Assembly Biosciences Reports Third Quarter 2021 Financial Results and Recent Highlights

November 4, 2021

SOUTH SAN FRANCISCO, Calif., Nov. 04, 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 third quarter ended September 30, 2021.

John McHutchison, AO, MD, chief executive officer and president of Assembly Bio, said, “We are excited to advance our latest core inhibitor ABI-4334, with a potential best-in-class profile, and we are working quickly and diligently to move this candidate into clinical development as soon as possible next year. In parallel, we have expanded evaluation of triple combination regimens to treat HBV, which include the potential backbone therapy of our lead investigational core inhibitor candidate vebicorvir (VBR) plus standard-of-care nucleos(t)ide reverse transcriptase inhibitor (NrtI) therapy together with an additional complementary mechanism. Our two ongoing Phase 2 studies include interferon (peg-IFNα) and Arbutus’ RNAi therapeutic candidate, and we look forward to initiating a third Phase 2, all-oral triple combination cohort with Antios’ ASPIN, ATI-2173. We anticipate initial data from all three of these studies during 2022. Meanwhile, we are pleased to feature our science and portfolio at scientific and clinical meetings, demonstrating our commitment to pursuing finite and curative therapies for the more than a quarter of a billion individuals living with chronic HBV infection worldwide.”

Recent Updates

- ABI-4334, a next-generation core inhibitor candidate that has been optimized for potency against the formation of cccDNA, was selected for advancement into clinical development. The company is conducting preclinical work, with the aim of completing regulatory filings and initiating a clinical study as soon as possible in 2022.
- Enrollment and dosing continue in two Phase 2 triple combination studies evaluating Assembly Bio’s lead core inhibitor candidate, VBR + NrtI therapy along with Arbutus Biopharma’s RNAi therapeutic candidate, AB-729, and separately with peg-IFNα.
- A clinical collaboration agreement was announced with Antios Therapeutics to evaluate a triple combination of VBR + NrtI and ATI-2173, Antios’ investigational proprietary active site polymerase inhibitor nucleotide (ASPIN) in a ten patient cohort.
- Further development of ABI-H2158 (2158) was discontinued following the observation of elevated alanine aminotransferase (ALT) levels consistent with drug-induced hepatotoxicity in a Phase 2 trial. The decision reflects the company’s strategy of advancing the candidates that exhibit the strongest safety and efficacy profiles for later-stage clinical studies.
- William Delaney, PhD, chief scientific officer, highlighted Assembly Bio’s approach and core inhibitor portfolio during recent scientific conferences focused on HBV.
    - Participated in a round-table discussion during ICE-HBV: HBV Cure: The Mechanisms Behind Combination Therapies
    - Presented on the “Discovery and Development of Novel Inhibitors of HBV Core Protein for the Treatment for Chronic Hepatitis B” during The Science of HBV Cure Meeting 2021

Anticipated Milestones and Events

- Interim on-treatment data from triple combination studies with VBR + NrtI, and complementary mechanisms RNAi and peg-IFNα anticipated during 2022
- Initiate triple combination cohort with VBR + NrtI and ATI-2173 in H1 2022 with 12-week on-treatment data expected by year-end 2022
- Initiate Phase 1b study in ABI-H3733 in 2022
- Complete regulatory filings for ABI-4334 and initiate clinical development during 2022

Upcoming Conferences

- Three abstracts, including one late-breaking submission, will be presented at the annual meeting of the American Association for the Study of Liver Diseases (AASLD), The Liver Meeting Digital Experience™ (TLMdX) being hosted virtually November 12-15, 2021
- Luisa Stamm, MD, PhD, chief medical officer, will present during the International Workshop on HBV Cure 2021, November 10, 2021 at 11 am ET
- Jefferies London Healthcare Conference. A webcast of the fireside chat will be available in the “Events and Presentations” page in the “Investors” section of the company’s website at www.assemblybio.com on November 18, 2021 at 8:00 am GMT
- William Delaney, PhD, chief scientific officer, will present “Development of HBV Core Inhibitors for the treatment of Chronic

Hepatitis B Infection" during HEP DART 2021, December 7, 2021 at 5:45 - 7:30 pm MST

