measures
- Subjects continue to be monitored for safety and have not shown any new treatment-associated AEs after the first 90 days post-dosing
- Development of SGT-001 has concluded, with the next-generation SGT-003 program using an updated construct with novel muscle-tropic capsid currently in IND-enabling studies
- Additional updates on the IGNITE DMD study are expected to be provided following completion of the 5-year follow up timepoint for all subjects