



Translate Bio Announces Second Quarter 2020 Financial Results and Reviews Recent Progress

August 6, 2020

-- Expanded collaboration with partner Sanofi Pasteur for all infectious diseases further unites Translate Bio's leading mRNA technology and large-scale manufacturing with Sanofi's world class vaccine development and distribution --

-- Continued progress in advancing COVID-19 vaccine candidates supports goal to initiate first-in-human clinical trial Q4 2020 --

-- Strong financial position to continue to invest in platform innovation and therapeutic program development --

LEXINGTON, Mass., Aug. 06, 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 second quarter ended June 30, 2020 and reviewed recent corporate achievements and updates.

"While navigating the challenges of the COVID-19 pandemic, we continue to make progress in our preclinical programs – both in therapeutics for pulmonary diseases and in vaccine development under our collaboration with Sanofi Pasteur," said Ronald Renaud, chief executive officer of Translate Bio. "Additionally, for our Phase 1/2 clinical trial for MRT5005 for the treatment of cystic fibrosis (CF), we and the clinical sites are assessing the potential for patients to safely return to the clinic for study enrollment and dosing."

Mr. Renaud continued, "This quarter, we also announced an important expansion of our work with Sanofi. We believe that this expanded agreement allows us to broadly develop mRNA vaccines with a leader in the vaccine space, leveraging their resources and expertise to potentially deliver novel infectious disease vaccines globally. Our two teams continue to work together to advance multiple programs towards clinical development, with a primary focus on the COVID-19 vaccine program and the initiation of a first-in-human clinical trial in the fourth quarter of this year."

"As we enter the second half of the year, we believe we are in a strong financial position to continue to invest in platform innovation and to build on our proprietary delivery capabilities to support advancement of our therapeutic development programs," added Mr. Renaud.

Second Quarter 2020 and Recent Updates

- **Expanded collaboration with Sanofi Pasteur to develop mRNA vaccines for all infectious diseases:** In June 2020, Translate Bio and Sanofi Pasteur announced the expansion of their existing 2018 collaboration and license agreement to develop mRNA vaccines for all infectious diseases. In the third quarter, under the expanded agreement, Translate Bio received \$425.0 million, consisting of a \$300.0 million upfront payment and a \$125.0 million common stock investment. Translate Bio will also be eligible for potential future milestones and other payments up to \$1.9 billion and tiered royalties based on worldwide sales of the developed vaccines.
- **Completed \$125 million public offering of common stock:** In June 2020, the Company completed a public offering of 5,681,819 shares of common stock at a public offering price of \$22.00 per share, for gross proceeds of \$125.0 million.

Anticipated Milestones

- COVID-19 vaccine: advance development candidate to Investigational New Drug (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 single-ascending dose group and multiple-ascending dose portion of Phase 1/2 clinical trial
- Preclinical pulmonary programs: advance next-generation CF, Primary Ciliary Dyskinesia, Idiopathic Pulmonary Fibrosis and Pulmonary Arterial Hypertension 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 participate in the following virtual investment banking conferences:
 - Citi's 15th Annual BioPharma Virtual Conference, September 9-10, 2020
 - SVB Leerink CyberX Series: Vaccine Forum, September 23-24, 2020
 - SVB Leerink CyberX Series: Rare & Genetics, October 1, 2020
- The Company will give a presentation at the North American Cystic Fibrosis Conference, October 21-23, 2020, during a session entitled: *Novel Nucleic Acid Strategies to Treat the Fundamental CF Defect*

Second Quarter 2020 Financial Results and Financial Guidance

Translate Bio ended the second quarter of 2020 with \$292.2 million in cash, cash equivalents and short-term investments and 69,359,509 shares of common stock outstanding. The Company expects that its existing cash, cash equivalents and short-term investments, together with the upfront payment and common stock equity investment of approximately \$425.0 million from Sanofi received in the third quarter of 2020, will be sufficient to fund its operating expenses and capital expenditure requirements for at least the next 36 months.

