Translate Bio Announces Fourth Quarter and Full Year 2020 Financial Results and Highlights Recent Progress

February 25, 2021

-- Additional interim data expected in early Q2 from Phase 1/2 clinical trial of MRT5005 for the treatment of cystic fibrosis (CF) --

-- Two infectious disease mRNA vaccine programs expected to enter clinic in 2021: COVID-19 in Q1 and influenza in mid-2021, in collaboration with partner Sanofi Pasteur --

-- Established TBIO 2025 long-term strategic plan to leverage established mRNA platform and measured growth to capture mRNA opportunities in multiple therapeutic areas --

LEXINGTON, Mass., Feb. 25, 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 and business highlights for the fourth quarter and full year ended December 31, 2020.

“2020 ushered in a new era of mRNA possibilities—for vaccines and therapeutics—in which the promise of mRNA medicines became a reality,” said Ronald Renaud, chief executive officer of Translate Bio. “We are optimistic and remain focused on our mission of developing mRNA medicines to treat or prevent diseases and we look forward to several anticipated milestones in 2021, including the next interim analysis from our clinical trial in patients with CF early in the second quarter, and the planned initiation of two clinical programs by our partner, Sanofi Pasteur: a COVID-19 vaccine candidate in the first quarter and an influenza vaccine candidate in mid-2021.”

Renaud continued, “With a deep mRNA scientific foundation, a strong cash position and positive momentum across our pipeline, we believe we are well-positioned to capture the significant potential of mRNA. We have established TBIO 2025, a strategic plan that emphasizes several areas for value creation with a focus on advancing multiple investigational new drug applications (INDs), new pipeline programs and platform innovation over the next five years. This plan will be aimed at enhancing speed, flexibility and control across our research engine so that we continue to be at the forefront of the discovery and development of transformative mRNA medicines.”

2020 and Recent Accomplishments

- **MRT5005 for the Treatment of CF, Phase 1/2 Clinical Trial:** Completed dosing in cohorts for the second interim data analysis, which is expected to be reported in early Q2 2021. These include multiple-ascending dose (MAD) groups (8, 12 and 16 mg), and a single-ascending dose (SAD) group (20 mg).
- **Other Pulmonary Programs:** Advanced next-generation CF and primary ciliary dyskinesia (PCD) programs with positive preclinical data generated to support planned initiation of IND-enabling studies in the second half of 2021.
- **Infectious Disease Vaccine Programs:** Executed two expansions of the collaboration with Sanofi Pasteur, for COVID-19 in March 2020 and for all infectious disease vaccines in June 2020. Advanced preclinical COVID-19 and influenza vaccine programs to enable expected initiation of clinical trials in 2021.
- **Long-term Strategic Planning:** Established TBIO 2025, a strategic plan focused on several areas of value creation and measured growth - adding key in-house capabilities, deepening pulmonary and delivery expertise, increasing research and development (R&D) investments as well as supporting infrastructure with a continued goal of advancing platform innovation and driving multiple programs into the clinic. This long-term plan incorporates an R&D strategy with a continued focus on mRNA therapeutics for pulmonary indications, an expanded effort in mRNA therapeutics for liver diseases and an exploration of new areas for application of the technology including therapeutic antibodies and protein degradation. It also includes the continued comprehensive effort to develop mRNA vaccines for infectious diseases with Sanofi Pasteur.

Anticipated 2021 Milestones

- **COVID-19 Vaccine (MRT5500)**: Initiate Phase 1/2 clinical trial in Q1 2021 (Sanofi Pasteur collaboration)
- **Flu Vaccine**: Advance lead lipid nanoparticle (LNP)/mRNA formulations to clinical proof of technology trial anticipated to begin mid-year 2021 (Sanofi Pasteur collaboration)
- **CF Clinical Program (MRT5005)**:
  - Report interim results from 20 mg SAD dose group and 8, 12, 16 mg MAD dose groups of the ongoing Phase 1/2 clinical trial in early Q2 2021
  - Report interim results from 20 mg MAD dose group and daily dosing cohort
- **CF Discovery Program (Next-generation CF)**: Advance lead candidate into IND-enabling studies in 2H 2021
- **PCD**: Advance lead candidate into IND-enabling studies in 2H 2021
- **Pulmonary Arterial Hypertension**: Conduct preclinical studies to validate targets
- **Liver**: Apply next-generation liver delivery LNPs to identify liver diseases for further evaluation
- **mRNA Platform**: Identify next-generation LNPs to support liver, lung and additional disease program development, and explore new areas for application of mRNA technology including therapeutic antibodies and protein degradation

Upcoming Events

- The Company plans to participate in the following virtual investor conference:
  - SVB Leerink Virtual 10th Annual Global Healthcare Conference: Ronald Renaud, chief executive officer, will participate in a fireside chat on Friday, February 26, 2021 at 9:20 a.m. EST.

Fourth Quarter and Full Year 2020 Financial Results and Financial Guidance

Translate Bio ended the fourth quarter of 2020 with $654.0 million in cash, cash equivalents and investments and 75,029,625 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 loss of $20.6 million and $31.0 million for the three months ended December 31, 2020 and 2019, respectively, and a net loss of $53.8 million and $113.3 million for the years ended December 31, 2020 and 2019, respectively.

