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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 22, 2020**

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**Translate Bio, Inc.**  
(Exact name of registrant as specified in its charter)

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**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)

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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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of exchange on which registered</u>
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.

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## Cautionary Note Regarding Forward Looking Statements

This Current Report on Form 8-K and Exhibit 99.1 hereto contain 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 expectations of Translate Bio, with respect to the benefits of its collaboration with Sanofi Pasteur, including the potential to receive various milestone and other future payments under the collaboration; the potential of Translate Bio's mRNA platform; Translate Bio's expectations regarding its financial positioning after giving effect to the expanded collaboration with Sanofi Pasteur; the period in which Translate Bio expects to have available cash to fund its operations; and the anticipated initiation of clinical trials for a COVID-19 vaccine in the fourth quarter 2020 and for a flu vaccine in mid-year 2021; 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 current and potential future impacts of the ongoing COVID-19 pandemic on Translate Bio's business, financial condition, operations and liquidity; Translate Bio'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 successful advancement of the collaboration agreement between Translate Bio and Sanofi Pasteur; 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 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 Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2020 filed with the Securities and Exchange Commission on May 7, 2020 and in any other subsequent filings made by Translate Bio. Any forward-looking statements contained in this Current Report on Form 8-K and Exhibit 99.1 hereto 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, except as required by law.

## **Item 1.01 Entry Into a Material Definitive Agreement.**

### **Second Amendment to Collaboration and License Agreement**

On June 22, 2020, Translate Bio MA, Inc. (the “Company”), a wholly owned subsidiary of Translate Bio, Inc., a Delaware corporation (“Translate Bio”), entered into a Second Amendment to the Collaboration and License Agreement (the “Amendment”) with Sanofi Pasteur Inc. (“Sanofi Pasteur”), which amended that certain Collaboration and License Agreement entered into between the Company and Sanofi Pasteur as of June 8, 2018 (as previously amended, the “Agreement”). The Amendment amends the Agreement to expand the scope of the collaboration and the licenses granted to Sanofi Pasteur. The Amendment will become effective on the closing date (the “Effective Date”), which is anticipated to be three business days following receipt of clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (the “Antitrust Clearance”), assuming such clearance is received.

Pursuant to the Amendment, the Company and Sanofi Pasteur agreed to jointly conduct research and development activities to advance mRNA vaccines for up to seven infectious disease pathogens. The parties have agreed to extend the term of the collaboration until June 2022 (the “Collaboration Term”), with an option for Sanofi Pasteur to extend for one additional year. If Sanofi Pasteur elects to so extend, the collaboration may be further expanded to develop mRNA vaccines for up to an additional three infectious disease pathogens. The parties have agreed to update collaboration plans and collaboration budgets for the collaboration activities.

Under the terms of the Amendment, the Company has agreed to expand the licenses granted under the Agreement to grant to Sanofi Pasteur exclusive, worldwide licenses under applicable patents, patent applications, know-how and materials, including those arising under the collaboration, to develop, commercialize and manufacture mRNA vaccines to prevent, treat or cure diseases, disorders or conditions in humans caused by any infectious disease pathogens, with certain specified exceptions (the “Licensed Fields”). As a result, the license option in the Agreement, under which Sanofi Pasteur had an option to acquire licenses to additional pathogens from the Company, has been removed from the Agreement under the Amendment.

Pursuant to the Amendment, Sanofi Pasteur agreed to concurrently enter into the Securities Purchase Agreement further described below and to pay the Company an additional upfront payment of \$300.0 million within 10 business days after the Effective Date. If Sanofi Pasteur chooses to exercise its option to extend the Collaboration Term for an additional year, Sanofi Pasteur has agreed to pay the Company an additional \$75.0 million. The Agreement and the Amendment collectively provide that the Company is eligible to receive aggregate potential payments of up to \$1,940.0 million upon the achievement of additional specified development, regulatory, manufacturing and commercialization milestones. In particular, the Company is entitled to receive development, regulatory and sales milestone payments of up to \$148.0 million for each Licensed Field other than the SARS-CoV-2 Licensed Field, development, regulatory and sales milestone payments of up to \$250.0 million in the SARS-CoV-2 Licensed Field, and one-time manufacturing milestone payments of up to \$200.0 million. Under the terms of the Amendment, Sanofi Pasteur has also agreed to pay the Company royalties on net sales of mRNA vaccines in the SARS-CoV-2 Licensed Field in accordance with the terms of and at the same high single digits to low teens percentages set forth in the Agreement, except where such vaccines are provided as a donation or transferred to a third party without any profit margin.

