# 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): December 18, 2019**

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

| Delaware | 001-38360 | 90-0943402 |
|---|---|---|
| (State or Other Jurisdiction of Incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

**141 Portland Street, Fifth Floor**
**Cambridge, MA 02139**
**(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 8.01 Other Events.**

On December 18, 2019, Solid Biosciences Inc. (the "Company") issued a press release announcing biomarker data from two patients dosed in the second cohort of IGNITE DMD, the Company's Phase I/II clinical trial of SGT-001. The data from these patients show SGT-001 microdystrophin expression and associated neuronal nitric oxide synthase ("nNOS") function, providing evidence that SGT-001 has the potential to result in therapeutic benefit for patients with Duchenne muscular dystrophy ("Duchenne" or "DMD"). The Company also announced that the previously reported serious adverse event experienced by the third patient in the 2E14 vg/kg dose group has fully resolved, and the patient has resumed his normal activities. The Company has received the clinical hold letter from the U.S. Food and Drug Administration ("FDA") and will continue working internally, and with the FDA and other external experts, to address the clinical hold and determine the path forward.

Six patients have been dosed with SGT-001 as part of IGNITE DMD; three at the 5E13 vg/kg dose and three at the 2E14 vg/kg dose. Three-month biopsies were recently analyzed from the fourth and fifth patients, both administered SGT-001 at 2E14 vg/kg. Using immunofluorescence assays, 10%-20% of microdystrophin positive muscle fibers were determined to express SGT-001 microdystrophin in the fourth patient and 50%-70% microdystrophin positive fibers in the fifth patient. Immunofluorescence also showed clear stabilization and co-localization of nNOS and beta-sarcoglycan with SGT-001 microdystrophin in both patients. Inclusion of this nNOS coding region of the dystrophin protein may result in microdystrophin protein that has unique activity, potentially providing important functional benefits such as diminished muscle fatigue and protection against ischemic muscle damage. Using western blot, the expression levels for the fourth patient were detectable and estimated to be near the assay's level of quantification which is 5% of non-dystrophic control samples, with one assay replicate at 5.5%. Expression for the fifth patient was 17.5% of normal control samples. The levels of serum creatine kinase, a highly variable biochemical marker of muscle damage, declined from baseline in both patients. Collectively, these data provide evidence supporting the biological activity of SGT-001.

**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 statements regarding the Company's IGNITE DMD clinical trial, the safety or potential efficacy of SGT-001 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 satisfactorily respond to requests from the FDA for further information and data regarding IGNITE DMD; successfully resolve the clinical hold with regard to IGNITE DMD; obtain and maintain necessary approvals from the FDA and other regulatory authorities and investigational review boards at clinical trial sites; enroll patients in its clinical trials; continue to advance SGT-001 in clinical trials; replicate in clinical trials positive results found in preclinical studies and earlier stages of clinical development; advance the development of its product candidates under the timelines it anticipates in current and future clinical trials; successfully scale its manufacturing process; obtain, maintain or protect intellectual property rights related to its product candidates; compete successfully with other companies that are seeking to develop DMD/Duchenne treatments and gene therapies; manage expenses; and raise the substantial additional capital needed to achieve its business objectives. 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 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.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SOLID BIOSCIENCES INC.

Date: December 18, 2019

By: /s/ Jennifer Ziolkowski
Name: Jennifer Ziolkowski
Title: Chief Financial Officer