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): July 31, 2019

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 2.02 Results of Operations and Financial Condition.

On July 31, 2019, Translate Bio, Inc. (the "Company") issued a press release reporting financial results for the fiscal quarter ended June 30, 2019. The full text of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 in this Current Report on Form 8-K (including Exhibit 99.1) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events.

On July 31, 2019, the Company issued a press release announcing interim results from its Phase 1/2 clinical trial of MRT5005 in patients with cystic fibrosis.

A copy of the press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits:

Exhibit No.	Description
99.1	Translate Bio, Inc. Press Release dated July 31, 2019 entitled "Translate Bio Announces Second Quarter 2019 Financial Results and Provides Corporate Update"
99.2	Translate Bio, Inc. Press Release dated July 31, 2019 entitled "Translate Bio Announces Interim Results from Phase 1/2 Clinical Trial of MRT5005 in Patients with Cystic Fibrosis"

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TRANSLATE BIO, INC.

Date: July 31, 2019

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

Translate Bio Announces Second Quarter 2019 Financial Results and Provides Corporate Update

— Announced interim results from single-ascending dose portion of Phase 1/2 clinical trial in cystic fibrosis (CF) —

— Received FDA clearance to advance 2nd program into clinical development, MRT5201 for ornithine transcarbamylase (OTC) deficiency –

— Conference call to discuss interim Phase 1/2 clinical trial results for MRT5005 at 8:00 am ET today —

LEXINGTON, Mass. – July 31, 2019 – Translate Bio (Nasdaq: TBIO), a clinical-stage messenger RNA (mRNA) therapeutics company developing a new class of potentially transformative medicines to treat diseases caused by protein or gene dysfunction, today announced financial results for the second quarter ended June 30, 2019 and reviewed recent corporate achievements and updates.

"We ended the second quarter with two clinical-stage programs in development for rare, genetic diseases, demonstrating the potential of our mRNA therapeutic platform and moving us closer to reaching patients with few or no treatment options today," said Ronald Renaud, chief executive officer of Translate Bio. "We're also excited to share our first clinical data in cystic fibrosis, and view this as a crucial step in developing a potential treatment for CF patients who do not benefit from currently available therapies. In addition, we look forward to beginning our single-ascending dose Phase 1/2 clinical trial in OTC deficiency later this year as well."

Second Quarter 2019 and Recent Updates

- **Announced interim results from single-ascending dose (SAD) portion of Phase 1/2 clinical trial of MRT5005 in patients with CF:** The Company announced interim results from a first-in-human Phase 1/2 clinical trial evaluating single- and multiple-ascending doses of MRT5005 in patients with CF. MRT5005 is designed to address the underlying cause of CF regardless of genetic mutation by delivering mRNA encoding fully functional cystic fibrosis transmembrane conductance regulator (CFTR) protein to cells in the lung through nebulization. Today's results, the first evaluation of an inhaled mRNA therapeutic, summarize the SAD portion of the clinical trial in 12 patients through one-month follow-up post treatment. The multiple-ascending dose (MAD) portion of the trial is currently ongoing with results expected in 2020.

- **Received U.S. Food and Drug Administration (FDA) clearance to proceed with a SAD Phase 1/2 clinical trial for OTC deficiency:** In June 2019, Translate Bio announced that it received clearance from the FDA to proceed with a SAD Phase 1/2 clinical trial of MRT5201 in adult patients with OTC deficiency, for which the Company plans to initiate patient screening in the second half of 2019. MRT5201 is a first-in-class treatment designed to directly address the underlying cause of OTC deficiency by providing mRNA encoding the fully functional OTC enzyme in patients with the disease. The Company is currently conducting additional preclinical studies that are required to support future clinical development of MRT5201, including a MAD clinical trial, and plans to submit data from these preclinical studies to the FDA in the fourth quarter of 2019.
- **Appointed Dr. George Demetri to the Board of Directors:** In July 2019, the Company announced the appointment of George D. Demetri, M.D., a physician-scientist at the Dana-Farber Cancer Institute and a professor of medicine at Harvard Medical School, to its Board of Directors. This appointment adds significant clinical development expertise as Translate Bio advances its clinical programs in CF and OTC deficiency.