Third Quarter 2021 Financial Results

- **Cash, cash equivalents and marketable securities** were $190.1 million as of September 30, 2021, compared to $199.1 million as of June 30, 2021. This result includes the $10.1 million of net proceeds from the issuance of common shares under Assembly Bio's at-the-market (ATM) program. 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 three months ended September 30, 2021, compared to $34.6 million for the same period in 2020. Revenue for the three months ended September 30, 2021, consists of deferred revenue allocated to 2158 under the collaboration agreement with BeiGene following the announcement that Assembly Bio discontinued development of the candidate. The decrease year-over-year is due to the recognition of the amount allocated to VBR as revenue in Q3 2020 upon entering into the BeiGene agreement as well as the termination of the microbiome collaboration agreement with Allergan following AbbVie Inc.'s acquisition of Allergan. In Q1 2021 Assembly Bio completed the wind-down of its microbiome program.

- **Research and development expenses** were $18.5 million for the three months ended September 30, 2021, compared to $26.9 million for the same period in 2020. The decrease is primarily due to a decrease of $8.3 million related to the wind-down of the microbiome program. Research and development expenses include non-cash stock-based compensation expenses of $1.1 million for the three months ended September 30, 2021, and $2.8 million for the same period in 2020. The decrease is primarily due to a decrease in the fair value of equity grants as well as a decrease in headcount and outstanding awards resulting from the wind-down of the microbiome program.

- **General and administrative expenses** were $6.7 million for the three months ended September 30, 2021, compared to $11.7 million for the same period in 2020. General and administrative expenses include non-cash stock-based compensation expenses of $0.5 million for the three months ended September 30, 2021, and $3.3 million for the same period in 2020. The decrease is due to a decrease in the fair value of equity grants as well as a reversal of previously recognized expenses related to the forfeited awards to a former officer.

- **Net loss attributable to common stockholders** was $18.8 million, or $0.41 per basic and diluted share, for the three months ended September 30, 2021, compared to $3.3 million, or $0.09 per basic and diluted share, for the same period in 2020. The increase was due to less revenue being recognized under the company's collaboration agreements to offset expenses in 2021.

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; 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 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)

	September 30, 2021 (Unaudited)	December 31, 2020
ASSETS		
Current assets		
Cash and cash equivalents	$ 70,760	$ 59,444
Marketable securities - short-term	110,142	156,969
Accounts receivable from collaborations	769	1,230
Prepaid expenses and other current assets	6,548	6,850
Total current assets	188,219	224,493
Marketable securities - long-term	9,180	—
Property and equipment, net	1,241	1,600
Operating lease right-of-use (ROU) assets	6,773	9,131
Other assets	1,922	6,392
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 248,973**	**$ 283,254**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,628	$ 4,598
Accrued clinical expenses	3,744	4,444
Other accrued expenses	5,457	11,987
Operating lease liabilities - short-term	3,099	3,404
Total current liabilities	14,928	24,433
Deferred tax liabilities	2,531	2,531
Deferred revenue	2,733	8,987
Operating lease liabilities - long-term	4,136	6,725

Total liabilities	**24,328**	**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, $0.001 par value; 100,000,000 shares authorized as of September 30, 2021 and December 31, 2020; 47,077,052 and 34,026,680 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	47	34
Additional paid-in capital	796,057	742,387
Accumulated other comprehensive loss	(288)	(270)
Accumulated deficit	(571,171)	(501,573)
Total stockholders' equity	224,645	240,578
Total liabilities and stockholders' equity	**$ 248,973**	**$ 283,254**

ASSEMBLY BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Collaboration revenue	$ 6,254	$ 34,611	$ 6,254	$ 78,068
Operating expenses:				
Research and development	18,474	26,941	53,777	73,314
General and administrative	6,655	11,689	22,276	29,888
Total operating expenses	25,129	38,630	76,053	103,202
Loss from operations	**(18,875)**	**(4,019)**	**(69,799)**	**(25,134)**
Other income:				
Interest and other income, net	72	670	201	2,400
Total other income	72	670	201	2,400
Net loss	**$ (18,803)**	**$ (3,349)**	**$ (69,598)**	**$ (22,734)**
Other comprehensive (loss) income				
Unrealized (loss) gain on marketable securities	(15)	(262)	(18)	43
Comprehensive loss	**$ (18,818)**	**$ (3,611)**	**$ (69,616)**	**$ (22,691)**
Net loss per share, basic and diluted	$ (0.41)	$ (0.09)	$ (1.63)	$ (0.64)
Weighted average common shares outstanding, basic and diluted	45,569,276	35,506,042	42,725,109	35,321,393