



Translate Bio Announces First Quarter 2021 Financial Results and Provides Corporate Update

May 6, 2021

-- Advanced infectious disease vaccine programs with Sanofi Pasteur through initiation of COVID-19 clinical trial and publication of preclinical results; Influenza trial anticipated to begin mid-year --

-- Reported interim data from Phase 1/2 clinical trial of MRT5005 for the treatment of cystic fibrosis (CF) --

-- Enhanced internal capabilities across pulmonary programs, manufacturing and financial operations with key leadership additions and promotions --

LEXINGTON, Mass., May 06, 2021 (GLOBE NEWSWIRE) -- Translate Bio (Nasdaq: TBIO), a clinical-stage messenger RNA (mRNA) therapeutics company developing a new class of potentially transformative medicines to treat or prevent debilitating or life-threatening diseases, today announced financial results for the first quarter ended March 31, 2021 and reviewed recent corporate updates.

"This quarter, we continued to make important progress in growing our team and advancing our pipeline of mRNA therapeutics and vaccines. With interim data from our ongoing trial of MRT5005 in CF reported in March, we've taken critical steps toward developing the first inhaled mRNA therapeutic to treat a genetic lung disease," said Ronald Renaud, chief executive officer, Translate Bio. "Looking ahead, we anticipate completing the Phase 1/2 clinical trial of MRT5005 and continuing to advance translational and nonclinical studies for both MRT5005 and our next-generation CF program to support and optimize future clinical development in CF. We also plan to advance our work in mRNA infectious disease vaccines with our partner Sanofi Pasteur, including reporting data from our COVID-19 program in the third quarter of this year, and beginning a clinical trial for our influenza program mid-year."

Renaud continued, "We are continuing to execute on our 5-year strategic plan, TBIO 2025, with the goal of further advancing platform innovation and driving multiple programs into the clinic. We believe our recent leadership appointments bring expertise in pulmonary science, manufacturing, and operations that will be critical to our continued growth."

First Quarter 2021 and Recent Updates

mRNA Vaccines:

- **Initiated COVID-19 mRNA vaccine clinical trial (MRT5500) with Sanofi:** In March 2021, the Company announced the start of the Phase 1/2 clinical trial for MRT5500, an mRNA vaccine candidate against SARS-CoV-2, the virus that causes COVID-19. Translate Bio received a \$25 million payment from Sanofi Pasteur based on achievement of this milestone. Interim results from this trial are expected in the third quarter of 2021. Additionally, there is ongoing preclinical work evaluating MRT5500 as well as other constructs against the emerging SARS-CoV-2 variants to inform the incorporation of variant strains into current or future development plans.
- **Published COVID-19 mRNA vaccine preclinical results:** In April 2021, the Company announced the peer-reviewed publication of preclinical results of its COVID-19 vaccine candidate, MRT5500, in the journal *npj Vaccines*. Preclinical evaluation of MRT5500 demonstrated a favorable immune response profile against SARS-CoV-2 and protection against the disease in an infection challenge model.

mRNA Therapeutics:

- **Reported results from second interim data analysis from ongoing Phase 1/2 clinical trial of MRT5005 in patients with CF:** In evaluating safety and tolerability, the primary outcome measure, data to date from the ongoing Phase 1/2 clinical trial suggest that repeat dosing of MRT5005 was generally safe and well tolerated. Percent predicted forced expiratory volume in 1 second (ppFEV₁), a measure of lung function, was assessed as a safety measure at pre-defined timepoints throughout the trial; no significant change in ppFEV₁ was observed. The Phase 1/2 clinical trial is ongoing and the Company anticipates reporting the findings from the clinical trial, including an additional multiple-ascending dose (MAD) dose group (20 mg) and a daily dosing cohort (4 mg once-daily for 5 days), at a future medical meeting. The Company plans to continue with ongoing and additional translational studies with MRT5005 and its next-generation CF candidate to support and optimize future clinical development, including research into dosing, formulation and nebulization.
- **Advanced preclinical pulmonary programs:** The Company advanced its next-generation CF and primary ciliary dyskinesia (PCD) programs with positive preclinical data generated to support planned initiation of investigational new drug application (IND)-enabling studies in the second half of 2021.