Anticipated Milestones

- MRT5005 (CF): Report results from additional SAD dose group and MAD portion of Phase 1/2 clinical trial in 2020
- MRT5201 (OTC Deficiency): Initiate patient screening in SAD Phase 1/2 clinical trial in the second half of 2019; Complete additional preclinical studies and submit data from these studies to the FDA in fourth quarter of 2019
- Identify lead preclinical candidates for additional lung and liver disease targets

Upcoming Events

- The Company will present and host one-on-one meetings at the following conferences:
  - *SVB Leerink Spotlight Series: Rare & Genetic Diseases,* August 7-8, 2019, Boston, MA
  - *Citi's 14th Annual Biotech Conference*, September 4-5, 2019, Boston, MA
  - *Chardan's 3rd Annual Genetic Medicines Conference*, October 7-8, 2019 NY, NY
- The Company will present additional details from the Phase 1/2 clinical trial interim data set of MRT5005 at the *North American Cystic Fibrosis Conference* taking place October 31 – November 2, 2019 in Nashville, TN

Second Quarter 2019 Financial Results and Financial Guidance

Translate Bio ended the second quarter of 2019 with $146.9 million in cash, cash equivalents and short-term investments and 51,010,368 shares of common stock outstanding. In May 2019, the Company raised gross proceeds of $47.5 million through a private placement of 5,582,940 shares of its common stock. The Company expects that its existing cash, cash equivalents and investments will enable it to fund its operations into the second half of 2020.

Translate Bio reported a net loss of $27.8 million and $27.5 million for the three months ended June 30, 2019 and 2018, respectively.

Collaboration revenue was $1.2 million in the three months ended June 30, 2019 which was derived from the collaboration and license agreement that the Company entered into with Sanofi Pasteur in 2018. There was no collaboration revenue in the three months ended June 30, 2018.

Operating expenses for the three months ended June 30, 2019 were $29.4 million, compared to $29.1 million for the same period in 2018, and were comprised of the following:

- Research and development expenses of $16.6 million during the second quarter of 2019, compared to $15.2 million for the same period in 2018. The increase is primarily due to an increase in costs associated with the continued advancement of the Company's CF program and MRT discovery program.
- General and administrative expenses of $7.9 million during the second quarter of 2019, compared to $6.0 million for the same period in 2018. The increase is primarily due to an increase in personnel-related costs.
- In the three months ended June 30, 2019 and 2018, the Company recognized non-cash operating expenses of $4.9 million and $7.9 million, respectively, for changes in the fair value of contingent consideration liabilities, related to future potential milestone and earnout payment obligations and, prior to the Company's IPO, anti-dilution rights with respect to common stock issued to Shire. The expense recognized in the three months ended June 30, 2019 is attributed primarily to the progress of the Company's CF and OTC deficiency programs and the time value of money due to the passage of time.

Conference Call Information

Translate Bio will host a conference call and webcast today at 8:00 AM ET to discuss the interim results from the single-ascending dose portion of Phase 1/2 clinical trial of MRT5005 in patients with CF. The live webcast can be accessed on the investor page of Translate Bio's website at https://investors.translate.bio/investors/news-and-events. The conference call can be accessed by dialing (877) 377-8524 (toll-free domestic) or (629) 228-0742 (international) and using the conference ID 2659949. A replay of the webcast will be available on Translate Bio's website approximately two hours after the completion of the event and will be archived for up to 30 days.

