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	**001-38550**	**61-1807780**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

29 Hartwell Avenue **Lexington, Massachusetts**	**02421**
(Address of principal executive offices)	**(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 March 26, 2020, Translate Bio MA, Inc. (the "Company"), a wholly owned subsidiary of Translate Bio, Inc. ("Translate Bio"), entered into a First Amendment to Collaboration and License Agreement (the "Amendment") with Sanofi Pasteur, Inc. ("Sanofi"), which amended that certain Collaboration and License Agreement entered into between the parties as of June 8, 2018 (the "Agreement"). Pursuant to the Agreement, the parties agreed to develop a mRNA vaccine platform and mRNA vaccines for up to five infectious disease pathogens (the "Licensed Fields"). The Amendment amends the Agreement to include vaccines against SARS-CoV-2 as an additional Licensed Field, increasing the number of Licensed Fields to up to six. The aim of the Amendment is to help address the SARS-CoV-2 pandemic.

Pursuant to the Amendment, the parties agreed that no upfront fee is payable by Sanofi to the Company with respect to the addition of SARS-CoV-2 as a Licensed Field. The parties also agreed that certain provisions of the Agreement, including provisions related to milestone payments, royalties and royalty reductions, shall not apply to vaccine products for the prevention, treatment or cure of SARS-CoV-2 that are purchased by a governmental authority while SARS-CoV-2 is a declared pandemic. The parties agreed to negotiate in good faith the royalty terms applicable to such products, which terms shall reflect the economic conditions applicable to commercializing such products and shall not exceed the royalty terms for the existing Licensed Fields.

In the event that the parties are unable to mutually agree on terms relating to the conduct of clinical development and commercialization of a product related to SARS-CoV-2, or if Sanofi is in breach of its material obligations with respect to SARS-CoV-2, the Company has the right to terminate and revoke the license granted to Sanofi with respect to SARS-CoV-2 with sixty (60) days written notice, and SARS-CoV-2 shall cease to be a Licensed Field under the Agreement. Upon any such termination and revocation by the Company, the parties have agreed to negotiate in good faith a termination agreement with respect to the Company's use of any technology arising from the collaboration that is owned by Sanofi or jointly-owned by the parties, that is necessary or useful to the further development or commercialization of a product directed to SARS-CoV-2.

Pursuant to the Amendment, the parties have agreed to a collaboration budget covering the costs of the initial collaboration activities, which will consist of discovery and pre-clinical research. The parties agreed to enter into an additional amendment related to activities directed to clinical development or commercialization of a product related to SARS-CoV-2, which could include the applicable royalty terms.

Pursuant to the Amendment, the Company granted to Sanofi exclusive, worldwide licenses to certain intellectual property rights of the Company, to develop, commercialize and manufacture mRNA vaccines against SARS-CoV-2. Sanofi granted to the Company non-exclusive, sublicenseable licenses under certain patent rights claiming certain improvements or technology arising from the SARS-CoV-2 collaboration. The terms of such licenses are identical to those granted in other Licensed Fields in the Agreement, provided that the economic terms and responsibilities for clinical development and commercialization are subject to the parties' mutual agreement and the Agreement's further amendment.

The foregoing summary of the Amendment is qualified in its entirety by reference to the full text of the Amendment, a copy of which Translate Bio intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter ending March 31, 2020.

Item 8.01 Other Events.

On March 27, 2020, Translate Bio issued a press release announcing the Amendment.

A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release dated March 27, 2020 entitled “Sanofi and Translate Bio to collaborate and develop novel mRNA vaccine candidate against COVID-19”

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 27, 2020

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

Sanofi Pasteur and Translate Bio to collaborate to develop a novel mRNA vaccine candidate against COVID-19

The two companies will jointly investigate multiple candidates with the goal of advancing an efficacious and safe SARS-CoV-2 vaccine into clinical development

PARIS, France and LEXINGTON, Mass.– March 27, 2020 – Sanofi Pasteur, the vaccines global business unit of Sanofi (EURONEXT: SAN and NASDAQ: SNY), and Translate Bio (Nasdaq: TBIO), a clinical-stage messenger RNA (mRNA) therapeutics company will collaborate to develop a novel mRNA vaccine for COVID-19. This collaboration leverages an existing agreement from 2018 between the two companies to develop mRNA vaccines for infectious diseases.

Translate Bio has begun to produce multiple mRNA constructs and will use its mRNA platform to discover, design and manufacture SARS-CoV-2 vaccine candidates. Sanofi will provide deep vaccine expertise and support from its external research networks to advance vaccine candidates for potential further development. Translate Bio has established 100 gram single-batch production with its clinical-stage mRNA therapeutics platform. Build-out is underway of dedicated manufacturing space through a contract manufacturing partner to accommodate at least two 250 gram batches per month. Depending on the final human dose, the mRNA platform of Translate Bio has excellent promise to meet the future demands for a pandemic response.

For Sanofi, this marks a second collaboration in its efforts to develop a novel COVID-19 vaccine candidate. In February 2020, Sanofi announced a collaboration with the Biomedical Advanced Research and Development Authority (BARDA) to advance a novel COVID-19 vaccine candidate. The agreement with BARDA calls for Sanofi to initiate development of a recombinant, protein-based vaccine candidate against COVID-19.

