Assembly Biosciences Reports Second Quarter 2022 Financial Results and Recent Highlights

August 9, 2022

SOUTH SAN FRANCISCO, Calif., Aug. 09, 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 announced financial results and recent highlights for the second quarter ended June 30, 2022.

“We are excited to advance clinical development of our next-generation, more potent core inhibitors and to continue the expansion of our pipeline. Our recently introduced small molecule interferon-α receptor agonist research program provides a complementary immunomodulatory approach to our HBV and HDV strategy that we believe can engage interferon-α’s validated mechanism while limiting its substantial side effect profile. We also look forward to introducing our new viral targets outside of HBV in the third quarter of 2022, leveraging the deep antiviral expertise and experience of our research organization against diseases with significant unmet medical need,” said John McHutchison, AO, MD, chief executive officer of Assembly Bio. “Additionally, we recently announced our data-driven decision to discontinue clinical development of our first-generation core inhibitor vebicorvir (VBR) and have restructured the organization to support our refocused clinical and pre-clinical pipeline, which has also extended our projected cash runway into the first half of 2024.”

Recent Updates

- Introduced a new research program focused on a novel, small molecule interferon-α receptor (IFNAR) agonist designed to selectively activate the interferon-α pathway within the liver and offer the convenience of oral dosing, with the aim of engaging interferon-α’s validated antiviral and immune modulatory mechanisms while reducing systemic exposure to improve tolerability.
- Initiated a randomized, multi-center double-blind and placebo-controlled Phase 1b trial of the company’s next-generation investigational core inhibitor ABI-H3733 (3733) evaluating safety, pharmacokinetics and antiviral activity in adults with chronic HBV infection. Initial data are anticipated in the second half of 2022.
- Discontinued clinical development of first-generation investigational core inhibitor, VBR, and restructured the organization to prioritize advancement of the company’s more potent next-generation core inhibitor candidates, 3733 and ABI-4334 (4334), and research activities, including its small molecule HBV/hepatitis delta virus (HDV) entry inhibitor, IFNAR agonist and two additional undisclosed viral targets.
- Conference Participation:
    - Bill Delaney, PhD, presented on May 31, 2022, at the Singapore Science of HBV Cure Meeting on “Progress in the Development in Core Inhibitors for the Treatment of Chronic Hepatitis B Infection.”
    - Six posters were presented at the International Liver Congress™ (ILC), the Annual Meeting of the European Association for the Study of the Liver (EASL), held June 22-26, 2022, including results from Assembly Bio’s next-generation core inhibitor programs in the following posters:
        - ABI-4334, a novel inhibitor of hepatitis B virus core protein, promotes formation of empty capsids and prevents cccDNA formation by disruption of incoming capsids
        - Improving the pharmacokinetic profile of the hepatitis B virus core inhibitor ABI-H3733 following oral administration: results from new formulation activities

Anticipated Milestones and Events

- Announce expansion of research scope and exploratory research programs focused on other viruses outside of HBV in the third quarter of 2022. Assembly Bio plans to host a webcast to introduce two of the programs and details will be announced closer to the event.
- Initiate Phase 1a study for 4334 in 2H 2022.
- Report initial Phase 1b data for 3733 in 2H 2022.
- Report Phase 1a data for 4334 as early as year end.

Upcoming Conferences

- John McHutchison, AO, MD, chief executive officer, will present during the H.C. Wainwright 24th Annual Global Investment Conference, September 12-14, 2022.
- Nuruddin Unchwaniwala, PhD, scientist II, clinical virology, will present at the 2022 International HBV Meeting taking place September 18-20, 2022 on “Next generation core inhibitors demonstrate increased potency and distinct biochemical properties compared to first-generation core inhibitors.”

- Grace Wang, MD, MS, RD, vice president, clinical development, will present at the International Workshop on HBV Cure 2022 taking place November 2, 2022 on “Next generation core inhibitors (capsid assembly modulators).”

Second Quarter 2022 Financial Results

- **Cash, cash equivalents and marketable securities** were $128.6 million as of June 30, 2022, compared to $146.5 million as of March 31, 2022. The company’s cash position is projected to fund operations into the first half of 2024.
- **Research and development expenses** were $17.8 million for the three months ended June 30, 2022, compared to $16.7 million for the same period in 2021. The increase is primarily due to increases in our 3733, 4334 and research and discovery programs.
- **General and administrative expenses** were comparable year over year with $6.8 million for the three months ended June 30, 2022 and $6.9 million for the same period in 2021.
- **Net loss attributable to common stockholders** was $24.5 million, or $0.51 per basic and diluted share, for the three months ended June 30, 2022, compared to $23.6 million, or $0.55 per basic and diluted share, for the same period in 2021.

About Assembly Biosciences
Assembly Bio is a clinical-stage biotechnology company pioneering the development of therapeutics for viral diseases, including pursuing finite and potentially curative therapies for the 296 million people living with hepatitis B virus (HBV) worldwide. Assembly Bio is advancing a leading portfolio of more potent, next-generation core inhibitor drug candidates that aim to break the complex viral replication cycle of HBV 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 successfully execute its reprioritization and restructuring activities; potential adverse legal, reputational, operational and financial effects on Assembly Bio resulting from the reprioritization and restructuring activities; Assembly Bio’s ability to initiate and complete clinical studies involving its therapeutic product candidates, including studies contemplated by Assembly Bio’s 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 ABI-H3733, if successful, in the China territory will be dependent on, and subject to, Assembly Bio’s collaboration agreement governing this 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)

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 43,063	$ 45,627
Marketable securities - short-term	73,626	101,000
Accounts receivable from collaborations	523	336
Prepaid expenses and other current assets	7,082	7,241
Total current assets	124,294	154,204
Marketable securities - long-term	11,908	27,972
Property and equipment, net	899	1,139
Operating lease right-of-use (ROU) assets	4,711	6,042
Other assets	1,635	1,703
Total assets	**$ 143,447**	**$ 191,060**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,454	$ 2,659
Accrued research and development expenses	4,446	3,400
Other accrued expenses	4,750	6,863
Operating lease liabilities - short-term	3,311	3,151
Total current liabilities	14,961	16,073
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	1,773	3,325
Total liabilities	**19,467**	**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, $0.001 par value; 150,000,000 and 100,000,000 shares authorized as of June 30, 2022 and December 31, 2021, respectively; 48,362,736 and 48,120,437 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	48	48
Additional paid-in capital	803,910	800,728
Accumulated other comprehensive loss	(998)	(419)
Accumulated deficit	(678,980)	(631,428)
Total stockholders' equity	123,980	168,929
Total liabilities and stockholders' equity	**$ 143,447**	**$ 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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 17,792	$ 16,749	$ 34,997	$ 35,303
General and administrative	6,781	6,917	12,738	15,621
Total operating expenses	24,573	23,666	47,735	50,924
Loss from operations	**(24,573)**	**(23,666)**	**(47,735)**	**(50,924)**
Other income:				
Interest and other income, net	112	71	183	129
Total other income	112	71	183	129
Net loss	**$ (24,461)**	**$ (23,595)**	**$ (47,552)**	**$ (50,795)**
Other comprehensive loss				
Unrealized loss on marketable securities	(90)	(2)	(579)	(3)
Comprehensive loss	**$ (24,551)**	**$ (23,597)**	**$ (48,131)**	**$ (50,798)**
Net loss per share, basic and diluted	$ (0.51)	$ (0.55)	$ (0.99)	$ (1.23)
Weighted average common shares outstanding, basic and diluted	48,293,495	42,876,268	48,208,735	41,286,831