



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

August 5, 2021

- Entered into a definitive agreement under which Sanofi will acquire, subject to customary conditions to closing, all outstanding shares of Translate Bio with a goal of advancing deployment of mRNA technology across vaccines and therapeutics development --
- Advanced mRNA infectious disease vaccine programs, including Sanofi Pasteur initiation of influenza clinical trial; clinical trial results from two mRNA vaccines anticipated this year --
- Continued progress in development of mRNA therapeutics for pulmonary diseases including preclinical next-generation cystic fibrosis (CF) and primary ciliary dyskinesia (PCD) programs --

LEXINGTON, Mass., Aug. 05, 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 second quarter ended June 30, 2021 and reviewed recent corporate updates.

"Since we started our partnership with Sanofi in 2018, we have moved two mRNA vaccine candidates through preclinical development to investigational new drug (IND) application submission, and initiated Phase 1 clinical trials for COVID-19 and seasonal influenza. We have made significant progress in the development of our mRNA vaccines through this collaboration, demonstrating some of the key attributes of our mRNA platform, including speed, flexibility and scale," said Ronald Renaud, chief executive officer, Translate Bio. "This transaction is a validation of our mRNA platform and a testament to the talented Translate Bio team. Joining Sanofi will deepen our existing relationship, and we believe it will strengthen the team's ability to bring innovative and life-changing medicines to patients. Sanofi's diverse therapeutics portfolio can also further demonstrate the advantages of our technology in areas beyond vaccines, building on the pioneering work done over the last 10+ years at Translate Bio."

Second Quarter 2021 and Recent Updates

mRNA Vaccine Programs for Infectious Diseases (Sanofi Pasteur Collaboration)

- **Initiated seasonal influenza mRNA vaccine clinical trial (MRT5400 and MRT5401) with Sanofi Pasteur:** In June 2021, the Company announced the start of the Phase 1 clinical trial for MRT5400 and MRT5401, two formulations of a monovalent seasonal influenza mRNA vaccine. The Phase 1 clinical trial will inform the next steps of the mRNA-based influenza vaccine program. Interim results from this trial are expected by the end of 2021.
- **Achieved influenza manufacturing milestone:** In June 2021, the Company achieved a manufacturing milestone under the collaboration with Sanofi Pasteur related to its influenza mRNA vaccine program. Translate Bio received a \$50 million payment from Sanofi Pasteur for the successful manufacture, release and delivery of clinical drug product to supply the Phase 1 seasonal influenza clinical trial.

mRNA Therapeutics Programs

- **Generated positive preclinical data for next-generation CF program:** Data demonstrates CFTR protein expression in the lungs of animals after the delivery of the next-generation CF product candidate using the intended inhaled route of administration.
- **Presented positive preclinical PCD data at the American Thoracic Society (ATS) 2021 International Conference:** In May 2021, the Company presented positive results from a preclinical study of a novel mRNA-based therapeutic designed to treat PCD. The study results suggest that delivery of an mRNA-based therapeutic to the lungs can lead to the expression of DNAI1, which could potentially restore mucociliary clearance.

Second Quarter 2021 Financial Results and Financial Guidance

Translate Bio ended the second quarter of 2021 with \$667.2 million in cash, cash equivalents and investments and 75,343,712 shares of common stock outstanding.

Translate Bio reported a net income of \$17.1 million for the three months ended June 30, 2021, compared to a net loss of \$36.3 million for the same period in 2020.

Collaboration revenue was \$72.6 million and \$16.3 million for the three months ended June 30, 2021 and 2020, respectively. Revenue was derived from the collaboration with Sanofi and is recorded as a percentage of the estimated transaction price based on the extent of progress toward completion. The transaction price increased in the three months ended June 30, 2021 compared to the same period in 2020 which resulted in an increase in revenue.

Operating expenses for the three months ended June 30, 2021 were \$56.6 million, compared to \$53.0 million for the same period in 2020, and were comprised of the following:

- Research and development expenses of \$40.5 million during the second quarter of 2021, compared to \$29.0 million for the

same period in 2020. The increase is primarily due to continued development of the Company's discovery program as well as increases in occupancy and personnel-related costs.

- General and administrative expenses of \$11.9 million during the second quarter of 2021, compared to \$8.6 million for the same period in 2020. The increase is primarily due to increases in personnel-related costs and professional fees.
- Operating expenses of \$4.2 million for change in the fair value of contingent consideration related to future potential milestone and earnout payment obligations. The operating expense 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, 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 expectations with respect to its collaboration with Sanofi Pasteur, including the anticipated reporting of interim data from influenza vaccine clinical trials in the second half of 2021, and the development of mRNA vaccines and the delivery of infectious vaccines globally; Translate Bio's plans to advance its additional disease programs and platform, strengthen its team's internal capabilities; 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," "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: risks related to Sanofi's and Translate Bio's ability to complete the proposed acquisition on the proposed terms or on the proposed timeline, including the receipt of required regulatory approvals, the possibility that competing offers will be made, other risks associated with executing business combination transactions; disruption from the proposed acquisition making it more difficult to conduct business as usual or to maintain relationships with customers, employees, manufacturers, suppliers or patient groups; 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; uncertainties relating to the discovery and development of therapies and vaccine candidates based on mRNA; 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; the current and potential future impacts of the COVID-19 pandemic on the Company's business, financial condition, operations and liquidity 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, 2021 filed with the Securities and Exchange Commission on August 5, 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Collaboration revenue	\$ 72,649	\$ 16,319	\$ 107,249	\$ 20,974
Operating expenses:				
Research and development	40,477	29,002	81,617	50,442
General and administrative	11,921	8,601	22,738	16,060

Change in fair value of contingent consideration	4,242	15,347	(39,737)	5,895
Total operating expenses	56,640	52,950	64,618	72,397
Income (loss) from operations	16,009	(36,631)	42,631	(51,423)
Other income, net	154	343	308	853
Income (loss) before income taxes	16,163	(36,288)	42,939	(50,570)
Income tax benefit	981	—	727	—
Net income (loss)	\$ 17,144	\$ (36,288)	\$ 43,666	\$ (50,570)

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

	<u>June 30,</u> <u>2021</u>	<u>December 31,</u> <u>2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 249,471	\$ 342,027
Investments	417,727	312,001
Collaboration receivables	24,030	26,598
Prepaid expenses and other current assets	20,958	11,741
Restricted cash	4,826	4,826
Total current assets	717,012	697,193
Property and equipment, net	18,249	15,372
Right-of-use assets, net	68,123	72,957
Goodwill	21,359	21,359
Intangible assets, net	74,507	79,127
Other assets	5,620	3,928
Total assets	\$ 904,870	\$ 889,936
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 13,736	\$ 8,839
Accrued expenses	15,079	13,202
Current portion of deferred revenue	41,014	67,563
Current portion of operating lease liability	11,685	11,733
Total current liabilities	81,514	101,337
Contingent consideration	112,493	152,230
Deferred revenue, net of current portion	252,055	228,659
Operating lease liability, net of current portion	46,171	50,953
Total liabilities	492,233	533,179
Stockholders' equity:		
Common stock	75	75
Additional paid-in capital	782,144	769,965
Accumulated deficit	(369,617)	(413,283)
Accumulated other comprehensive income	35	—
Total stockholders' equity	412,637	356,757
Total liabilities and stockholders' equity	\$ 904,870	\$ 889,936



Source: Translate Bio, Inc.