



Assembly Biosciences Reports Third Quarter 2020 Financial Results and Business Update

November 5, 2020

SOUTH SAN FRANCISCO, Calif., Nov. 05, 2020 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome, today reported financial results and a business update for the third quarter ended September 30, 2020.

"We continue to make progress to develop our pipeline of core inhibitor candidates for the treatment of patients with HBV," said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences. "We have made great strides toward initiating the Vebicorvir Phase 3 registrational program, as well as advancing ABI-H2158 and ABI-H3733, our more potent, next-generation core inhibitor compounds, in the clinic."

Recent Updates

HBV Portfolio

- *Vebicorvir (VBR or ABI-H0731): Assembly Bio's lead core inhibitor candidate*
 - HBV field's first core inhibitor combination study (Study 211) to assess off-treatment response did not achieve a meaningful rate of sustained virologic response (SVR) as 39 of 41 patients have relapsed.
 - Assembly Bio to host webcast and conference call today at 5:00 p.m. ET. The live audio webcast may be accessed through the "Events & Presentations" page in the "Investors" section of Assembly Bio's website at <https://investor.assemblybio.com/events-presentations>.
 - For more information, see the data press release "Assembly Bio Provides Update on the Ongoing Phase 2 Extension Study of Vebicorvir in Patients with Chronic Hepatitis B Virus Infection" issued today, available on [Assembly Bio's website](#).
 - Reached agreement with the Chinese regulatory body, National Medical Products Administration, Center for Drug Evaluation, and advanced discussions with the U.S. Food and Drug Administration (FDA) on a Phase 3 registrational program for VBR as a chronic suppressive therapy (CST) for HBV infection.
 - Entered into a license and collaboration agreement with BeiGene, Ltd. for Assembly Bio's portfolio of three clinical-stage core inhibitors (VBR, ABI-H2158, ABI-H3733) in the China territory, including Hong Kong, Macau and Taiwan.
 - Entered into a clinical trial collaboration agreement with Arbutus Biopharma Corporation to evaluate the triple combination of VBR, RNAi therapeutic AB-729 and standard-of-care NrtI therapy in patients with chronic HBV infection.
 - Presented clinical data for Assembly Bio's HBV core inhibitors in an oral presentation and three posters at EASL 2020 The Digital International Liver Congress™.
- *ABI-H2158 (2158): Assembly Bio's second core inhibitor candidate*
 - Continued to enroll patients in the ongoing multi-center, randomized, placebo-controlled Phase 2 trial to evaluate 2158 with entecavir versus placebo with entecavir in treatment naïve patients with HBeAg positive chronic HBV infection.
- *ABI-H3733 (3733): Assembly Bio's third core inhibitor candidate*
 - Continued the ongoing Phase 1 trial to evaluate the safety, tolerability, and pharmacokinetics following single ascending dose and multiple ascending dose administrations in healthy subjects.

Corporate Highlights

- Appointed Gina Consylman to the Board of Directors and Audit Committee in October 2020.

Anticipated Milestones and Events

HBV Portfolio

- Four abstracts, including two late-breaking submissions, will be presented at the annual meeting of the American Association for Liver Diseases (AASLD), The Liver Meeting® Digital Experience (TLMdX) being hosted virtually November 13-16, 2020.

- *Vebicorvir*
 - Phase 3 registrational studies for CST expected to initiate in H1 2021 in collaboration with BeiGene.
 - Phase 2 triple combination study with Arbutus Biopharma expected to initiate in H1 2021.
 - Phase 2 triple combination study evaluating the addition of interferon to VBR and NrtI expected to initiate in H1 2021.
 - Interim data from Phase 2 intensification study in partially virologically suppressed patients anticipated in 2021.
- 2158
 - Interim data from Phase 2 study anticipated in 2021.

Upcoming Conference

- Jefferies Virtual London Healthcare Conference: November 17-19, 2020.

