



Assembly Biosciences Reports Second Quarter 2021 Financial Results and Recent Highlights

August 5, 2021

SOUTH SAN FRANCISCO, Calif., Aug. 05, 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 highlights for the second quarter ended June 30, 2021.

"With Assembly Bio's singular focus to pursue finite and curative treatment regimens for HBV, we continue to advance our clinical programs with urgency. We anticipate reporting further progress from our pipeline in the second half of this year, including interim data from our Phase 2 trial with ABI-H2158 with a focus on safety and on-treatment changes in key viral biomarkers such as pgRNA, HBeAg and HBcrAg, as well as the nomination of a fourth core inhibitor candidate with potential for a best-in-class profile," said John McHutchison, AO, MD, chief executive officer and president of Assembly Bio. "Over the past three months, we had the opportunity to share additional data at EASL 2021 characterizing our core inhibitor portfolio and have strengthened our leadership team with the promotions of Jason Okazaki to chief operating officer and Michael Samar to chief financial officer and the addition of two esteemed experts in virology, hepatitis and industry to our Board of Directors. These appointments continue to deepen the strategic guidance and experience available to us as we advance our clinical programs."

Recent Updates

- Announced the promotions of Jason Okazaki to chief operating officer and Michael Samar to chief financial officer.
- Announced key appointments to the board of directors with the additions of Nobel Prize Laureate Sir Michael Houghton, PhD, recognized for his contributions to the discovery of hepatitis C, and Lisa Johnson-Pratt, MD, who brings decades of experience in drug development and commercialization.
- Presented data from Assembly Bio's three clinical-stage core inhibitor programs, vebicorvir (VBR or ABI-H0731), ABI-H2158 (2158), and ABI-H3733 (3733), in an oral presentation and two poster presentations at EASL 2021.

Anticipated Milestones and Events

- Nominate a fourth core inhibitor candidate designed for a best-in-class profile in mid 2021.
- On track to share interim data from Phase 2 study with 2158 in H2 2021.

Upcoming Conferences

- Baird's 2021 Global Healthcare Conference: September 14-15, 2021
- [ICE-HBV: HBV Cure: The Mechanisms Behind Combination Therapies](#): William Delaney, PhD, Assembly Bio's chief scientific officer will participate in a round-table discussion on September 30, 2021

Second Quarter 2021 Financial Results

- **Cash, cash equivalents and marketable securities** were \$199.1 million as of June 30, 2021, compared to \$214.9 million as of March 31, 2021. This result includes the \$6.0 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 June 30, 2021, compared to \$39.4 million for the same period in 2020. The decrease is due to the termination of the microbiome collaboration agreement with Allergan following AbbVie Inc's acquisition of Allergan. In Q1 2021 Assembly Bio completed the wind-down of its microbiome program.
- **Research and development expenses** were \$16.7 million for the three months ended June 30, 2021, compared to \$23.3 million for the same period in 2020. The decrease is primarily due to a decrease of \$7.6 million in research and development expenses related to the wind-down of the microbiome program. This decrease was partially offset by an increase of \$1.0 million in research and development expenses related to the HBV program. Research and development expenses include non-cash stock-based compensation expenses of \$0.7 million for the three months ended June 30, 2021 and \$3.6 million for the same period in 2020. The decrease is primarily due to a decrease in the fair value of equity grants as well as a decrease in headcount and outstanding awards resulting from the wind-down of the microbiome program.
- **General and administrative expenses** were \$6.9 million for the three months ended June 30, 2021, compared to \$9.5 million for the same period in 2020. General and administrative expenses include non-cash stock-based compensation expenses of \$1.2 million for the three months ended June 30, 2021 and \$3.5 million for the same period in 2020. The decrease is primarily due to a decrease in the fair value of equity grants.

- **Net income (loss) attributable to common stockholders** was (\$23.6) million, or (\$0.55) per basic and diluted share, for the three months ended June 30, 2021, compared to \$7.3 million, or \$0.21 per basic and \$0.19 per diluted share, for the same period in 2020. The decrease was due to the recognition of the remaining deferred revenue balance when the microbiome agreement with Allergan was terminated 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 HBV 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 HBV 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.

Contacts

Investor and Corporate:

Lauren Glaser

Senior Vice President, Investor Relations and Corporate Affairs

(415) 521-3828

lglaser@assemblybio.com

Media:

Sam Brown Inc.

Audra Friis

(917) 519-9577

ASMBMedia@sambrown.com

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

June 30, 2021	December 31, 2020
(Unaudited)	

ASSETS

Current assets		
Cash and cash equivalents	\$ 59,517	\$ 59,444
Marketable securities	139,560	156,969
Accounts receivable from collaborations	297	1,230
Prepaid expenses and other current assets	6,184	6,850
Total current assets	<u>205,558</u>	<u>224,493</u>
Property and equipment, net	1,359	1,600
Operating lease right-of-use (ROU) assets	7,488	9,131
Other assets	6,093	6,392
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	<u><u>\$ 262,136</u></u>	<u><u>\$ 283,254</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 2,866	\$ 4,598
Accrued clinical expenses	3,676	4,444
Other accrued expenses	4,320	11,987
Operating lease liabilities - short-term	3,048	3,404
Total current liabilities	<u>13,910</u>	<u>24,433</u>
Deferred tax liabilities	2,531	2,531
Deferred revenue	8,987	8,987
Operating lease liabilities - long-term	4,914	6,725
Total liabilities	<u><u>30,342</u></u>	<u><u>42,676</u></u>
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 June 30, 2021 and December 31, 2020; 43,779,059 and 34,026,680 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	44	34
Additional paid-in capital	784,391	742,387
Accumulated other comprehensive loss	(273)	(270)
Accumulated deficit	(552,368)	(501,573)
Total stockholders' equity	<u>231,794</u>	<u>240,578</u>
Total liabilities and stockholders' equity	<u><u>\$ 262,136</u></u>	<u><u>\$ 283,254</u></u>

ASSEMBLY BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE (LOSS) INCOME

(In thousands except for share and per share amounts)

(Unaudited)

Three Months Ended June 30, Six Months Ended June 30,

	2021	2020	2021	2020
Collaboration revenue	\$ —	\$ 39,376	\$ —	\$ 43,457
Operating expenses:				
Research and development	16,749	23,327	35,303	46,373
General and administrative	6,917	9,470	15,621	18,199
Total operating expenses	23,666	32,797	50,924	64,572
(Loss) income from operations	(23,666)	6,579	(50,924)	(21,115)
Other income:				
Interest and other income, net	71	691	129	1,730
Total other income	71	691	129	1,730
Net (loss) income	\$ (23,595)	\$ 7,270	\$ (50,795)	\$ (19,385)
Other comprehensive (loss) income				
Unrealized (loss) gain on marketable securities	(2)	190	(3)	305
Comprehensive (loss) income	\$ (23,597)	\$ 7,460	\$ (50,798)	\$ (19,080)
Net (loss) income per share, basic	\$ (0.55)	\$ 0.21	\$ (1.23)	\$ (0.55)
Weighted average common shares outstanding, basic	42,876,268	35,307,669	41,286,831	35,229,570
Net (loss) income per share, diluted	\$ (0.55)	\$ 0.19	\$ (1.23)	\$ (0.55)
Weighted average common shares outstanding, diluted	42,876,268	37,291,474	41,286,831	35,229,570