Assembly Biosciences Reports Fourth Quarter and Year End 2020 Financial Results and Recent Highlights

February 25, 2021

SOUTH SAN FRANCISCO, Calif., Feb. 25, 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 fourth quarter and year ended December 31, 2020.

“Our strategy for 2021 and beyond is to focus entirely on developing finite and curative therapies that have the potential to free patients with chronic HBV infection from a lifetime of therapy. We are well positioned to do this by advancing our more potent next generation core inhibitors, which include three novel compounds in the clinic and a fourth candidate in pre-IND development, exploring multiple triple combination studies of vebicorvir with complementary mechanisms of action, and expanding our internal research efforts to discover and develop candidates against novel targets,” said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Bio.

Fourth Quarter 2020 and Recent Highlights

- Strategy and resources fully focused on pursuing finite and curative therapies for chronic HBV:
  • As announced separately today, Assembly Bio will forgo initiation of Phase 3 registrational studies of vebicorvir (VBR) as a chronic suppressive therapy to concentrate research and development efforts on identifying a finite and curative therapy.
  • By directing all resources to support its finite and curative strategy, the company expects to advance these initiatives more quickly, while simultaneously extending its cash runway into 2023.
  • Assembly Bio is hosting a 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.
- Initiated a Phase 2 triple combination study evaluating the addition of peg-IFNα to the VBR+ nucleos(t)ide analog reverse transcriptase inhibitor (NrtI) antiviral backbone in patients with chronic HBV infection.
- Entered into collaboration with Door Pharmaceuticals to discover and develop a novel class of HBV cccDNA disruptors that target different phases of the HBV replication cycle distinct from and complementary to those targeted by Assembly Bio’s existing pipeline compounds.
- Presented four posters at the American Association for the Study of Liver Diseases (AASLD) Annual Meeting in November 2020, including data from the company’s HBV core inhibitor research and development programs, as well as a collaborative translational study using Assembly Bio’s sensitive HBV nucleic acid assays.
- Reported data in early November 2020 from Study 211 on the dual combination of VBR+NrtI to assess off-treatment response in patients with chronic HBV infection, which did not achieve a meaningful rate of sustained virologic response (SVR).
- Substantially completed wind-down of Assembly Bio’s Microbiome program.
- Appointed Nicole S. White, PhD, as Senior Vice President of Pharmaceutical Development and Manufacturing.
- Appointed Gina Consylman, Senior Vice President, Chief Financial Officer of Ironwood Pharmaceuticals, Inc. to Board of Directors.

2021 Key Objectives and Anticipated Progress

- Initiate Phase 2 triple combination study with Arbutus Biopharma Corporation evaluating VBR, RNAi therapeutic AB-729, and NrtI therapy in virologically-suppressed patients in H1 2021.
- Nominate a best-in-class fourth core inhibitor candidate in H1 2021.
- Anticipate interim data from Phase 2 study with ABI-H2158 in H2 2021.
- Expect to progress two additional internal programs evaluating differentiated and undisclosed targets.

Fourth Quarter 2020 and Year End Financial Results

- **Cash, cash equivalents and marketable securities** were $216.4 million as of December 31, 2020, compared to $237.9 million as of September 30, 2020, and $274.0 million as of the year ended December 31, 2019. This result includes the $5.5 million of net proceeds from the issuance of common shares under Assembly Bio’s at-the-market (ATM) program. Subsequently, net proceeds from Assembly Bio’s ATM program during January and February 2021 to-date were $25.5 million. The company’s cash position is projected to fund operations into 2023.