Expansion of Leadership Team:

- **Appointed Dr. Rand Sutherland as President:** In March 2021, the Company announced Dr. Rand Sutherland joined the team as President. Dr. Sutherland brings 20 years of combined industry, medical and academic expertise in pulmonary and rare diseases to this role. As President of Translate Bio, Dr. Sutherland is responsible for research and development, corporate development and program management, including portfolio and pipeline strategy with a focus on prioritizing and

optimizing the Company's R&D opportunities while evaluating corporate and business development prospects.

- **Strengthened leadership team with key additions and promotions:** In April 2021, the Company announced several key leadership appointments, including Brendan Smith as Chief Financial Officer, Greg Troiano as Chief Manufacturing Officer, and Jim Sullivan as Senior Vice President, Pulmonary Discovery. These roles support the Company's long-term strategic plan, TBIO 2025, that emphasizes several areas for value creation across the Company including adding key in-house quality and manufacturing capabilities, deepening pulmonary expertise and increasing R&D investments with a goal of advancing platform innovation and driving multiple programs into the clinic.

Anticipated 2021 Milestones

mRNA Vaccines:

- **COVID-19 Vaccine (MRT5500):** Report interim results from the ongoing Phase 1/2 clinical trial in the third quarter of 2021 (Sanofi Pasteur collaboration)
- **Influenza Vaccine:** Advance lead lipid nanoparticle (LNP)/mRNA formulations to begin clinical proof-of-technology trial mid-year 2021 (Sanofi Pasteur collaboration)
- **Additional Vaccine Programs:** Advance ongoing preclinical studies for targets against additional viral and bacterial pathogens

mRNA Therapeutics:

- **CF Clinical Program (MRT5005):** Complete enrollment and dosing for the ongoing Phase 1/2 clinical trial and report data at a future medical meeting, including the 20 mg MAD group and a daily dosing cohort assessing 4 mg once-daily for 5 days
- **CF Discovery Program (Next-generation CF):**
 - Advance lead candidate into IND-enabling studies in the second half of 2021
 - Continue ongoing and additional translational studies with MRT5005 and a next-generation CF candidate to support and optimize future clinical development, including research into dosing, formulation and nebulization
- **Primary Ciliary Dyskinesia (PCD):** Advance lead candidate into IND-enabling studies in the second half of 2021
- **Additional Pulmonary:** Conduct preclinical studies to validate targets, including pulmonary arterial hypertension and respiratory infectious diseases
- **Liver:** Progress efforts to identify next-generation LNPs to enable advancement of Company's liver-directed therapeutic portfolio
- **mRNA Platform:**
 - Delivery: Identify next-generation LNPs to support additional disease program development
 - Next Wave Areas: Explore new areas for application of mRNA technology including therapeutic antibodies and protein degradation

Upcoming Scientific Presentations

- Preclinical Presentation in Primary Ciliary Dyskinesia at the American Thoracic Society (ATS) 2021 International Conference: A Messenger RNA (mRNA)-Based Therapeutic Designed to Treat Primary Ciliary Dyskinesia (Abstract #A1138), Mini Symposium, May 18 from 10:00– 11:30 am ET

Upcoming Investor Events

- Jefferies Virtual Healthcare Conference, June 1–3
- 42nd Annual Goldman Sachs Global Healthcare Conference, June 8–10
- 2nd Annual SVB Leerink CyberRx Series: Vaccine Forum, June 21–22
- William Blair Biotech Focus Conference 2021, July 14–15

First Quarter 2021 Financial Results and Financial Guidance

Translate Bio ended the first quarter of 2021 with \$654.8 million in cash, cash equivalents and investments and 75,217,672 shares of common stock outstanding. The Company expects that its existing cash, cash equivalents and investments will enable it to fund its operating expenses and capital expenditure requirements through 2023.

Translate Bio reported a net income of \$26.5 million and a net loss of \$14.3 million for the three months ended March 31, 2021 and 2020, respectively.

Collaboration revenue was \$34.6 million and \$4.7 million for the three months ended March 31, 2021 and 2020, respectively, which was derived from the Sanofi Pasteur collaboration. Revenue is recorded as a percentage of the estimated transaction price based on the extent of progress towards completion. Activities for the vaccine program increased in the three months ended March 31, 2021 compared to the same period in 2020, resulting in a larger percent of the transaction price recognized.

