

**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 26, 2020**

Translate Bio, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38550
(Commission
File Number)

61-1807780
(IRS Employer
Identification No.)

29 Hartwell Avenue
Lexington, Massachusetts
(Address of principal executive offices)

02421
(Zip Code)

Registrant's telephone number, including area code: (617) 945-7361

Not applicable

(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(s) | Name of exchange on which registered |
|---------------------------------|------------------------------|---|
| Common Stock, \$0.001 par value | TBIO | 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 March 26, 2020, Translate Bio, Inc. (the “Company”) announced certain updates related to its MRT5005 clinical development program in cystic fibrosis (“CF”). The Company announced that the U.S. Food and Drug Administration (the “FDA”) has granted Rare Pediatric Disease designation for MRT5005 for the treatment of CF. The Company also announced that it anticipates the COVID-19 pandemic will cause related interruptions in enrollment, dosing and follow-up in the Company’s ongoing Phase 1/2 clinical trial in patients with CF. As a result, the Company plans to provide updated timing on when it expects to report interim data from the additional single-ascending dose (“SAD”) group and the multiple-ascending dose (“MAD”) portion of the clinical trial at a later date.

Cautionary Note Regarding 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. Such forward-looking statements include, but are not limited to, those regarding: the Company’s expectations regarding interruptions in patient enrollment, dosing and follow-up in the ongoing Phase 1/2 clinical trial of MRT5005; the Company’s expectations on when it will report interim data from the additional SAD group and the MAD portion of the trial; and the Company’s plans, strategies and prospects for its business, including its lead development programs. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “forward,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from current expectations and beliefs, including but not limited to: the Company’s ability to advance the development of its platform and programs under the timelines it projects, demonstrate the requisite safety and efficacy of its product candidates and replicate in clinical trials any positive findings from preclinical studies; the content and timing of decisions made by the FDA, other regulatory authorities and investigational review boards at clinical trial sites, including decisions as it relates to ongoing and planned clinical trials; the Company’s ability to obtain, maintain and enforce necessary patent and other intellectual property protection; the availability of significant cash required to fund operations; competitive factors; the COVID-19 pandemic; general economic and market conditions and other important risk factors set forth under the caption “Risk Factors” in the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2019 filed with the Securities and Exchange Commission on March 12, 2020 and in any other subsequent filings made by the Company. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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.

TRANSLATE BIO, INC.

Date: March 26, 2020

By: /s/ Paul Burgess
Paul Burgess
Chief Operating Officer, Chief Legal Officer and Secretary