
**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): September 9, 2019

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 1.01 Entry into a Material Definitive Agreement.

On September 9, 2019, Translate Bio, Inc. (the “Company”) entered into a Suite Retention and Development Agreement (the “Agreement”) with Albany Molecular Research, Inc (“AMRI”) pursuant to which the parties will arrange for the design, construction and use of a series of cleanroom suites (the “Suites”) at AMRI’s manufacturing facility (the “Facility”). The Suites, once constructed, will be for the exclusive use by the Company and any of its collaboration partners for the manufacture of its product candidates during the term of the Agreement.

Pursuant to the Agreement, AMRI shall enter into a design and construction contract with a third-party general contractor for the design and construction of the Suites according to the Company’s objectives (the “Build-Out”). The Company agreed to provide \$6.0 million to finance the costs of the Build-Out, which AMRI will invoice to the Company as the costs are incurred on a monthly basis. In the event that the costs of the Build-Out exceed \$6.0 million, the parties will share overage costs equally up to total Build-Out costs of \$11.0 million. The Company would be solely responsible for Build-Out costs in excess of \$11.0 million. Within five business days after execution of the Agreement, the Company shall pay AMRI \$1.0 million for certain initial services and deliverables.

The Agreement has an initial term of five years following the completion of the Build-Out (the “Initial Term”). The Company has the right to extend the Initial Term for an additional three-year term at prevailing commercially reasonable rates to be agreed between the parties.

After the Build-Out is complete, the Company is required to make monthly payments of \$1.0 million during the Initial Term (the “Monthly Payment”), which following the first year of the Initial Term, may be increased by AMRI in an amount equal to 3% of the then-current Monthly Payment on an annual basis. The Company’s aggregate Monthly Payment obligations under the Agreement, assuming AMRI implements the 3% annual increase as permitted under the Agreement, would be approximately \$63.7 million.

AMRI is required to maintain the Suites for the exclusive use by the Company and is required to provide certain development services to the Company, which include formulation development, creation of the master batch record, management of raw materials, manufacturing and storage of drug substance.

The Company has the right to terminate the Agreement for convenience after the date that is 36 months from the date of payment of the first Monthly Payment (the “Initial Three-Year Period”). In the event that the Company terminates the Agreement for convenience, it must pay AMRI a lump-sum payment of \$6.0 million.

If the Agreement is terminated by AMRI in the event of a material breach by the Company, AMRI is entitled to a lump sum payment from the Company equivalent to the Monthly Fee multiplied by the number of months remaining in the Initial Three-Year Period plus \$6.0 million. In the event of a change of control of the Company, the termination payment owed by the successor-in-interest to the Company would be the Monthly Fee multiplied by the number of months remaining in the Initial Term plus \$6.0 million.

Item 2.06 Material Impairments.

On September 9, 2019, the Company announced a decision to discontinue the development of MRT5201 for the treatment of ornithine transcarbamylase (“OTC”) deficiency (the “OTC program”). The Company’s condensed consolidated balance sheet as of June 30, 2019 included \$18.6 million of in-process research and development intangible assets and \$23.2 million in contingent consideration liability related to the OTC program.

As a result of the discontinuation, on September 12, 2019, the Company determined that it will be required under generally accepted accounting principles to incur a non-cash impairment charge in its statement of operations for the three and nine months ended September 30, 2019 associated with the in-process research and development intangible assets. The Company will also remeasure the contingent consideration liability related to the OTC program as a result of the discontinuation.

The Company has not yet been able to establish a meaningful estimate of the amount or range of amounts of the impairment charge or the impact of the remeasurement of the contingent consideration liability. The Company does not expect to incur any future cash expenditures resulting from the impairment charge.

The Company will file an amended Current Report on Form 8-K when it has determined the estimated amount of the impairment charge and the impact of the remeasurement of the contingent consideration liability and will disclose the final amounts in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2019.

Item 8.01 Other Events.

On September 9, 2019, the Company announced updates to its pipeline program, including the prioritization of the development of pulmonary disease programs including the ongoing development of MRT5005, its clinical candidate for the treatment of cystic fibrosis ("CF"), as well as the evaluation of targets in additional pulmonary diseases. Additionally, the Company has decided to discontinue the development of MRT5201, a liver targeted treatment for OTC deficiency. The Company's decision to discontinue the development of MRT5201 for OTC deficiency was based on data from recently completed preclinical studies which did not support the desired pharmacokinetic and safety profile for advancement of the program.

Following the discontinuation of the development of MRT5201, the Company continues to expect that its cash, cash equivalents and short-term investments of \$146.9 million as of June 30, 2019 will be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2020. The future viability of the Company beyond that point is dependent on the Company's ability to raise additional capital to finance its operations.

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 relating to impairment charges associated with the discontinuation of its OTC program; the Company's plans to prioritize the development of lung disease programs and evaluate targets in additional lung diseases; the Company's expectations regarding its positioning to advance its programs and achieve its drug development goals; the Company's expectation that its cash, cash equivalents and short-term investments of \$146.9 million as of June 30, 2019 will be sufficient to fund its operating expenses and capital expenditure requirements into the second half of 2020; and the Company's plans, strategies and prospects for its business, including its lead development programs. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "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 U.S. Food and Drug Administration, other regulatory authorities and investigational review boards at clinical trial sites, including 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; general economic and market conditions and other important risk factors set forth under the caption "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2019 and in any other subsequent filings made by the Company with the Securities and Exchange Commission. 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: September 12, 2019

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