Assembly Biosciences Reports Fourth Quarter and Year End 2021 Financial Results and Recent Highlights

March 10, 2022

SOUTH SAN FRANCISCO, Calif., March 10, 2022 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and other viral diseases, today reported financial results and recent highlights for the fourth quarter and year ended December 31, 2021.

“Our expanded strategy and pipeline progress in 2021 have positioned us to reach a number of important milestones in 2022 with both our core inhibitor portfolio and our research programs beyond core inhibition and HBV,” said John McHutchison, AO, MD, chief executive officer and president of Assembly Bio. “The Phase 2 triple combination studies evaluating our lead investigational core inhibitor candidate, vebicorvir (VBR), plus standard-of care NrtI with other complementary mechanisms are progressing, and we anticipate initial on-treatment data during the second half of the year. We also plan to begin a Phase 1b trial of ABI-H3733, with initial antiviral data anticipated before year end, and to initiate clinical development of ABI-4334, our newest core inhibitor candidate that has been optimized for potency against the formation of cccDNA. Importantly, during the first half of 2022, we intend to share more about research programs underway that leverage our team’s deep virologic drug development expertise to explore new targets in HBV as well as other viral diseases. We look forward to introducing the first of these during a web event at the end this month.”

Fourth Quarter 2021 and Recent Highlights

- Announced clinical collaboration agreement with Antios Therapeutics to evaluate a triple combination of VBR + nucleos(t)ide reverse transcriptase inhibitor (NrtI) and ATI-2173, Antios’ investigational proprietary active site polymerase inhibitor nucleotide (ASPIN)
- Presented two posters and an oral presentation at AASLD The Liver Meeting™ in November 2021:
    - Preclinical characterization, including single-digit nanomolar potency for ABI-4334 against both pgRNA encapsidation and cccDNA formation
    - Favorable pharmacokinetics and safety in a Phase 1a study ABI-H3733
    - Phase 2 open-label study data for VBR demonstrate the contribution of core inhibition to deepen viral suppression
- Presented an oral and poster presentation on Assembly Bio’s core inhibitor programs at HEP DART in December 2021
- Completed enrollment in a Phase 2 triple combination study evaluating VBR + NrtI and interferon (PEG-IFNα)
- Promoted Nicole White, PhD, to chief manufacturing officer
- Received EASL’s acceptance of five abstracts on Assembly Bio’s core inhibitor candidates for presentation at the International Liver Congress 2022, to be held June 22-26

2022 Anticipated Milestones and Events

First Half

- Provide updates on strategy and research programs beyond HBV core inhibition to other HBV targets and share plans to explore other viruses
    - Assembly Bio will provide the first update on these research programs during a virtual event with a physician expert on Thursday, March 31 at 11:00 a.m. ET. Additional details will be announced closer to the event.
- Complete enrollment in a Phase 2 triple combination study evaluating VBR + NrtI and AB-729, Arbutus Biopharma’s RNAi therapeutic candidate
- Initiate Phase 1b study of ABI-H3733 in patients with chronic HBV infection
- Initiate triple combination cohort with VBR + NrtI and ATI-2173, Antios’ ASPIN

Second Half

- Initiate first-in-human Phase 1a study of ABI-4334, a next-generation core inhibitor optimized for potency against the formation of covalently closed circular DNA (cccDNA)
- Report interim on-treatment data from two triple combination studies: (1) VBR + NrtI and AB-729 and (2) VBR + NrtI and Peg-IFNα
- Report initial Phase 1b data for ABI-H3733
- Report Phase 1a data for ABI-4334 as early as year-end

Upcoming Conferences

- William Delaney, PhD, chief scientific officer, will present “Discovery and Development of HBV Core Inhibitors for the Treatment of Chronic Hepatitis B Infection” during the International Conference on Antiviral Research (ICAR), on March 25, 2022.
- Luisa Stamm, MD, PhD, chief medical officer, and Katie Kitrinos, PhD, vice president clinical virology, will present during the 2nd Annual Chronic HBV Drug Development Summit, April 25-27, 2022.