- **Revenues** from collaborative research were $1.0 million for the three months ended December 31, 2020, compared to $4.8 million for the same period in 2019, and $79.1 million for the year ended December 31, 2020, compared to $16.0 million in 2019. The year-over-year increase was primarily due to the $31.0 million recognized under the collaboration agreement with BeiGene, Ltd. (BeiGene) and the remaining deferred revenue balance of $37.0 million incurred under the collaboration agreement with Abbvie Inc. (Allergan Pharmaceuticals International Limited prior to Abbvie's acquisition of Allergan).
- **Research and development expenses** were $33.5 million for the three months ended December 31, 2020, compared to $22.6 million for the same period in 2019, and $106.8 million for the year ended December 31, 2020, compared to $85.8 million in 2019. The increase was primarily due to an increase of $14.4 million in research and development expenses related to the HBV program and one-time expenses of $5.7 million related to the microbiome program wind down. Research and development expenses include non-cash stock-based compensation expenses of $11.4 million for both of the years ended December 31, 2020 and 2019.
- **General and administrative expenses** were $7.2 million for the three months ended December 31, 2020 compared to $10.8 million for the same period in 2019, and $37.1 million for the year ended December 31, 2020 compared to $32.9 million in 2019. The increase was primarily due to an increase of $2.7 million of expenses related to entering into the collaboration agreement with BeiGene. General and administrative expenses include non-cash stock-based compensation expenses of $10.5 million for year ended December 31, 2020 and $9.2 million for the same period in 2019.
- **Net loss attributable to common stockholders** was $39.4 million, or $1.10 per basic and diluted share, for the three months ended December 31, 2020, compared to $27.1 million, or $1.06 per basic and diluted share, for the same period in 2019. For the year ended December 31, 2020, net loss was $62.2 million, or $1.75 per basic and diluted share, compared to $97.6 million, or $3.72 per basic and diluted share, for the year ended December 31, 2019.

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.

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

	December 31, 2020	December 31, 2019
ASSETS		
Current assets		
Cash and cash equivalents	$ 59,444	$ 46,732
Marketable securities	156,969	227,311
Accounts receivable from collaboration	1,230	3,374
Prepaid expenses and other current assets	6,850	5,363
Total current assets	224,493	282,780
Property and equipment, net	1,600	1,830
Operating lease right-of-use (ROU) assets	9,131	11,975
Other assets	6,392	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 283,254**	**$ 339,907**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,598	$ 1,731
Accrued clinical expenses	4,444	4,826
Other accrued expenses	11,987	8,286
Deferred revenue - short-term	—	6,411
Operating lease liabilities - short-term	3,404	3,186
Total current liabilities	24,433	24,440
Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	8,987	30,637
Operating lease liabilities - long-term	6,725	9,082
Total liabilities	**42,676**	**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 December 31, 2020 and 2019; 34,026,680 and 32,558,307 shares issued and outstanding as of December 31, 2020 and 2019, respectively	34	32
Additional paid-in capital	742,387	712,807
Accumulated other comprehensive loss	(270)	(201)
Accumulated deficit	(501,573)	(439,421)
Total stockholders' equity	240,578	273,217

Total liabilities and stockholders' equity	**$ 283,254**	**$ 339,907**

ASSEMBLY BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands except for share and per share amounts)

	Year Ended December 31,		
	2020	**2019**	**2018**
Collaboration revenue	$ 79,105	$ 15,963	$ 14,804
Operating expenses:			
Research and development	106,823	85,757	72,741
General and administrative	37,058	32,919	34,798
Total operating expenses	143,881	118,676	107,539
Loss from operations	**(64,776)**	**(102,713)**	**(92,735)**
Other income			
Interest and other income, net	2,624	4,305	3,083
Total other income	2,624	4,305	3,083
Loss before income taxes	**(62,152)**	**(98,408)**	**(89,652)**
Income tax benefit	—	774	(1,099)
Net loss	**$ (62,152)**	**$ (97,634)**	**$ (90,751)**
Other comprehensive (loss) income			
Unrealized (loss) gain on marketable securities, net of tax	(69)	146	45
Comprehensive loss	**$ (62,221)**	**$ (97,488)**	**$ (90,706)**
Net loss per share, basic and diluted	$ (1.75)	$ (3.72)	$ (3.98)
Weighted average common shares outstanding, basic and diluted	35,427,120	26,258,790	22,801,644