



Assembly Biosciences Reports Third Quarter 2022 Financial Results and Recent Highlights and Announces Upcoming Conference Participation

November 8, 2022

Phase 1a Trial of Next-Generation Core Inhibitor, ABI-4334, Now Underway Following Clinical Trial Application (CTA) Clearance

SOUTH SAN FRANCISCO, Calif., Nov. 08, 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 third quarter ended September 30, 2022.

"During the third quarter, we have advanced clinical development of both of our next-generation, more potent core inhibitors with the Phase 1b study of 3733 on track to report initial data by the end of this year and the initiation of the first clinical study for 4334," said John McHutchison, AO, MD, chief executive officer of Assembly Bio. "This quarter also marked the further expansion of our pipeline with the introduction of our first research programs outside of HBV and hepatitis delta virus. These programs, targeting high-recurrence genital herpes and transplant-associated herpesviruses, apply the deep expertise of our organization in small molecule antiviral drug development to develop differentiated approaches for viral diseases with significant unmet medical need. We are thrilled with the progress of our preclinical and clinical programs, and we remain encouraged about the potential for our next-generation core inhibitors with the recently presented data at AASLD and upcoming clinical data readout for 3733."

Recent Updates

- Received CTA clearance and initiated a blinded, placebo-controlled Phase 1a trial in New Zealand of the company's next-generation investigational core inhibitor, ABI-4334 (4334), evaluating safety, tolerability and pharmacokinetics of single and multiple ascending doses of 4334 in healthy subjects.
- Introduced the first two new research programs expanding Assembly Bio's portfolio beyond HBV and hepatitis delta virus (HDV):
 - A long-acting herpes simplex virus type 2 (HSV-2) helicase inhibitor to treat high-recurrence genital herpes, and
 - A pan-herpes non-nucleoside polymerase inhibitor to treat multiple transplant-associated herpesvirus infections.
- Announced the retirement of John McHutchison as chief executive officer (CEO) effective at the end of 2022 and the election of Jason Okazaki, currently president and chief operating officer, to succeed Dr. McHutchison as CEO and president and a member of the board of directors. Dr. McHutchison will continue to serve on the board of directors and assume the role of chair of the Science and Technology Committee.
- Presented four posters at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting®, held November 4-8, 2022, including results from Assembly Bio's next-generation core inhibitor 4334 and the first presentations of data from the company's HBV/HDV entry inhibitor and interferon- α receptor (IFNAR) agonist research programs:
 - ABI-4334, a novel hepatitis B virus core inhibitor, accelerates capsid assembly and inhibits cccDNA formation via multiple pathways
 - Preclinical characterization of a novel class of highly potent small molecule hepatitis B and D virus entry inhibitors
 - Preclinical characterization of a novel liver-focused small molecule efficiently inhibiting hepatitis B virus by activating type I interferon signaling
 - Evaluation of the vebicorvir, NrtI, and AB-729 combination in virologically suppressed patients with HBeAg negative chronic hepatitis B virus infection: Interim analysis from an open label Phase 2 study
- Additional Conference Participation:
 - Presented at the International Workshop on HBV Cure 2022 held November 2, 2022, on "Next generation core inhibitors (capsid assembly modulators)."
 - Presented at the 2022 International HBV Meeting held September 18-20, 2022, on "Next generation core inhibitors demonstrate increased potency and distinct biochemical properties compared to first-generation core inhibitors."
 - Presented at Discovery on Target 2022 held October 17-20, 2022, on "HBV core inhibitors for the treatment of chronic viral infection."
 - Mr. Okazaki and William Delaney, PhD, chief scientific officer, presented during the H.C. Wainwright 3rd Annual HBV Virtual Conference held October 18, 2022.
 - Dr. McHutchison presented during the H.C. Wainwright 24th Annual Global Investment Conference held September 12-14, 2022.

Anticipated Milestones and Events

- Initial Phase 1b data for ABI-H3733 (3733) in 2H 2022.
- Full Phase 1b data for 3733 in 1H 2023.
- Full Phase 1a data for 4334 in 1H 2023.
- Two development candidate nominations from Assembly Bio's expanded research portfolio in 2023.

