Generation Bio Reports Business Highlights and Second Quarter 2021 Financial Results

August 11, 2021

CAMBRIDGE, Mass., Aug. 11, 2021 (GLOBE NEWSWIRE) -- Generation Bio Co. (Nasdaq: GBIO), a biotechnology company innovating genetic medicines for people living with rare and prevalent diseases, reported recent business highlights and second quarter 2021 financial results.

“This quarter we announced our shift to rapid enzymatic synthesis, or RES, for production of our closed-ended DNA, ceDNA, constructs and our signing of a lease to establish significant internal current Good Manufacturing Practice, or cGMP, manufacturing capacity. These are important steps toward our goal of extending the reach of our durable, redosable genetic medicines to patients with prevalent diseases,” said Geoff McDonough, M.D., chief executive officer of Generation Bio. “We will continue to advance the platform throughout the rest of the year and expect factor VIII expression data with ceDNA produced using RES in non-human primates for our hemophilia A program by year-end.”

Business Highlights

- **Transition of Portfolio to Next-Generation Rapid Enzymatic Manufacturing Process Underway:** In July 2021, Generation Bio announced plans to deploy next-generation RES for manufacturing its closed-ended DNA (ceDNA) constructs across all portfolio programs. The company also signed a lease agreement to build out a state-of-the-art cGMP facility of approximately 104,000 square feet in Waltham, Mass. to scale RES for clinical and initial commercial supply. The facility is expected to be operational in 2023, enabling an Investigational New Drug (IND) application and clinical development for the company’s lead program in hemophilia A. The company is using its existing infrastructure for current production of research material using RES. As Generation Bio transitions to RES, it expects to update its program development strategy and timelines for its pipeline.

Second Quarter 2021 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $425.2 million as of June 30, 2021, compared with $262.3 million as of December 31, 2020.
- **R&D Expenses**: Research and development (R&D) expenses were $22.7 million for the quarter ended June 30, 2021, compared to $13.5 million for the quarter ended June 30, 2020.
- **G&A Expenses**: General and administrative (G&A) expenses were $8.2 million for the quarter ended June 30, 2021, compared to $4.3 million for the quarter ended June 30, 2020.
- **Net Loss:** Net loss was $30.8 million, or $0.55 basic and diluted net loss per share, for the quarter ended June 30, 2021, compared to a net loss of $17.7 million, or $1.50 basic and diluted net loss per share, for the quarter ended June 30, 2020.

About Generation Bio

Generation Bio is innovating genetic medicines to provide durable, redosable treatments for people living with rare and prevalent diseases. The company’s non-viral genetic medicine platform incorporates a novel DNA construct called closed-ended DNA, or ceDNA; a unique cell-targeted lipid nanoparticle delivery system, or ctLNP; and a highly scalable capsid-free manufacturing process that uses proprietary cell-free rapid enzymatic synthesis, or RES, to produce ceDNA. The platform is designed to enable multi-year durability from a single dose, to deliver large genetic payloads, including multiple genes, to specific tissues, and to allow titration and redosing to adjust or extend expression levels in each patient. RES has the potential to expand Generation Bio’s manufacturing scale to hundreds of millions of doses to support its mission to extend the reach of genetic medicine to more people, living with more diseases, around the world.

For more information, please visit www.generationbio.com.

Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the company, including statements about our strategic plans or objectives, our technology platform, our research and clinical development plans, the expected timing of the submission of IND applications and preclinical data, our manufacturing plans, our expectations regarding our new facility and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the conduct of research activities, the initiation and completion of preclinical studies and clinical trials and clinical development of the company’s product candidates; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; whether results from preclinical studies will be predictive of the results of later preclinical studies and clinical trials; uncertainties regarding the timing and ability to complete the build-out of the company’s manufacturing facility and regarding the new manufacturing process; expectations regarding the timing of submission of IND applications; expectations for regulatory approvals to conduct trials or to market products; challenges in the manufacture of genetic medicine products; whether the company’s cash resources are sufficient to fund the company’s operating expenses and capital expenditure requirements for the period anticipated; the impact of the COVID-19 pandemic on the company’s business and operations; as well as the other risks and uncertainties set forth in the “Risk Factors” section of our most recent annual report on Form 10-K and quarterly report on Form 10-Q, which are on file with the Securities and Exchange Commission, and in

subsequent filings the company may make with the Securities and Exchange Commission. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof. The company anticipates that subsequent events and developments will cause the company's views to change. However, while the company may elect to update these forward-looking statements at some point in the future, the company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the company's views as of any date subsequent to the date on which they were made.

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GENERATION BIO CO.
CONSOLIDATED BALANCE SHEET DATA
(Unaudited)
(In thousands)

Earnings Release Balance Sheet	**June 30, 2021**	**December 31, 2020**
Cash, cash equivalents and marketable securities	$ 425,193	$ 262,327
Working capital	418,810	256,515
Total assets	490,792	294,155
Total stockholders' equity	433,402	268,013

GENERATION BIO CO.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,	
	2021	**2020**
Operating expenses:		
Research and development	$ 22,656	$ 13,456
General and administrative	8,186	4,308
Total operating expenses	30,842	17,764
Loss from operations	(30,842)	(17,764)
Other income:		
Interest income	51	33
Net loss and net loss attributable to common stockholders	$ (30,791)	$ (17,731)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.55)	$ (1.50)
Weighted average common shares outstanding, basic and diluted	56,318,025	11,801,704
Comprehensive loss:		
Net loss	$ (30,791)	$ (17,731)
Other comprehensive loss:		
Unrealized losses on marketable securities	(6)	(4)
Comprehensive loss	$ (30,797)	$ (17,735)