Translate Bio Announces First Quarter 2020 Financial Results and Provides Corporate Update

May 7, 2020

-- Pursuing development of mRNA vaccine against COVID-19 through expanded collaboration with Sanofi Pasteur --

-- Existing large-scale manufacturing capacity expected to help meet needs of pandemic --

-- In vivo testing ongoing for multiple COVID-19 vaccine candidates to support lead candidate selection; goal to initiate first-in-human clinical trial Q4 2020 --

LEXINGTON, Mass., May 07, 2020 (GLOBE NEWSWIRE) -- 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 first quarter ended March 31, 2020 and reviewed recent corporate achievements and updates.

“The need for novel therapies with the potential to reach millions of people has never been more evident, and we are committed to advancing our programs and platform during this unprecedented time. We have kept critical areas of our business moving forward while prioritizing the safety of our employees,” said Ronald Renaud, chief executive officer of Translate Bio. “We are humbled to be part of the global effort to develop a vaccine against COVID-19 through our collaboration with Sanofi Pasteur. Using our innovative mRNA platform and large-scale manufacturing capacity, as well as Sanofi’s vaccine expertise, we are working rapidly to achieve our goal of advancing a novel mRNA vaccine to the clinic in the fourth quarter of this year.”

First Quarter 2020 and Recent Updates

- **Collaboration with Sanofi Pasteur to develop a novel mRNA vaccine for COVID-19:** Sanofi Pasteur and Translate Bio announced a collaboration pursuing development of a novel mRNA vaccine for COVID-19. This collaboration leverages the original agreement from 2018 between the two companies to develop up to five mRNA vaccines for infectious diseases. Multiple COVID-19 vaccine candidates are being evaluated *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.

- **Continued build-out of manufacturing capacity**: Build-out of dedicated manufacturing space through a contract manufacturing partner is underway with the potential to accommodate multiple 250-gram batches per month. Depending on the final human COVID-19 vaccine dose and subject to continued investment and third-party supplier arrangements, the Company estimates that it could have manufacturing capacity to produce 90-360 million doses annually by the first half of 2021.

- **MRT5005 granted Rare Pediatric Disease (RPD) designation:** The U.S. Food and Drug Administration (FDA) granted Rare Pediatric Disease (RPD) designation for MRT5005 for the treatment of cystic fibrosis (CF). MRT5005, the first inhaled mRNA therapeutic candidate, is designed to deliver mRNA encoding fully functional cystic fibrosis transmembrane conductance regulator (CFTR) protein to cells in the lung through nebulization.

- **MRT5005 clinical trial interruptions due to COVID-19 pandemic response:** The Company announced COVID-19 pandemic-related interruptions in enrollment and dosing in an ongoing Phase 1/2 clinical trial of MRT5005 in patients with CF and plans to provide updated timing on the expected interim data readout of the additional single-ascending dose (SAD) group and the multiple-ascending dose (MAD) portion of the clinical trial at a later date.

- **Continued focus on pulmonary programs:** The Company continued to advance its ongoing discovery efforts focused on a next-generation CF program and additional pulmonary diseases, including primary ciliary dyskinesia (PCD), idiopathic pulmonary fibrosis (IPF) and pulmonary arterial hypertension (PAH). The Company anticipates sharing more details throughout 2020.

Anticipated Milestones

- COVID-19 vaccine: advance development candidate to IND filing with the goal of clinical trial initiation in Q4 2020 (Sanofi Pasteur collaboration)
- Flu vaccine: advance development candidate to IND filing with clinical trial initiation anticipated mid-year 2021 (Sanofi Pasteur collaboration)
- MRT5005 (CF): report results from additional SAD dose group and MAD portion of Phase 1/2 clinical trial
- Preclinical pulmonary programs: advance next-generation CF, PCD, IPF and PAH programs toward selection of development candidate

- Platform: identify next-generation lipid nanoparticles (LNPs) to support liver, lung and additional disease program development

Upcoming Events

- The Company will present and host one-on-one meetings at the following virtual investment banking conferences:
  - Bank of America Healthcare Conference 2020, May 12-15, 2020
  - Jefferies Virtual Healthcare Conference, June 2-4, 2020

First Quarter 2020 Financial Results and Financial Guidance

Translate Bio ended the first quarter of 2020 with $155.1 million in cash, cash equivalents and short-term investments and 60,037,663 shares of common stock outstanding. The Company expects that its existing cash, cash equivalents and short-term investments, together with net proceeds of approximately $36.6 million raised through common stock sales under its Open Market Sale Agreement which settled subsequent to March 31, 2020, will enable it to fund its operating expenses and capital expenditure requirements into the third quarter of 2021.

