Assembly Biosciences Reports First Quarter 2021 Financial Results and Recent Updates

May 6, 2021

SOUTH SAN FRANCISCO, Calif., May 06, 2021 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV), today reported financial results and recent updates for the first quarter ended March 31, 2021.

“In the first quarter of 2021, we solidified all our efforts and focus on hepatitis B and the sole pursuit of finite and curative therapies to replace burdensome life-long treatment regimens for the more than 250 million people living with this disease,” said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Bio. “Our strategy is clear and we have made significant progress, continuing to advance all our clinical programs while expanding and accelerating our novel discovery efforts. We are particularly excited that our first Phase 2 proof-of-concept triple combination studies – key drivers of our clinical strategy – are now underway.”

Recent Updates

- Initiated two triple combination studies:
  - Phase 2 study evaluating Assembly Bio’s lead core inhibitor candidate, vebicorvir (VBR), with standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NrtI) therapy and Arbutus Biopharma’s RNAi therapeutic candidate, AB-729
  - Phase 2 study evaluating VBR with NrtI therapy and interferon (peg-IFNα)

Anticipated Milestones and Events

- Nominate a fourth core inhibitor candidate with a best-in-class profile in Q2 2021
- Interim data from Phase 2 study with ABI-H2158 in H2 2021

Upcoming Conferences

- Chief Scientific Officer, William Delaney, PhD, to present at the Chronic Hepatitis B Drug Development Virtual Summit, May 6, 2021, during a session on “Targeting HBV Core Protein to Improve Treatment for cHBV patients.”
- Jefferies Global Healthcare Conference: June 1-3, 2021
- The International Liver Congress™(ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL) taking place virtually June 23-26, 2021 Assembly Bio has three abstracts accepted for presentation:
  - Enhanced potency and target coverage for both antiviral inhibition and cccDNA establishment of next generation core inhibitors ABI-H2158 and ABI-H3733
  - Viral response and safety following treatment discontinuation in Study 211, the open-label extension study of VBR in combination with NrtI therapy
  - No emergent core inhibitor resistance in patients with chronic HBV infection treated with VBR in combination with NrtI

First Quarter 2021 Financial Results

- **Cash, cash equivalents and marketable securities** were $214.9 million as of March 31, 2021, compared to $216.4 million as of December 31, 2020. This result includes $34.1 million of net proceeds from the issuance of common shares under Assembly Bio’s at-the-market (ATM) program. The company’s cash position is projected to fund operations into 2023.
- **Revenues** from collaborative research were $0 for the three months ended March 31, 2021, compared to $4.1 million for the same period in 2020. The decrease is due to the termination of the microbiome collaboration agreement with Allergan Pharmaceuticals following AbbVie Inc’s acquisition of Allergan. In Q1 2021 Assembly Bio completed the previously announced winddown of its microbiome program.
- **Research and development expenses** were $18.6 million for the three months ended March 31, 2021, compared to $23.0 million for the same period in 2020. The decrease is primarily due to a decrease of $8.2 million related to the wind-down of Assembly Bio’s microbiome program. This decrease was partially offset by an increase of $3.7 million in research and development expenses related to the company’s HBV program. Research and development expenses include non-cash stock-based compensation expenses of $(2.1) million for the three months ended March 31, 2021 and $1.9 million for the same period in 2020. The decrease is primarily due to the reversal of $2.4 million of previously

recognized stock-based compensation expense related to forfeited awards of former microbiome program employees.

- **General and administrative expenses** were $8.7 million for both the three months ended March 31, 2021 and 2020. General and administrative expenses include non-cash stock-based compensation expenses of $1.8 million for the three months ended March 31, 2021 and $3.0 million for the same period in 2020.
- **Net loss attributable to common stockholders** was $27.2 million, or $0.69 per basic and diluted share, for the three months ended March 31, 2021, compared to $26.7 million, or $0.76 per basic and diluted share, for the same period in 2020.

About Assembly Biosciences

Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 270 million people living with hepatitis B virus (HBV) worldwide. A pioneer in the development of a new class of potent, oral core inhibitor drug candidates, Assembly Bio's approach aims to break the complex viral replication cycle of HBV to free patients from a lifetime of therapy. Assembly Bio's strategy toward cure includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies and a research program focused on the discovery of novel HBV targets. For more information, visit **assemblybio.com**.

Forward-Looking Statements

The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ. These risks and uncertainties include: Assembly Bio's ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio's clinical collaboration agreements, in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Assembly Bio's product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly Bio's product candidates from other companies' candidates; continued development and commercialization of Assembly Bio's product candidates, if successful, in the China territory will be dependent on, and subject to, Assembly Bio's collaboration agreement governing its activity in the China territory; Assembly Bio's ability to maintain financial resources necessary to continue its clinical studies and fund business operations; any impact that the COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical studies or timing of discussions with regulatory authorities; and other risks identified from time to time in Assembly Bio's reports filed with the U.S. Securities and Exchange Commission (the SEC). You are urged to consider statements that include the words may, will, would, could, should, might, believes, hopes, estimates, projects, potential, expects, plans, anticipates, intends, continues, forecast, designed, goal or the negative of those words or other comparable words to be uncertain and forward-looking. Assembly Bio intends such forward-looking statements to be covered by the safe harbor provisions contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. More information about Assembly Bio's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly Bio's filings with the SEC, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly Bio assumes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

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ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	March 31, 2021	December 31, 2020

	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 78,253	$ 59,444
Marketable securities	136,631	156,969
Accounts receivable from collaborations	203	1,230
Prepaid expenses and other current assets	6,547	6,850
Total current assets	221,634	224,493
Property and equipment, net	1,493	1,600
Operating lease right-of-use (ROU) assets	8,104	9,131
Other assets	6,034	6,392
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 278,903**	**$ 283,254**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,562	$ 4,598
Accrued clinical expenses	4,342	4,444
Other accrued expenses	3,659	11,987
Operating lease liabilities - short-term	2,934	3,404
Total current liabilities	14,497	24,433
Deferred tax liabilities	2,531	2,531
Deferred revenue	8,987	8,987
Operating lease liabilities - long-term	5,644	6,725
Total liabilities	**31,659**	**42,676**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of March 31, 2021 and December 31, 2020; 40,104,684 and 34,026,680 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	40	34
Additional paid-in capital	776,248	742,387
Accumulated other comprehensive loss	(271)	(270)
Accumulated deficit	(528,773)	(501,573)
Total stockholders' equity	247,244	240,578
Total liabilities and stockholders' equity	**$ 278,903**	**$ 283,254**

ASSEMBLY BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)

(Unaudited)

	Three Months Ended March 31,	
	2021	2020
Collaboration revenue	$ —	$ 4,081
Operating expenses:		
Research and development	18,554	23,046
General and administrative	8,704	8,729
Total operating expenses	27,258	31,775
Loss from operations	**(27,258)**	**(27,694)**
Other income:		
Interest and other income, net	58	1,039
Total other income	58	1,039
Net loss	**$ (27,200)**	**$ (26,655)**
Other comprehensive (loss) income		
Unrealized (loss) gain on marketable securities	(1)	115
Comprehensive loss	**$ (27,201)**	**$ (26,540)**
Net loss per share, basic and diluted	$ (0.69)	$ (0.76)
Weighted average common shares outstanding, basic and diluted	39,679,734	35,079,756