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 in which the Effective Date occurs. A summary of the terms of the Agreement is set forth in Translate Bio’s Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, which was filed with the Securities and Exchange Commission (the “SEC”) on May 7, 2020.

### **Supply Agreement**

In connection with the execution of the Amendment, Sanofi Pasteur and the Company also entered into a supply agreement (the “Supply Agreement”) governing the terms of the supply of products by the Company. Pursuant to the Supply Agreement, the Company have agreed to use commercially reasonable efforts to manufacture and supply Sanofi Pasteur with non-clinical and clinical supply of products and other research materials in certain Licensed Fields, as set forth in the Amendment. Under the Amendment, the parties have agreed to enter into a separate supply agreement, which is expected to be entered into this calendar year, for Phase 3 and commercial supply of products in the SARS-CoV-2 Licensed Field. Sanofi Pasteur will pay the Company for the non-clinical and clinical supply at the Company’s cost to manufacture plus a specified markup.

The Supply Agreement provides that it will remain in effect until terminated in accordance with its terms. However, the Company's obligation to manufacture and supply products is limited to a defined duration based on the Licensed Field of the applicable product, as set forth in the Amendment. The Supply Agreement may be terminated by the mutual consent of the parties. Sanofi Pasteur may terminate the Supply Agreement for convenience after a specified notice period, or in the event that the Company does not provide the supply in a timely manner. The Company may terminate the Supply Agreement in the event of a breach by Sanofi Pasteur of its payment obligations and such breach remains uncured for a specified period.

The foregoing summary of the Supply Agreement is qualified in its entirety by reference to the full text of the Supply Agreement, a copy of which Translate Bio intends to file as an exhibit to its Quarterly Report on Form 10-Q for the quarter in which the Effective Date occurs.

### **Securities Purchase Agreement**

In connection with the execution of the Amendment, Sanofi, a French corporation and affiliate of Sanofi Pasteur (the "Investor"), and Translate Bio also entered into a securities purchase agreement (the "Securities Purchase Agreement") on June 22, 2020 (the "Signing Date") for the sale and issuance of 4,884,434 shares of common stock (the "Shares") to the Investor at a price of \$25.59 per share, for an aggregate purchase price of approximately \$125.0 million.

The consummation of the transactions contemplated by the Securities Purchase Agreement is subject to specified conditions, including: (i) the parties' obtaining Antitrust Clearance; (ii) the Amendment remaining in full force and effect; (iii) the Registration Rights Agreement (as defined below) having been executed; (iv) no material adverse effect having occurred with respect to Translate Bio; and (v) the satisfaction or waiver of other customary closing conditions. The parties have agreed to hold the closing of the purchase and sale of the Shares (the "Closing") no earlier than the second business day and no later than the fifth business day after the Antitrust Clearance.

The Securities Purchase Agreement may be terminated upon the mutual consent of the parties. Either party may terminate the Securities Purchase Agreement if the Closing has not occurred prior to December 19, 2020. Either party also may terminate the Securities Purchase Agreement prior to the Closing if specified conditions set forth therein become incapable of fulfillment and have not been waived by the other party.

In addition, pursuant to the terms of the Securities Purchase Agreement, the Investor will agree not to, without the prior written approval of Translate Bio and subject to specified conditions, directly or indirectly acquire shares of the Translate Bio's outstanding common stock, make a tender, exchange, or other offer to acquire shares of Translate Bio's outstanding common stock, solicit proxies or consents with respect to any matter, or undertake other specified actions related to the potential acquisition of additional equity interests in Translate Bio (the "Standstill Restrictions"). Further, the Investor will also agree not to, and to cause its affiliates not to, sell or transfer the Shares without the prior written approval of Translate Bio, subject to specified conditions (the "Lock-Up Restrictions").

The Standstill Restrictions terminate 12 months after the Closing. The Lock-Up Restrictions terminate 18 months from the Closing.

