

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): **May 7, 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:

<b>Title of each class</b>	<b>Trading Symbol</b>	<b>Name of exchange on which registered</b>
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 May 7, 2020, Solid Biosciences Inc. announced that it received written communication from the U.S. Food and Drug Administration (the “FDA”) regarding the clinical hold placed on the Company’s IGNITE DMD Phase I/II clinical trial. The clinical trial remains on clinical hold and the Company will continue to work with the FDA to address their requests.

In April 2020, the Company submitted a response to the FDA that included changes to the clinical protocol designed to enhance patient safety, as well as information related to improvements to its manufacturing process. The FDA has responded by maintaining the clinical hold and requesting further data and analyses relating to this manufacturing process. The Company is in the process of generating these data and expects to submit this information to the FDA before the end of the third quarter of 2020.

#### **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 Company’s expected response to the FDA with respect to the clinical hold on the IGNITE DMD clinical trial, the potential lifting of the clinical hold on the Company’s IGNITE DMD clinical trial, and 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 on the timeline expected or at all; 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: May 7, 2020

By: /s/ Jennifer Ziolkowski

Name: Jennifer Ziolkowski

Title: Chief Financial Officer