Upcoming Conferences

- Mr. Okazaki and Dr. Delaney will present in a fireside chat during the Jefferies London Healthcare Conference at 5:35 p.m. GMT on November 15, 2022. A live webcast will be available on the Events and Presentations section of Assembly Bio's website and a replay will be accessible following the event. To register for the live webcast and replay, please visit: <https://investor.assemblybio.com/events-presentations>.

Third Quarter 2022 Financial Results

- **Cash, cash equivalents and marketable securities** were \$108.7 million as of September 30, 2022, compared to \$128.6 million as of June 30, 2022. The company's cash position is projected to fund operations into the first half of 2024.
- **Research and development expenses** were \$18.1 million for the three months ended September 30, 2022, compared to \$18.5 million for the same period in 2021. The decrease is primarily due to the discontinued development of ABI-H2158 and VBR, partially offset by increases in our 3733, 4334, and research and discovery programs.
- **General and administrative expenses** were \$5.3 million for the three months ended September 30, 2022, compared to \$6.7 million for the same period in 2021. The decrease is primarily due to a decrease in professional fees.
- **Net loss attributable to common stockholders** was \$23.1 million, or \$0.48 per basic and diluted share, for the three months ended September 30, 2022, compared to \$18.8 million, or \$0.41 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 novel therapeutics for serious viral diseases. 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 hepatitis B virus (HBV) to achieve finite and potentially curative therapies for the 296 million people living with HBV worldwide. The company's research pipeline includes differentiated antiviral approaches against HBV/hepatitis delta virus and herpesviruses. 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 previously announced reprioritization and restructuring activities, including the CEO transition; 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)

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	\$ 54,673	\$ 45,627
Marketable securities - short-term	53,978	101,000
Accounts receivable from collaborations	1,246	336
Prepaid expenses and other current assets	5,181	7,241
Total current assets	<u>115,078</u>	<u>154,204</u>
Marketable securities - long-term	—	27,972
Property and equipment, net	867	1,139
Operating lease right-of-use (ROU) assets	3,958	6,042
Other assets	1,613	1,703
Total assets	<u>\$ 121,516</u>	<u>\$ 191,060</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	\$ 1,942	\$ 2,659
Accrued research and development expenses	4,462	3,400
Other accrued expenses	5,686	6,863
Operating lease liabilities - short-term	3,371	3,151
Total current liabilities	<u>15,461</u>	<u>16,073</u>
Deferred revenue	2,733	2,733
Operating lease liabilities - long-term	918	3,325
Total liabilities	<u>19,112</u>	<u>22,131</u>
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 September 30, 2022 and December 31, 2021, respectively; 48,481,194 and 48,120,437 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	48	48
Additional paid-in capital	805,480	800,728
Accumulated other comprehensive loss	(999)	(419)
Accumulated deficit	(702,125)	(631,428)
Total stockholders' equity	<u>102,404</u>	<u>168,929</u>
Total liabilities and stockholders' equity	<u>\$ 121,516</u>	<u>\$ 191,060</u>

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)
(Unaudited)

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Collaboration revenue	\$ —	\$ 6,254	\$ —	\$ 6,254
Operating expenses:				
Research and development	18,130	18,474	53,127	53,777
General and administrative	5,271	6,655	18,009	22,276
Total operating expenses	<u>23,401</u>	<u>25,129</u>	<u>71,136</u>	<u>76,053</u>
Loss from operations	<u>(23,401)</u>	<u>(18,875)</u>	<u>(71,136)</u>	<u>(69,799)</u>
Other income:				
Interest and other income, net	256	72	439	201
Total other income	<u>256</u>	<u>72</u>	<u>439</u>	<u>201</u>
Net loss	<u>\$ (23,145)</u>	<u>\$ (18,803)</u>	<u>\$ (70,697)</u>	<u>\$ (69,598)</u>
Other comprehensive loss				
Unrealized loss on marketable securities	(1)	(15)	(580)	(18)
Comprehensive loss	<u>\$ (23,146)</u>	<u>\$ (18,818)</u>	<u>\$ (71,277)</u>	<u>\$ (69,616)</u>
Net loss per share, basic and diluted	<u>\$ (0.48)</u>	<u>\$ (0.41)</u>	<u>\$ (1.46)</u>	<u>\$ (1.63)</u>
Weighted average common shares outstanding, basic and diluted	<u>48,448,399</u>	<u>45,569,276</u>	<u>48,289,501</u>	<u>42,725,109</u>