Translate Bio reported a net loss of \$36.3 million and \$27.8 million for the three months ended June 30, 2020 and 2019, respectively.

Collaboration revenue was \$16.3 million and \$1.2 million for the three months ended June 30, 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 ended June 30, 2020 compared to the same period in 2019.

Operating expenses for the three months ended June 30, 2020 were \$53.0 million, compared to \$29.4 million for the same period in 2019, and were comprised of the following:

- Research and development expenses of \$29.0 million during the second quarter of 2020, compared to \$16.6 million for the same period in 2019. The increase is primarily due to continued development of the Company's vaccine and discovery programs as well as an increase in personnel-related costs, partially offset by a decrease in expenses related to the Company's MRT5201 and MRT5005 programs.
- General and administrative expenses of \$8.6 million during the second quarter of 2020, compared to \$7.9 million for the same period in 2019.
- Operating expenses of \$15.3 million for change in the fair value of contingent consideration related to future potential milestone and earnout payment obligations. The expense recognized was primarily attributed to an increase in the fair value of the contingent consideration liability due to the time value of money due to the passage of time and a decrease in the discount rate.

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 is also pursuing the development of mRNA vaccines for infectious diseases under a collaboration with Sanofi Pasteur. 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 for infectious disease and other diseases. 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 resume enrollment and dosing its paused Phase 1/2 clinical trial of MRT5005; 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, the anticipated IND filing with clinical trial initiation for a flu vaccine in mid-year 2021, and the development of mRNA vaccines and the delivery of infectious vaccines globally; Translate Bio's plans to advance its pipeline of mRNA therapeutics and validate targets for additional pulmonary diseases; Translate Bio's plans to advance its additional disease program 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 June 30, 2020 filed with the Securities and Exchange Commission on August 6, 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 June 30,

Six Months Ended June 30,

	2020		2019		2020		2019	
Collaboration revenue	\$ 16,319		\$ 1,174		\$ 20,974		\$ 2,648	
Operating expenses:								
Research and development	29,002		16,625		50,442		34,048	
General and administrative	8,601		7,850		16,060		14,403	
Change in fair value of contingent consideration	15,347		4,889		5,895		16,591	
Total operating expenses	52,950		29,364		72,397		65,042	
Loss from operations	(36,631)	(28,190)	(51,423)	(62,394)
Interest income	343		358		853		878	
Loss before benefit from income taxes	(36,288)	(27,832)	(50,570)	(61,516)
Benefit from income taxes	—		—		—		486	
Net loss	\$ (36,288)	\$ (27,832)	\$ (50,570)	\$ (61,030)

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

	June 30, 2020	December 31, 2019		
Assets				
Current assets:				
Cash and cash equivalents	\$ 272,193	\$ 84,580		
Short-term investments	20,029	104,098		
Collaboration receivables	15,131	4,596		
Prepaid expenses and other current assets	7,918	9,391		
Restricted cash	950	950		
Total current assets	316,221	203,615		
Property and equipment, net	15,154	12,539		
Right-of-use assets, net	10,130	10,400		
Goodwill	21,359	21,359		
Intangible assets, net	81,280	85,536		
Other assets	10,134	2,752		
Total assets	\$ 454,278	\$ 336,201		
Liabilities and Stockholders' Equity				
Current liabilities:				
Accounts payable	\$ 12,912	\$ 15,968		
Accrued expenses	11,126	7,072		
Current portion of deferred revenue	27,109	18,100		
Current portion of operating lease liability	619	530		
Total current liabilities	51,766	41,670		
Contingent consideration	109,550	103,655		
Deferred revenue, net of current portion	9,818	25,256		
Operating lease liability, net of current portion	11,751	12,084		
Total liabilities	182,885	182,665		
Stockholders' equity:				
Common stock	69	60		
Additional paid-in capital	680,850	512,231		
Accumulated deficit	(410,066)	(359,496)
Accumulated other comprehensive income	540	741		
Total stockholders' equity	271,393	153,536		
Total liabilities and stockholders' equity	\$ 454,278	\$ 336,201		

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Source: Translate Bio, Inc.