Collaboration revenue was $51.4 million and $3.9 million for the three months ended December 31, 2020 and 2019, respectively, and $138.8 million and $7.8 million for the years ended December 31, 2020 and 2019, respectively. The increase in collaboration revenue, all of which is derived from the collaboration with Sanofi, related to increased activities for the vaccine program as well as a cumulative catch-up of revenue resulting from increases in the transaction price during the twelve months ended December 31, 2020.

Operating expenses for the three months ended December 31, 2020 were $72.0 million, compared to $35.6 million for the same period in 2019, and were comprised of the following:

- Research and development expenses of $32.8 million during the fourth quarter of 2020, compared to $25.0 million for the same period in 2019. The increase is primarily due to continued development of the Company's vaccine program associated with the Sanofi collaboration and discovery program as well as an increase in occupancy costs and personnel-related costs, partially offset by a decrease in expenses related to the Company's MRT5005 program.

- General and administrative expenses of $10.7 million during the fourth quarter of 2020, compared to $7.3 million for the same period in 2019. The increase is primarily due to increases in personnel-related costs and professional fees.

- Change in the fair value of contingent consideration of $28.5 million during the fourth quarter of 2020, compared to $3.3 million for the same period in 2019, related to future potential milestone and earnout payment obligations. The operating expense recognized during the fourth quarter of 2020 was attributed to an increase in the fair value of the contingent consideration liability due to the time value of money due to passage of time and a decrease in the discount rate.

Operating expenses for the year ended December 31, 2020 were $194.1 million, compared to $123.6 million for the same period in 2019, and were comprised of the following:

- Research and development expenses of $109.6 million during the year ended December 31, 2020, compared to $76.4 million for the same period in 2019. The increase is primarily due to continued development of the Company's vaccine program associated with the Sanofi collaboration and discovery program as well as an increase in personnel-related costs, partially offset by a decrease in expenses related to the Company's MRT5005 and MRT5201 programs.

- General and administrative expenses of $35.9 million during the year ended December 31, 2020, compared to $28.6 million for the same period in 2019. The increase is due to an increase in personnel-related costs and professional fees.

- Change in the fair value of contingent consideration of $48.6 million during the year ended December 31, 2020, compared to less than $0.1 million for the same period in 2019, related to future potential milestone and earnout payment obligations. The operating expense recognized during the year ended December 31, 2020 was attributed to an increase in the fair value of the contingent consideration liability due to the time value of money due to 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.

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 report interim data from its Phase 1/2 clinical trial for MRT5005 in CF in the second quarter of 2021; the plans to commence clinical trials for a COVID-19 vaccine in the first quarter of 2021 and for a flu vaccine mid-year 2021; the advancement of lead candidates for next-generation CF and PCD programs in the second half of 2021; the goals and objectives of the TBIO 2025 long-term strategic plan; 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; Translate Bio's plans to advance its additional disease programs; 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," "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 fiscal quarter ended September 30, 2020 filed with the Securities and Exchange Commission on November 5, 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)

	Three Months Ended December 31,		Years Ended December 31,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ 51,392	$ 3,890	$ 138,811	$ 7,804
Operating expenses:				
Research and development	32,845	25,025	109,629	76,369
General and administrative	10,699	7,348	35,922	28,632
Change in fair value of contingent consideration	28,490	3,256	48,575	13
Impairment of intangible asset	—	—	—	18,559
Total operating expenses	72,034	35,629	194,126	123,573
Loss from operations	(20,642)	(31,739)	(55,315)	(115,769)
Other income, net	81	703	1,528	1,990
Loss before benefit from income taxes	(20,561)	(31,036)	(53,787)	(113,779)
Benefit from income taxes	—	—	—	486
Net loss	$ (20,561)	$ (31,036)	$ (53,787)	$ (113,293)

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

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 342,027	$ 84,580
Investments	312,001	104,098
Collaboration receivables	26,598	4,596
Prepaid expenses and other current assets	11,741	9,391
Restricted cash	4,826	950
Total current assets	697,193	203,615
Property and equipment, net	15,372	12,539
Right-of-use assets, net	72,957	10,400
Goodwill	21,359	21,359
Intangible assets, net	79,127	85,536
Other assets	3,928	2,752
Total assets	$ 889,936	$ 336,201
Liabilities and Stockholders' Equity		
Current liabilities:		

Accounts payable	$ 8,839	$ 15,968
Accrued expenses	13,202	7,072
Current portion of deferred revenue	67,563	18,100
Current portion of operating lease liability	11,733	530
Total current liabilities	101,337	41,670
Contingent consideration	152,230	103,655
Deferred revenue, net of current portion	228,659	25,256
Operating lease liability, net of current portion	50,953	12,084
Total liabilities	533,179	182,665
Stockholders' equity:		
Common stock	75	60
Additional paid-in capital	769,965	512,231
Accumulated deficit	(413,283)	(359,496)
Accumulated other comprehensive income	—	741
Total stockholders' equity	356,757	153,536
Total liabilities and stockholders' equity	$ 889,936	$ 336,201

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