Fourth Quarter 2021 and Year End Financial Results

- Cash, cash equivalents and marketable securities were $174.6 million as of December 31, 2021, compared to $190.1 million as of September 30, 2021, and $216.4 million as of the year ended December 31, 2020. This result includes $52.8 million of net proceeds from the issuance of common shares under Assembly Bio’s at-the-market (ATM) program during the year. The company’s cash position is projected to fund operations into the second half of 2023.
- Revenues from collaborative research were $6.3 million for the year ended December 31, 2021, compared to $79.1 million in 2020. The year-over-year decrease 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) both occurring in 2020.
- Research and development expenses were $68.5 million for the year ended December 31, 2021, compared to $106.8 million in 2020. The decrease was due to a decrease of $39.0 million in research and development expenses related to the wind-down of the company’s microbiome program. Research and development expenses include non-cash stock-based compensation expenses of $0.5 million for the year ended December 31, 2021, and $11.4 million for the same period in 2020. The decrease in stock-based compensation is primarily due to a decrease in the grant date fair value of option grants and reversals in previously recognized expense related to forfeited awards of former employees.
- General and administrative expenses were $28.8 million for the year ended December 31, 2021, compared to $37.1 million in 2020. General and administrative expenses include non-cash stock-based compensation expenses of $4.7 million for the year ended December 31, 2021, and $10.5 million for the same period in 2020. The decrease in stock-based compensation is due to a decrease in the grant date fair value of recent option grants and a reversal of previously recognized expense during 2021 related to forfeited awards from former employees.
- Net loss attributable to common stockholders was $129.9 million, or $3.00 per basic and diluted share, for the year ended December 31, 2021, compared to $62.2 million, or $1.75 per basic and diluted share in 2020. Net loss for the year ended December 31, 2021 includes $41.6 million in impairment charges of our goodwill and indefinite-lived intangible asset due to a sustained decline in our stock price and a higher discount rate applied to future cash flows.

About Assembly Biosciences

Assembly Bio is a clinical-stage biotechnology company committed to bringing finite and curative therapies to the 296 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 includes a leading portfolio of more potent, next-generation core inhibitors, proof-of-concept combination studies for HBV cure and research programs focused on the discovery of additional novel antiviral mechanisms for HBV, and other viral diseases. 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; results of nonclinical studies may not be representative of disease behavior in a clinical setting and may not be predictive of the outcomes of clinical studies; 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 HBV-related 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, enrollment 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.
CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 45,627	$ 59,444
Marketable securities - short-term	101,000	156,969
Accounts receivable from collaborations	336	1,230
Prepaid expenses and other current assets	7,241	6,850
Total current assets	154,204	224,493
Marketable securities - long-term	27,972	—
Property and equipment, net	1,139	1,600
Operating lease right-of-use (ROU) assets	6,042	9,131
Other assets	1,703	6,392
Indefinite-lived intangible asset	—	29,000
Goodwill	—	12,638
Total assets	**$ 191,060**	**$ 283,254**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,659	$ 4,598
Accrued research and development expenses	3,400	4,444
Other accrued expenses	6,863	11,987
Operating lease liabilities - short-term	3,151	3,404
Total current liabilities	16,073	24,433
Deferred tax liabilities	—	2,531

Deferred revenue	2,733	8,987
Operating lease liabilities - long-term	3,325	6,725
Total liabilities	**22,131**	**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, $0.001 par value; 100,000,000 shares authorized as of December 31, 2021 and December 31, 2020; 48,120,437 and 34,026,680 shares issued and outstanding as of December 31, 2021 and December 31, 2020, respectively	48	34
Additional paid-in capital	800,728	742,387
Accumulated other comprehensive loss	(419)	(270)
Accumulated deficit	(631,428)	(501,573)
Total stockholders' equity	168,929	240,578
Total liabilities and stockholders' equity	**$ 191,060**	**$ 283,254**

ASSEMBLY BIOSCIENCES, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)

	Year Ended December 31,	
	2021	**2020**
Collaboration revenue	$ 6,254	$ 79,105
Operating expenses:		
Research and development	68,524	106,823
General and administrative	28,780	37,058
Impairment of goodwill and indefinite-lived intangible asset	41,638	—
Total operating expenses	138,942	143,881
Loss from operations	**(132,688)**	**(64,776)**
Other income		
Interest and other income, net	302	2,624
Total other income	302	2,624
Loss before income taxes	**(132,386)**	**(62,152)**
Income tax benefit	2,531	—
Net Loss	**$ (129,855)**	**$ (62,152)**
Other comprehensive loss		
Unrealized loss on marketable securities	(149)	(69)
Comprehensive loss	**$ (130,004)**	**$ (62,221)**
Net loss per share, basic and diluted	$ (3.00)	$ (1.75)
Weighted average common shares outstanding, basic and diluted	43,280,383	35,427,120