

**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): October 1, 2020

Solid Biosciences Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-38360
(Commission
File Number)

90-0943402
(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 October 1, 2020, Solid Biosciences Inc. (the “Company”) announced that the U.S. Food and Drug Administration (the “FDA”) lifted the clinical hold placed on the Company’s IGNITE DMD Phase I/II clinical trial. As previously announced in July 2020, the FDA had requested further manufacturing information, updated safety and efficacy data for all patients dosed, and provided direction on total viral load to be administered per patient. Based on the Company’s response to these requests, the FDA acknowledged that the Company satisfactorily addressed all clinical hold questions.

In connection with the lifting of the clinical hold, the Company is reducing the maximum weight of the next two patients dosed in IGNITE DMD to 18 kg per patient, with safety outcomes from these two patients driving potential weight increase of patients dosed subsequently. This reduction, in conjunction with the delivery of fewer viral particles as a result of the Company’s manufacturing process improvements, will reduce patients’ total viral load while continuing dosing at the 2E14 vg/kg dose. Additionally, to mitigate the risk of serious drug-related adverse events, the Company is amending the IGNITE DMD clinical protocol to include the prophylactic use of both anti-complement inhibitor eculizumab and C1 esterase inhibitor, and increasing the prednisone dose in the first month post dosing.

The Company is currently working to complete all activities necessary to resume dosing, which it expects to occur in the first quarter of 2021.

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 timing and ability of the Company to resume dosing and move the IGNITE DMD clinical trial forward, 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 resume and/or continue IGNITE DMD on the timeline expected or at all; obtain and maintain necessary approvals from the FDA and other regulatory authorities; obtain and maintain the necessary approvals from investigational review boards at IGNITE DMD clinical trial sites and the IGNITE DMD data safety monitoring board; enroll patients in IGNITE DMD; 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 optimize and 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, on the timeline necessary, to resume dosing in the IGNITE DMD trial, continue development of SGT-001, 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 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: October 1, 2020

By: /s/ Jennifer Ziolkowski

Name: Jennifer Ziolkowski

Title: Chief Financial Officer