The foregoing description of the terms of the Securities Purchase Agreement is qualified in its entirety by reference to the full text of the Securities Purchase Agreement, a copy of which Translate Bio intends to file with the SEC as an exhibit to Translate Bio's Quarterly Report for the quarter in which the Closing occurs.

### **Registration Rights Agreement**

As a condition to the Closing, the Investor and Translate Bio must also enter into a registration rights agreement (the "Registration Rights Agreement") providing the Investor with certain registration rights with respect to the Shares.

Pursuant to the terms of and subject to the conditions set forth in the Registration Rights Agreement, Translate Bio has agreed to agree to provide the Investor with certain registration rights (the “Registration Rights”) such that, promptly, but no later than 30 days, following the Closing, Translate Bio has agreed to prepare and file with the SEC a registration statement covering the resale of the Shares (a “Registration Statement”). Translate Bio has agreed to use commercially reasonable efforts to keep such Registration Statement effective until the date on which all Shares (i) are sold pursuant to a Registration Statement or Rule 144 under the Securities Act of 1933, as amended, or (ii) may be sold without restriction pursuant to Rule 144 under the Securities Act of 1933, as amended. Translate Bio will be responsible for specified fees and expenses incurred in connection with the registration of the Investor’s Shares for resale. Translate Bio will grant to the Investor, and the Investor will grant to Translate Bio, customary indemnification rights in connection with the Registration Statement.

The foregoing description of the terms of the Registration Rights Agreement is qualified in its entirety by reference to the full text of the Registration Rights Agreement, a copy of which Translate Bio intends to file with the SEC as an exhibit to Translate Bio’s Quarterly Report for the quarter in which the Closing occurs.

### **Item 3.02 Unregistered Sales of Equity Securities**

The information set forth in Item 1.01 above under the caption “Securities Purchase Agreement” is incorporated herein by reference. Translate Bio expects the Shares to be issued in reliance on the exemption from registration under Section 4(a)(2) of the Securities Act of 1933, as amended, for a transaction by an issuer not involving any public offering within the meaning of Section 4(a)(2) thereunder.

### **Item 8.01 Other Events.**

#### **Press Release**

On June 23, 2020, Translate Bio issued a press release announcing the transactions described in Item 1.01 and 3.02 of this Current Report on Form 8-K. 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.

#### **Projected Cash Runway**

Assuming the completion of the transactions described in Item 1.01 of this Current Report on Form 8-K, Translate Bio believes that its existing cash, cash equivalents and short-term investments of \$155.1 million as of March 31, 2020, together with the net proceeds of approximately \$36.6 million from the issuances and sales of common stock pursuant to its at-the-market offering facility between March 30, 2020 and May 1, 2020, and the payments that it expects to receive from Sanofi Pasteur and the Investor assuming receipt of Antitrust Clearance and the closing of the transaction, will enable Translate Bio to fund its operating expenses and capital expenditure requirements for the next 36 months. However, Translate Bio has based this estimate on assumptions that may prove to be wrong, and Translate Bio could exhaust its available capital resources sooner than it expects.

### **Item 9.01 Financial Statements and Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#"><u>Press Release dated June 23, 2020 entitled “Sanofi and Translate Bio expand collaboration to develop mRNA vaccines across all infectious disease areas”.</u></a>

**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: June 23, 2020

By: /s/ Paul Burgess

Paul Burgess

Chief Operating Officer, Chief Legal Officer and Secretary



**Sanofi and Translate Bio Expand Collaboration to Develop mRNA Vaccines across  
All Infectious Disease Areas**

- The two companies will build upon their existing collaboration to pursue novel mRNA vaccines aimed at broadly addressing current and future infectious diseases —
- Translate Bio to receive \$425 million in upfront payment and common stock equity investment and overall is eligible to receive up to \$1.9 billion of potential milestones/payments as well as tiered royalties on worldwide sales of developed vaccines —
- Sanofi to receive exclusive worldwide rights to develop, manufacture and commercialize infectious disease vaccines using Translate Bio technology —
- The expanded collaboration brings together Translate Bio’s leading mRNA technology and manufacturing with Sanofi’s world class vaccine development and distribution —

**PARIS and LEXINGTON, MASS.—June 23, 2020**—Sanofi Pasteur, the vaccines global business unit of Sanofi, and Translate Bio (NASDAQ: TBIO), a clinical-stage messenger RNA (mRNA) therapeutics company, have agreed to expand their existing 2018 collaboration and license agreement to develop mRNA vaccines for infectious diseases.