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. The Company's MRT platform is designed to develop product candidates that deliver mRNA carrying instructions to produce intracellular, transmembrane and secreted proteins for therapeutic benefit. Translate Bio believes that its MRT platform is applicable to a broad range of diseases caused by insufficient protein production or where production of proteins can modify disease, including diseases that affect the lung, liver, eye and central nervous system.

The Company also believes its MRT platform may be applied to various classes of treatments, such as therapeutic antibodies or vaccines in areas such as infectious disease and oncology. Translate Bio's two lead programs are being developed as treatments for cystic fibrosis (CF) and ornithine transcarbamylase (OTC) deficiency. For more information about the Company, please visit www.translate.bio or on Twitter at @TranslateBio.

Cautionary Note Regarding 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: the potential for MRT5005 to address the underlying cause of CF and benefit patients; Translate Bio's plans to report data from the additional SAD dose group and MAD portion of the Phase 1/2 clinical trial of MRT5005 in 2020; Translate Bio's plans to initiate patient screening for the SAD Phase 1/2 clinical trial for MRT 5201 in the second half of 2019; Translate Bio's plans to conduct additional preclinical studies for MRT5201 and its plan to submit data from these studies to the FDA in the fourth quarter of 2019; Translate Bio's plans to identify lead preclinical candidates for additional lung and liver disease targets; the period in which Translate Bio expects that its existing cash, cash equivalents and investments will enable it to fund its operations; Translate Bio's beliefs regarding the broad applicability of its MRT platform; the anticipated contributions of the new director; and Translate Bio'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: 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; Translate Bio's ability to obtain additional preclinical data to support further clinical development of MRT5201; 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2019 filed with the Securities and Exchange Commission on May 9, 2019 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.

TRANSLATE BIO, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS)
(UNAUDITED)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Collaboration revenue	$ 1,174	$ —	$ 2,648	$ —
Operating expenses:				
Research and development	16,625	15,219	34,048	27,921
General and administrative	7,850	5,991	14,403	10,769
Change in fair value of contingent consideration	4,889	7,852	16,591	12,760
Total operating expenses	29,364	29,062	65,042	51,450
Loss from operations	(28,190)	(29,062)	(62,394)	(51,450)
Other income (expense):				
Interest income	358	91	878	181
Other expense	—	(32)	—	(45)
Total other income (expense), net	358	59	878	136
Loss before benefit from income taxes	(27,832)	(29,003)	(61,516)	(51,314)
Benefit from income taxes	—	1,500	486	2,602
Net loss	$ (27,832)	$ (27,503)	$ (61,030)	$ (48,712)

TRANSLATE BIO, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(IN THOUSANDS)
(UNAUDITED)

	June 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 74,904	$ 55,199
Short-term investments	71,961	88,904
Prepaid expenses and other current assets	6,069	4,474
Restricted cash	950	1,025
Total current assets	153,884	149,602
Property and equipment, net	10,903	10,245
Right-of-use assets, net	10,650	—
Goodwill	21,359	21,359
Intangible assets, net	105,630	106,445
Deferred offering costs	123	—
Total assets	$ 302,549	$ 287,651
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,347	$ 5,168
Accrued expenses	7,246	6,547
Current portion of deferred revenue	9,015	2,572
Current portion of operating lease liability	449	—
Total current liabilities	20,057	14,287
Long-term portion of contingent consideration	120,233	103,642
Deferred revenue, net of current portion	34,192	41,841
Deferred tax liabilities	—	481
Deferred rent	—	2,105
Operating lease liability, net of current portion	12,370	—
Total liabilities	186,852	162,356
Stockholders' equity:		
Common stock	51	45
Additional paid-in capital	422,309	371,257
Accumulated deficit	(307,233)	(246,203)
Accumulated other comprehensive income	570	196
Total stockholders' equity	115,697	125,295
Total liabilities and stockholders' equity	$ 302,549	$ 287,651

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Exhibit 99.2

Translate Bio Announces Interim Results from Phase 1/2 Clinical Trial of MRT5005 in Patients with Cystic Fibrosis