“We are committed to leveraging different ways to address the COVID-19 public health crisis by testing treatments, as well as two vaccines using different platforms. We believe the more approaches we explore, the better our likelihood of success in achieving this goal,” said David Loew, Global Head of Vaccines at Sanofi. “Having sufficient installed capacity will be key to satisfy the strong demand for vaccines we will probably see, and based on the experience we’ve had under the collaboration to date, we believe the Translate Bio mRNA platform could help us meet that need.”

“The Translate Bio and Sanofi Pasteur teams have generated encouraging preclinical data across multiple infectious disease targets as part of our ongoing mRNA vaccine collaboration. This work will serve as a strong foundation as we direct joint research efforts against COVID-19 to help address this public health threat,” said Ronald Renaud, chief executive officer of Translate Bio. “Our collaborative efforts to combat COVID-19 will leverage Translate Bio’s innovative mRNA platform as well as Sanofi’s vaccine expertise and ongoing COVID-19 research with the goal of advancing a novel mRNA vaccine rapidly to the clinic.”

About mRNA Vaccines

Vaccines work by mimicking disease agents to stimulate the immune system; building up a defense mechanism that remains active in the body to fight future infections. mRNA vaccines offer an innovative approach by delivering a nucleotide sequence encoding the antigen or antigens selected for their high

potential to induce a protective immune response. mRNA vaccines also represent a potentially innovative alternative to conventional vaccine approaches for several reasons - their high potency, ability to initiate protein production without the need for nuclear entry, capacity for rapid development and potential for low-cost manufacture and safe administration using non-viral delivery. This approach potentially enables the development of vaccines for disease areas where vaccination is not a viable option today. Additionally, a desired antigen or multiple antigens can be expressed from mRNA without the need to adjust the production process offering maximum flexibility and efficiency in development.

Sanofi Conference Call Information

Sanofi will host a conference call and webcast today at 3:30 pm CET/10:30 am ET to discuss this announcement, and Ronald Renaud, Translate Bio's chief executive officer, will be on the call for the question and answer period. The live webcast can be accessed at https://edge.media-server.com/mmc/p/rwbsdr83. Information about accessing the webcast can be found on the Sanofi investor relations website. A replay of the webcast will be available on Sanofi's website approximately one hour after the completion of the event and will be archived for up to one year.

About the Sanofi Pasteur/Translate Bio Collaboration

In 2018, Translate Bio entered into a collaboration and exclusive licensing agreement with Sanofi Pasteur Inc., the vaccines global business unit of Sanofi S.A., to develop mRNA vaccines for up to five infectious disease pathogens. This collaboration brings together Sanofi Pasteur's leadership in vaccines and Translate Bio's mRNA research and development expertise. Under the agreement, the companies are jointly conducting research and development activities to advance mRNA vaccines and mRNA vaccine platform development during a three-year research term. Translate Bio and Sanofi Pasteur have advanced the preclinical development vaccine programs including screening, optimization and production of mRNA and LNP formulations across multiple targets.

About Sanofi

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life

About Translate Bio

Translate Bio is a clinical-stage mRNA therapeutics company developing a new class of potentially transformative medicines to treat diseases caused by protein or gene dysfunction. Translate Bio is primarily focused on applying its technology to treat pulmonary diseases caused by insufficient protein production or where the reduction of proteins can modify disease. Translate Bio's lead program is being developed as a treatment for cystic fibrosis (CF) and is in an ongoing Phase 1/2 clinical trial. The Company also believes its technology is applicable to a broad range of diseases, including diseases that affect the liver. Additionally, the platform may be applied to various classes of treatments, such as therapeutic antibodies or vaccines in areas such as infectious disease and oncology. For more information about the Company, please visit www.translate.bio or on Twitter at @TranslateBio.

Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, the impact of global disruptions, including pandemics, cost containment initiatives and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2019. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

Translate Bio Forward-Looking Statements

This press release 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: Translate Bio’s expectations with respect to its collaboration with Sanofi, including Translate Bio’s plans to develop a novel mRNA vaccine for SARS-CoV-2 which could be rapidly advanced by Sanofi into further development and the parties’ ability to leverage existing preclinical data in their joint research efforts against SARS-CoV-2; Translate Bio’s expectations regarding its production capacity and its ability scale its manufacturing to supply vaccine doses;Translate Bio’s beliefs regarding the broad applicability of its MRT platform; and Translate Bio’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 successful advancement of the collaboration agreement between Translate Bio and Sanofi; uncertainties relating to the discovery and development of vaccine candidates based on mRNA; uncertainties relating to preclinical and clinical vaccine development, including delays and the risk of advancement into clinical trials, and a failure to demonstrate safety and efficacy of any vaccine candidate to the satisfaction of applicable regulatory authorities. Other risks Translate Bio faces include its 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; Translate Bio’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 Translate Bio’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 Translate Bio. Any forward-looking statements contained in this press release speak only as of the date hereof, and Translate Bio specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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