Operating expenses for the three months ended March 31, 2021 were \$8.0 million, compared to \$19.4 million for the same period in 2020, and were

comprised of the following:

- Research and development expenses of \$41.1 million during the first quarter of 2021, compared to \$21.4 million for the same period in 2020. The increase is primarily due to continued development of the Company's discovery and vaccine programs as well as increases in occupancy and personnel-related costs.
- General and administrative expenses of \$10.8 million during the first quarter of 2021, compared to \$7.5 million for the same period in 2020. The increase is primarily due to increases in recruiting fees, consulting and legal costs and an increase in personnel-related costs.
- Change in fair value of contingent consideration of \$44.0 million related to future potential milestone and earnout payment obligations. This decrease was primarily driven by revisions to the clinical development plan for MRT5005.

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, or to prevent infectious diseases by generating protective immunity. Translate Bio is primarily focused on applying its technology to treat pulmonary diseases with a lead pulmonary candidate being evaluated as an inhaled treatment for cystic fibrosis (CF) in a Phase 1/2 clinical trial. Additional pulmonary diseases are being evaluated in discovery-stage research programs that utilize a proprietary lung delivery platform. Translate Bio also believes its technology may apply broadly to a wide 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 protein degradation. Translate Bio is also pursuing the development of mRNA vaccines for infectious diseases under a collaboration with Sanofi Pasteur. 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: Translate Bio's plans to complete and report data from its Phase 1/2 clinical trial of MRT5005 for CF at a future medical meeting; plans to report interim data from its Phase 1/2 clinical trial of MRT5500 for COVID-19 in the third quarter of 2021; plans to commence clinical trials for an influenza vaccine mid-year 2021; plans to advance lead candidates for next-generation CF and PCD programs in the second half of 2021; plans to further advance platform innovation and drive multiple programs into the clinic; the goals and objectives of the TBIO 2025 long-term strategic plan; Translate Bio's expectations with respect to its recent leadership appointments; the potential for mRNA-based therapeutics to apply to the treatment of many diseases caused by protein or gene dysfunction; Translate Bio's beliefs regarding the broad applicability of its technology; Translate Bio's plans to advance its pipeline of mRNA therapeutics and validate targets for additional pulmonary diseases and advance its liver-directed therapeutic portfolio; and the period in which Translate Bio expects that its existing cash, cash equivalents and investments will enable it to fund its operating expenses and capital expenditure requirements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "forward," "intend," "may," "milestone," "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 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, including without limitation, 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; uncertainties relating to the discovery and development of vaccine candidates based on mRNA; 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 three months ended March 31, 2021 filed with the Securities and Exchange Commission on May 6, 2021 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.

Investor Relations

Teri Dahlman
Tel.: +1 (617) 817-8655
dahlman@translate.bio

Media Relations

Maura Gavaghan
Tel: +1 (617) 233-1154
mgavaghan@translate.bio

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

	Three Months Ended March 31,	
	2021	2020
Collaboration revenue	\$ 34,600	\$ 4,654
Operating expenses:		
Research and development	41,140	21,439
General and administrative	10,817	7,458
Change in fair value of contingent consideration	(43,979)	(9,452)
Total operating expenses	<u>7,978</u>	<u>19,445</u>

Income (loss) from operations	26,622	(14,791)
Other income, net	154	509
Income (loss) before income tax provision	26,776	(14,282)
Income tax provision	(254)	—
Net income (loss)	\$ 26,522	\$ (14,282)

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

	March 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 155,746	\$ 342,027
Investments	499,007	312,001
Collaboration receivables	23,240	26,598
Prepaid expenses and other current assets	16,721	11,741
Restricted cash	4,826	4,826
Total current assets	699,540	697,193
Property and equipment, net	16,563	15,372
Right-of-use assets, net	71,154	72,957
Goodwill	21,359	21,359
Intangible assets, net	77,106	79,127
Other assets	4,918	3,928
Total assets	\$ 890,640	\$ 889,936
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 17,068	\$ 8,839
Accrued expenses	16,240	13,202
Current portion of deferred revenue	72,373	67,563
Current portion of operating lease liability	12,084	11,733
Income tax liability	254	—
Total current liabilities	118,019	101,337
Contingent consideration	108,251	152,230
Deferred revenue, net of current portion	226,876	228,659
Operating lease liability, net of current portion	48,604	50,953
Total liabilities	501,750	533,179
Stockholders' equity:		
Common stock	75	75
Additional paid-in capital	775,499	769,965
Accumulated deficit	(386,761)	(413,283)
Accumulated other comprehensive income	77	—
Total stockholders' equity	388,890	356,757
Total liabilities and stockholders' equity	\$ 890,640	\$ 889,936



Source: Translate Bio, Inc.