— MRT5005 was generally well tolerated at low and mid-dose levels; no serious adverse events reported at any dose level —

— Marked increases in ppFEV1 (percent predicted forced expiratory volume in one second) observed after single dose of MRT5005, primarily at mid-dose —

— Findings support exploration of two additional dose cohorts —

— MRT5005 is the first mRNA therapeutic administered to patients for the treatment of a genetic disease —

— Conference call today at 8:00 am ET —

LEXINGTON, Mass. – July 31, 2019 – Translate Bio (Nasdaq: TBIO), a clinical-stage messenger RNA (mRNA) therapeutics company developing a new class of potentially transformative medicines to treat diseases caused by protein or gene dysfunction, today announced interim results from a first-in-human Phase 1/2 clinical trial evaluating single and multiple ascending doses of MRT5005 in patients with cystic fibrosis (CF). MRT5005 is designed to address the underlying cause of CF regardless of genetic mutation by delivering mRNA encoding fully functional cystic fibrosis transmembrane conductance regulator (CFTR) protein to cells in the lung through nebulization. Today's results, the first clinical investigation of an inhaled mRNA therapeutic, summarize the single ascending dose (SAD) portion of the clinical trial in 12 patients through one-month follow up post treatment. The multiple ascending dose (MAD) portion of the trial is ongoing with data expected in 2020.

"Effectively delivering the desired mRNA sequence is an essential step to producing functional CFTR proteins. While some variability in ppFEV1 from day to day in CF patients is expected in a trial of this size, we believe that the observed improvements in ppFEV1 from baseline and the timecourse of the effect support a CFTR-related mechanism and may suggest that MRT5005 can enable the production of functional protein," said Steven Rowe, M.D., director of the Gregory Fleming James Cystic Fibrosis Center, professor in the Division of Pulmonary, Allergy and Critical Medicine at University of Alabama, Birmingham, and principal investigator of the Phase 1/2 clinical trial of MRT5005. "These early promising data warrant continued evaluation of MRT5005 to optimize the dosing regimen and assess the effect with repeated administration. If future data confirms this early positive signal, MRT5005 has the potential to provide clinically meaningful benefit for people with CF independent of CFTR genotype."

“Despite significant advances in the treatment of patients with CF, there remains a critical unmet need for patients whose genetic mutations are considered non-amenable to CFTR modulators,” said Ann Barbier, M.D., Ph.D., chief medical officer of Translate Bio. “mRNA therapy represents a potential new approach to treating CF, and we look forward to sharing the results from the multiple-ascending dose part of the trial next year.”

Dr. Barbier continued, “On behalf of the team at Translate Bio, I would also like to extend our most sincere gratitude to the investigators, the Cystic Fibrosis Foundation, and most importantly, the patients who are participating and have participated in this clinical trial.”

“These encouraging interim results represent a milestone in the mRNA development landscape as this is the first time an mRNA therapeutic has been evaluated for its potential to treat a genetic disease,” said Ronald Renaud, chief executive officer of Translate Bio. **“**Also, as the first inhaled mRNA therapeutic, these data indicate the potential of mRNA therapeutics for the treatment of lung diseases, and support the planned expansion of our earlier-stage programs based on this pulmonary delivery platform.”

Phase 1/2 Clinical Trial Results

Study Design and Baseline Characteristics Summary

The interim results summarize data from 12 adult patients with CF who received a single dose of either MRT5005 or placebo (3:1 randomization). Patients who received MRT5005 were assigned to one of three dose groups (8, 16 or 24 mg). Of the 12 patients, 11 had at least one copy of the F508del mutation and one patient did not have a F508del mutation and was considered non-amenable to CFTR modulator treatment. Seven of the 12 patients were taking an approved CFTR modulator through screening, dosing and follow-up.