Third Quarter 2020 Financial Results

- **Cash, cash equivalents and marketable securities** were \$237.9 million as of September 30, 2020, compared to \$226.7 million as of June 30, 2020. This increase is due to the \$40.0 million upfront payment received in July 2020 as part of the collaboration agreement with BeiGene offset by cash used in operations. Assembly Bio's cash position is projected to fund operations into the second half of 2022.
- **Revenues** from collaborative research were \$34.6 million for the three months ended September 30, 2020 compared to \$4.2 million for the same period in 2019. This includes the recognition of \$31.0 million under the collaboration agreement with BeiGene as well as reimbursements incurred under the collaboration agreement with AbbVie Inc. (Allergan Pharmaceuticals International Limited prior to AbbVie's acquisition of Allergan).
- **Research and development expenses** were \$26.9 million for the three months ended September 30, 2020, compared to \$21.7 million for the same period in 2019. The increase was primarily due to an increase of \$4.0 million in research and development expenses related to the HBV program. Research and development expenses include non-cash stock-based compensation expenses of \$2.8 million for the three months ended September 30, 2020 and \$2.5 million for the same period in 2019.
- **General and administrative expenses** were \$11.7 million for the three months ended September 30, 2020 compared to \$8.5 million for the same period in 2019. The increase was primarily due to an increase of \$2.7 million in professional fees associated with entering into the BeiGene agreement. General and administrative expenses include non-cash stock-based compensation expenses of \$3.3 million for the three months ended September 30, 2020 and \$2.9 million for the same period in 2019.
- **Net loss attributable to common stockholders** was \$3.3 million, or \$0.09 per basic and diluted share, for the three months ended September 30, 2020 compared to \$25.0 million, or \$0.96 per basic and diluted share, for the same period in 2019.

About Assembly Biosciences

Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live microbial biotherapeutic candidates with Assembly Bio's fully integrated platform, including a robust process for strain identification and selection, GMP manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology. 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 trials involving its HBV Cure and Microbiome therapeutic product candidates 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; Assembly Bio may not observe sustained virologic response in patients who stop therapy in Study 211; the timing and ability to implement strategic alternatives with respect to Assembly Bio's Microbiome program; Assembly Bio's ability to maintain financial resources necessary to continue its clinical trials and fund business operations; any impact that the spread of the coronavirus and resulting COVID-19 pandemic may have on Assembly Bio's business and operations, including initiation and continuation of its clinical trials 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)

	September 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	\$ 58,311	\$ 46,732
Marketable securities	179,630	227,311
Accounts receivable from collaboration	3,590	3,374
Prepaid expenses and other current assets	4,856	5,363
Total current assets	<u>246,387</u>	<u>282,780</u>
Property and equipment, net	1,904	1,830
Operating lease right-of-use (ROU) assets	10,397	11,975
Other assets	5,980	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	<u>\$ 306,306</u>	<u>\$ 339,907</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,611	\$ 1,731
Accrued clinical expenses	4,451	4,826
Other accrued expenses	7,404	8,286
Deferred revenue - short-term	—	6,411
Operating lease liabilities - short-term	3,338	3,186
Total current liabilities	<u>16,804</u>	<u>24,440</u>

Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	8,987	30,637
Operating lease liabilities - long-term	7,435	9,082
Total liabilities	35,757	66,690

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 September 30, 2020 and December 31, 2019; 32,924,536 and 32,558,307 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	33	32
Additional paid-in capital	732,829	712,807
Accumulated other comprehensive loss	(158)	(201)
Accumulated deficit	(462,155)	(439,421)
Total stockholders' equity	270,549	273,217
Total liabilities and stockholders' equity	\$ 306,306	\$ 339,907

ASSEMBLY BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands except for share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Collaboration revenue	\$ 34,611	\$ 4,231	\$ 78,068	\$ 11,197
Operating expenses:				
Research and development	26,941	21,736	73,314	63,141
General and administrative	11,689	8,488	29,888	22,085
Total operating expenses	38,630	30,224	103,202	85,226
Loss from operations	(4,019)	(25,993)	(25,134)	(74,029)
Other income				
Interest and other income, net	670	983	2,400	3,446
Total other income	670	983	2,400	3,446
Loss before income taxes	(3,349)	(25,010)	(22,734)	(70,583)
Income tax benefit	—	15	—	33
Net loss	\$ (3,349)	\$ (24,995)	\$ (22,734)	\$ (70,550)
Other comprehensive (loss) income				
Unrealized (loss) gain on marketable securities, net of tax	(262)	(18)	43	142
Comprehensive loss	\$ (3,611)	\$ (25,013)	\$ (22,691)	\$ (70,408)
Net loss per share, basic and diluted	\$ (0.09)	\$ (0.96)	\$ (0.64)	\$ (2.74)
Weighted average common shares outstanding, basic and diluted	35,506,042	25,912,568	35,321,393	25,765,414