The expansion of this agreement will further unite Translate Bio’s expertise and knowledge from more than 10 years of mRNA research and development with Sanofi’s leadership in vaccine research and development. Under the expansion agreement, Translate Bio will receive a total upfront payment of \$425 million, consisting of a \$300 million cash payment and a private placement common stock investment of \$125 million at \$25.59 per share representing a 50 percent premium to the 20-day moving average share price prior to signing. Translate Bio will also be eligible for potential future milestones and other payments up to \$1.9 billion, including \$450 million of milestones under the 2018 agreement. Of these potential milestones and other payments, approximately \$360 million are anticipated over the next several years, inclusive of COVID-19 vaccine development milestones. In addition, Translate Bio is also eligible to receive tiered royalty payments based upon worldwide sales of the developed vaccines. Sanofi Pasteur will pay for all costs during the collaboration term. Under this agreement Sanofi Pasteur will receive exclusive worldwide rights for infectious disease vaccines.

*“As all eyes are on prevention of infectious disease through vaccines, this is a pointed moment in time where we are called upon to seek innovative ways to protect public health,”* said Thomas Triomphe, Executive Vice President, Sanofi Pasteur. *“We are excited by the novel technology and expertise Translate Bio brings, and we believe that adding this mRNA platform to our vaccines development capabilities will help us advance prevention against current and future infectious diseases.”*

*“The expansion of our collaboration with Sanofi Pasteur validates the progress we’ve made in the development of mRNA vaccines for infectious diseases since our work together began in 2018 and also speaks to the potential of our mRNA platform. We are excited to work with Sanofi in this*

*broadened capacity with the goal of ultimately delivering vaccines on a global scale, a need underscored by the current pandemic,” said Ronald Renaud, Chief Executive Officer of Translate Bio. “Translate Bio will also be well positioned financially to continue to build upon our internal capabilities with a focus on advancing innovations in platform discovery and on the development of ongoing and additional preclinical therapeutic programs as we aim to bring multiple programs towards clinical development.”*

Under the collaboration, Translate Bio is using its mRNA platform to discover, design and manufacture vaccine candidates and Sanofi Pasteur is providing its deep vaccine expertise to advance vaccine candidates into and through further development. Translate Bio will also transfer technology and processes to allow Sanofi Pasteur to develop and manufacture mRNA vaccines for infectious diseases.

The teams are currently evaluating multiple COVID-19 vaccine candidates *in vivo* for immunogenicity and neutralizing antibody activity to support lead candidate selection and the companies have the goal of initiating a first-in-human clinical trial in the fourth quarter of 2020.

The companies are also advancing an mRNA vaccine development candidate against influenza through preclinical studies with clinical trial initiation anticipated in mid-year 2021. Additional mRNA vaccine development programs under the collaboration include another viral pathogen and a bacterial pathogen.

The transactions, including the equity sale, are subject to customary closing conditions, including termination or expiration of any applicable waiting periods under the Hart-Scott-Rodino Act. For more information regarding the financial and other terms of the agreement, please refer to the Current Report on Form 8-K which will be filed by Translate Bio with the U.S. Securities & Exchange Commission on June 23, 2020.

Evercore acted as financial advisor to Translate Bio for the expansion of the collaboration agreement.

### **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.

### **About the Sanofi Pasteur and Translate Bio collaboration**

In 2018, Translate Bio entered into a collaboration and exclusive license agreement with Sanofi Pasteur Inc., the vaccines global business unit of Sanofi, to develop mRNA vaccines for up to five infectious disease pathogens. This agreement was first expanded in March 2020 to include the collaborative development of a novel mRNA vaccine for COVID-19. 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 research term of at least four years after the original signing in 2018. 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 mRNA therapeutic program is being developed as a treatment for cystic fibrosis (CF) and is in a 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](http://www.translate.bio) or on Twitter at [@TranslateBio](https://twitter.com/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, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties 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**

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