Safety, Tolerability and Pharmacokinetic Summary

The most common adverse events through Day 29 were cough and headache. There were no treatment-emergent serious adverse events (SAEs). All treatment-emergent adverse events (TEAEs) were considered mild to moderate. Five patients, 3 of whom were in the 24 mg dose group, experienced transient, mild to moderate febrile reactions deemed related to study drug. These events occurred approximately 4-10 hours post dosing, and were characterized by fever and symptoms such as headache, fatigue, chills or nausea, which were treated with medicines such as acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs), or an anti-emetic. Symptoms resolved within 24 hours, and all patients were discharged from the study center on Day 2 as planned. In these five patients, low levels of mRNA and/or lipid were detected in the blood.

Characteristics through Day 29	MRT5005 8 mg (N=3)	MRT5005 16 mg (N=3)	MRT5005 24 mg (N=3)	Pooled Placebo (N=3)
Overall Number of TEAEs reported	28	25	33	11
Not related	11	9	10	9
Related	17	16	23	2
Number of Serious TEAEs reported	0	0	0	0
Number of TEAEs leading to discontinuation	0	0	0	0
Number of TEAEs resulting in death	0	0	0	0
Number of TEAEs classified as pulmonary exacerbation	0	0	2*	0
Number of TEAEs by Severity				
Mild	23	24	21	11
Moderate	5	1	12	0
Severe	0	0	0	0

* Occurred at Day 25 and Day 27

Lung Function (ppFEV1) Summary

A primary measure of lung function, ppFEV1, was assessed at pre-defined timepoints throughout the trial. Patients in the pooled placebo group and the 8 mg dose group did not show a marked improvement in ppFEV1. In the eight day period after dosing, the three patients in the 16 mg dose group demonstrated maximal ppFEV1 increases of 11.1%, 13.6% and 22.2%, for a mean maximum increase from baseline (+/- standard deviation) of 15.7% (5.8). Of the three patients in the 16 mg dose group, two were on a stable CFTR modulator treatment regimen for at least 28 days, while the third had a genotype that is considered non-amenable to CFTR modulator treatments. Of the three patients in the 24 mg dose group, through Day 8, one patient experienced a maximum increase in ppFEV1 from baseline of 21.4%, while two patients did not show a marked increase in ppFEV1.

	Mean Baseline ppFEV1 % (SD)	Absolute Change from Baseline Mean ppFEV1 % (SD)				Maximum Change from Baseline through Day 8 Mean ppFEV1 % (SD)
		Day 1 *	Day 2	Day 3	Day 8	
8 mg	53.3 (7.2)	3.7 (0.9)	2.8 (1.8)	3.4 (2.3)	-1.2 (3.0)	4.4 (0.7)
16 mg	72.0 (6.6)	7.2 (7.3)	11.2 (10.3)	11.4 (5.1)	9.2 (1.8)	15.7 (5.8)
24 mg	79.2 (7.1)	2.5 (0.4)	8.6 (11.2)	6.6 (4.8)	2.3 (3.2)	9.7 (10.2)
Pooled Placebo	60.5 (18.5)	2.0 (3.8)	0.4 (2.4)	-0.2 (1.4)	-0.6 (4.0)	3.2 (2.7)

* 8 hours post dose

The Company anticipates presenting additional details from this interim data set at the North American Cystic Fibrosis Conference taking place October 31-November 2, 2019.

Phase 1/2 Clinical Trial Design

Based on the analysis of the SAD (Part A) interim results, the Company has proposed certain protocol changes in this ongoing Phase 1/2 clinical trial. In the SAD portion of the trial, the Company plans to amend the clinical trial protocol to include an additional 20 mg single dose cohort of four patients. In the MAD portion of the trial (Part B), the Company plans to amend the clinical trial protocol to add 12 and 20 mg dose cohorts with four patients each, the latter dosing cohort contingent on successful completion of the 20 mg single dose cohort and an acceptable safety profile in the lower MAD dose cohorts. The Company no longer plans to evaluate a 24 mg dose group in the MAD portion of the trial. The originally planned Part C of the clinical trial, which included bronchoscopies, is expected to be redesigned as a Part B expansion to instead focus on the enrollment of additional patients at dose levels of interest. As required, the Company plans to submit these protocol changes to the FDA. The Company expects to report results from the additional 20 mg SAD cohort and the ongoing MAD portion of the trial in 2020.