Translate Bio reported a net loss of $14.3 million and $33.2 million for the three months ended March 31, 2020 and 2019, respectively.

Collaboration revenue was $4.7 million and $1.5 million for the three months ended March 31, 2020 and 2019, respectively, which was derived from the collaboration with Sanofi. The increase was related to increased activities for the vaccine program in the three months March 31, 2020 compared to the same period in 2019.

Operating expenses for the three months ended March 31, 2020 were $19.4 million, compared to $35.7 million for the same period in 2019, and were comprised of the following:

- Research and development expenses of $21.4 million during the first quarter of 2020, compared to $17.4 million for the same period in 2019. The increase is primarily due to continued development of the Company's discovery and vaccine programs as well as an increase in personnel-related costs, partially offset by a decrease in its MRT5201 program.

- General and administrative expenses of $7.5 million during the first quarter of 2020, compared to $6.6 million for the same period in 2019. The increase is primarily due to an increase in personnel-related costs.

- Operating income of $9.5 million for change in the fair value of contingent consideration related to future potential milestone and earnout payment obligations. The operating income was attributed to an decrease in the fair value of the contingent consideration liability primarily due to an increase in the discount rate, partially offset by an increase in the fair value due to the continued progress of the MRT5005 program and the time value of money due to the passage of time.

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 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 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 update its timing to report data from the additional SAD dose group and MAD portion of the Phase 1/2 clinical trial of MRT5005; Translate Bio's plans to advance its pipeline of mRNA therapeutics and validate targets for additional pulmonary diseases; Translate Bio's expectations with respect to its collaboration with Sanofi, including the anticipated advancement towards an IND filing and initiating clinical trials for a COVID-19 vaccine in Q4 2020 and the anticipated IND filing for a flu vaccine in mid-year 2021; Translate Bio's plans to advance its preclinical pulmonary programs and platform; 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; 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: the current and potential future impacts of the COVID-19 pandemic on the Company'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; uncertainties relating to the discovery and development of vaccine candidates based on mRNA, and specifically as it relates to the novel coronavirus, COVID-19; 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, 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 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.
CONSOLIDATED STATEMENTS OF OPERATIONS
(IN THOUSANDS)
(UNAUDITED)

	Three Months Ended March 31,	
	2020	**2019**
Collaboration revenue	$ 4,654	$ 1,474
Operating expenses:		
Research and development	21,439	17,423
General and administrative	7,458	6,554
Change in fair value of contingent consideration	(9,452)	11,702
Total operating expenses	19,445	35,679
Loss from operations	(14,791)	(34,205)
Interest income, net	509	521
Loss before benefit from income taxes	(14,282)	(33,684)
Benefit from income taxes	—	486
Net loss	$ (14,282)	$ (33,198)

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

	March 31, 2020	**December 31, 2019**
Assets		
Current assets:		
Cash and cash equivalents	$ 97,468	$ 84,580
Short-term investments	57,627	104,098
Collaboration receivables	6,228	4,596
Deferred offering costs	177	—
Prepaid expenses and other current assets	6,744	9,391
Restricted cash	950	950
Total current assets	169,194	203,615
Property and equipment, net	13,781	12,539
Right-of-use assets, net	10,268	10,400
Goodwill	21,359	21,359
Intangible assets, net	84,844	85,536
Other assets	5,796	2,752
Total assets	$ 305,242	$ 336,201
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,297	$ 15,968
Accrued expenses	7,478	7,072
Current portion of deferred revenue	26,760	18,100
Current portion of operating lease liability	573	530
Total current liabilities	41,108	41,670
Contingent consideration	94,203	103,655
Deferred revenue, net of current portion	15,328	25,256
Operating lease liability, net of current portion	11,931	12,084
Total liabilities	162,570	182,665
Stockholders' equity:		
Common stock	60	60
Additional paid-in capital	515,535	512,231
Accumulated deficit	(373,778)	(359,496)

Accumulated other comprehensive income	855	741
Total stockholders' equity	142,672	153,536
Total liabilities and stockholders' equity	$ 305,242	$ 336,201

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Source: Translate Bio, Inc.