Assembly Biosciences Reports First Quarter 2022 Financial Results and Recent Highlights

May 12, 2022

SOUTH SAN FRANCISCO, Calif., May 12, 2022 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative, investigational therapeutics targeting hepatitis B virus (HBV) and other viral diseases, today reported financial results and recent highlights for the first quarter ended March 31, 2022.

John McHutchison, AO, MD, chief executive officer and president of Assembly Bio, said, “We are excited to expand our pipeline with the introduction of our HBV/hepatitis delta virus (HDV) small molecule entry inhibitor, which we believe could increase treatment options for the estimated 12 million people infected with this devastating disease that significantly increases the incidence and severity of liver disease and its complications, including cirrhosis and liver cancer. We are also looking forward to introducing our third HBV target next month. And, of course, we continue to execute on our strategy pursuing finite and curative HBV therapies, with vebicorvir (VBR) triple combination trials and the advancement of our next generation, more potent core inhibitors, on which we will share more in presentations at upcoming scientific and clinical meetings going forward.”

Recent Updates

- Introduced a new research program focused on a novel, orally bioavailable small-molecule approach to inhibit the intracellular entry of HBV and HDV, targeting nomination of a product candidate in the first half of 2023.
- Announced the expansion of Assembly Bio’s pipeline to include candidates focused on viruses outside of HBV.
- Completed enrollment and continued dosing in two Phase 2 triple combination studies evaluating Assembly Bio’s lead investigational core inhibitor, VBR + nucleos(t)ide analogs (Nrtl) therapy, along with Arbutus Biopharma’s RNAi therapeutic candidate, AB-729, and separately with peg-IFNα.
- Initiated triple combination study with VBR + NrtI and ATI-2173, Antios Therapeutics’ investigational active site polymerase inhibitor nucleotide (ASPIN).
- Participated in:
    - The International Conference on Antiviral Research (ICAR) on March 25, 2022.
        - William Delaney, PhD, chief scientific officer, presented on “Discovery and Development of HBV Core Inhibitors for the Treatment of Chronic Hepatitis B Infection.”
    - The Second Annual Chronic HBV Drug Development Summit on April 25-27, 2022.
        - Luisa Stamm, MD, PhD, chief medical officer, presented on “Interrogating Therapeutic Agents with Additive or Synergistic Activity against HBV for Combination Therapy.”
        - Katie Kitrinos, PhD, vice president, clinical virology, presented on “Novel HBV Biomarkers to Guide Treatment Management and Clinical Outcome Prediction.”

Anticipated Milestones and Events

- Announce second new HBV target beyond core inhibition.
    - Assembly Bio will provide an overview of its second HBV target beyond core inhibitors during a virtual event with a physician expert during June. Details will be announced closer to the event.
- Initiate Phase 1b study in ABI-H3733 (3733) in 1H 2022.
- Initiate Phase 1a study for ABI-H4334 (4334) in 2H 2022.
- Report initial Phase 1b data for 3733 in 2H 2022.
- Report Phase 1a data for ABI-4334 as early as year-end.
- Announce exploratory research program plans focused on other viruses mid-year 2022.
- Report interim on-treatment data from two triple combination studies: (1) VBR + NrtI and AB-729 and (2) VBR + NrtI and Peg-IFNα.

Upcoming Conferences

- William Delaney, PhD, will present at the Singapore Science of HBV Cure Meeting taking place May 30 – June 2, 2022, on “Progress in the Development in Core Inhibitors for the Treatment of Chronic Hepatitis B Infection.”
- Assembly Bio has five abstracts that have been accepted for presentation at the International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL), taking place virtually and in person in London on June 22-26, 2022. Titles of accepted poster presentations as follows:
    - ABI-4334, a novel inhibitor of HBV core protein, promotes formation of empty capsids and prevents covalently closed circular DNA formation by disruption of incoming capsids

- Improving the pharmacokinetic profile of 3733 following oral administration: results from new formulation activities
- Deeper virologic suppression with the addition of VBR, a first-generation HBV core inhibitor, to entecavir correlates with reduced inflammation and fibrosis-4 index in treatment naïve patients with HBeAg positive chronic HBV
- Evaluation of the drug-drug interaction profile of VBR: Findings include Phase 1 and Phase 2a studies
- Evaluation of the disposition and mass balance recovery of VBR in rats and humans

First Quarter 2022 Financial Results

- **Cash, cash equivalents and marketable securities** were $146.5 million as of March 31, 2022, compared to $174.6 million as of December 31, 2021. The company's cash position is projected to fund operations into the fourth quarter of 2023.

- **Research and development expenses** were $17.2 million for the three months ended March 31, 2022, compared to $18.6 million for the same period in 2021. The decrease is primarily due to the termination of Assembly Bio's 211, 205 and 2158 clinical studies in prior year and restructuring charges incurred in prior year related to the wind-down of Assembly Bio's microbiome program, partially offset by increases in the 3733, 4334 and research and discovery programs.

- **General and administrative expenses** were $6.0 million for the three months ended March 31, 2022, compared to $8.7 million for the same period in 2021. The decrease is due to cost savings across the board but primarily due to a decrease in stock-based compensation expenses.

- **Net loss attributable to common stockholders** was $23.1 million, or $0.48 per basic and diluted share, for the three months ended March 31, 2022, compared to $27.2 million, or $0.69 per basic and diluted share, for the same period in 2021.

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 investigational core inhibitors, 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 inhibitor drug candidates, 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.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands except for share amounts and par value)

	March 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 51,174	$ 45,627
Marketable securities - short-term	71,826	101,000
Accounts receivable from collaborations	524	336
Prepaid expenses and other current assets	7,253	7,241
Total current assets	130,777	154,204
Marketable securities - long-term	23,459	27,972
Property and equipment, net	1,019	1,139
Operating lease right-of-use (ROU) assets	5,300	6,042
Other assets	2,175	1,703
Total assets	**$ 162,730**	**$ 191,060**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 1,407	$ 2,659
Accrued research and development expenses	3,596	3,400
Other accrued expenses	2,499	6,863
Operating lease liabilities - short-term	3,207	3,151
Total current liabilities	10,709	16,073
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	2,497	3,325
Total liabilities	**15,939**	**22,131**
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, 2022 and December 31, 2021; 48,132,937 and 48,120,437 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	48	48
Additional paid-in capital	802,170	800,728
Accumulated other comprehensive loss	(908)	(419)

Accumulated deficit	(654,519)	(631,428)
Total stockholders' equity	146,791	168,929
Total liabilities and stockholders' equity	**$ 162,730**	**$ 191,060**

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,	
	2022	**2021**
Operating expenses:		
Research and development	$ 17,205	$ 18,554
General and administrative	5,957	8,704
Total operating expenses	23,162	27,258
Loss from operations	**(23,162)**	**(27,258)**
Other income:		
Interest and other income, net	71	58
Total other income	71	58
Net loss	**$ (23,091)**	**$ (27,200)**
Other comprehensive loss		
Unrealized loss on marketable securities	(489)	(1)
Comprehensive loss	**$ (23,580)**	**$ (27,201)**
Net loss per share, basic and diluted	$ (0.48)	$ (0.69)
Weighted average common shares outstanding, basic and diluted	48,123,930	39,679,734