The randomized, double-blind, placebo-controlled Phase 1/2 clinical trial of MRT5005 was designed to enroll at least 32 adult patients with CF who have two Class I and/or Class II mutations. After accounting for the planned protocol amendments, the Company expects to enroll up to 40 adult patients with CF. The primary endpoint of the trial is to assess the safety and tolerability of single and multiple escalating doses of MRT5005 administered by nebulization. Percent predicted forced expiratory volume in one second (ppFEV1), which is a well-defined and accepted endpoint measuring lung function, is also being measured at pre-defined timepoints throughout the trial. The Phase 1/2 clinical trial of MRT5005 for the treatment of CF is being conducted in collaboration with the Cystic Fibrosis Foundation Therapeutics Development Network.

About MRT5005

MRT5005 is the first clinical-stage mRNA product candidate designed to address the underlying cause of CF by delivering mRNA encoding fully functional cystic fibrosis transmembrane conductance regulator (CFTR) protein to the lung epithelial cells through nebulization. MRT5005 is designed to treat all patients with CF, regardless of the underlying genetic mutation, including those with limited or no CFTR protein. MRT5005 has been granted Orphan Drug Designation in the U.S. and EU for the treatment of CF.

About Cystic Fibrosis

Cystic fibrosis is the most common fatal inherited disease in the United States, affecting more than 30,000 patients in the U.S. and more than 70,000 patients worldwide. CF is caused by genetic mutations that result in dysfunctional or absent CFTR protein. This defect causes mucus buildup in the lungs, pancreas and other organs. Mortality is primarily driven by a progressive

decline in lung function. According to the Cystic Fibrosis Foundation, the median age at death for patients with CF was 30.6 years in 2017. There is no cure for CF. CFTR modulators that are currently marketed or in clinical development have effect only in patients with specific mutations, and patients still experience pulmonary exacerbations and a progressive decline in lung function, which represents a significant unmet need.

Conference Call Information

Translate Bio will host a conference call and webcast today at 8:00 AM ET to discuss the interim results from the single-ascending dose portion of Phase 1/2 clinical trial of MRT5005 in patients with CF. The live webcast can be accessed on the investor page of Translate Bio's website at https://investors.translate.bio/investors/news-and-events. The conference call can be accessed by dialing (877) 377-8524 (toll-free domestic) or (629) 228-0742 (international) and using the conference ID 2659949. A replay of the webcast will be available on Translate Bio's website approximately two hours after the completion of the event and will be archived for up to 30 days.

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Cautionary Note Regarding 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: the potential for MRT5005 to address the underlying cause of CF, Translate Bio's plans to continue to dose patients in its MAD portion of its Phase 1/2 clinical trial of MRT5005 and the expected patient enrollment size; the anticipated availability of the clinical data regarding MRT5005 in 2020; Transate Bio's plans to amend the protocol of its Phase 1/2 clinical trial of MRT5005; the potential of mRNA therapeutics for the treatment of genetic disease, including diseases of the lung; Translate Bio's plans to report additional details on the interim data set from its Phase 1/2 clinical trial of MRT5005; and Translate Bio'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: 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 later-stage clinical trials any positive findings from preclinical studies or early-stage clinical trials; Translate Bio's ability to enroll patients in its ongoing clinical trial; whether interim data from the Phase 1/2 clinical trial of MRT5005 will be predictive of the final results of that trial; 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; 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 quarterly period ended March 31, 2019 and in any other subsequent filings made with the Securities and Exchange Commission 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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