Assembly Biosciences Reports Second Quarter 2020 Financial Results and Recent Highlights

August 5, 2020

SOUTH SAN FRANCISCO, Calif., Aug. 05, 2020 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB), a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome, today reported financial results and recent highlights for the second quarter ended June 30, 2020.

“We have continued to advance the clinical development of our HBV core inhibitors during 2020 with the achievement of key milestones. In June, patients began coming off combination therapy in our Phase 2 open-label extension study of ABI-H0731 and will now be followed to evaluate the sustained virologic response (SVR) rate. We expect to be able to report data from these patients off treatment for 24 weeks (SVR24), early next year,” said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences. “Additionally, in July we established an important collaboration with BeiGene, a premier scientific partner with key operational capabilities in China. This will allow us to accelerate the clinical development and commercialization of our core inhibitor candidates in China, where up to 90 million individuals are infected with hepatitis B.”

Second Quarter 2020 and Recent Highlights

HBV Portfolio

- *China Collaboration with BeiGene*
  - On July 20, 2020, Assembly announced its license and collaboration agreement with BeiGene, Ltd. for Assembly’s portfolio of three clinical-stage core inhibitors (ABI-H0731, ABI-H2158, ABI-H3733) in China including Hong Kong, Macau and Taiwan.
  - Assembly received $40 million upfront and is eligible to receive approximately $500 million in total potential future milestone payments. Assembly is also eligible to receive tiered royalties on net product sales. BeiGene will contribute the initial funding for clinical development in China, with development costs for the territory shared equally thereafter.
- *ABI-H0731(‘731): Assembly’s lead core inhibitor candidate*
  - Patients achieving stopping criteria are continuing to transition off combination therapy in the Phase 2 open-label extension study (Study 211) and are being monitored for sustained virologic response.
  - Assembly initiated a Phase 2 exploratory study evaluating treatment intensification with ‘731 in combination with a nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) in patients with chronic HBV infection who are not completely virologically suppressed on NrtI therapy alone. Approximately 10-30% of patients do not completely suppress HBV DNA after a year or more on standard of care NrtI therapy, and these patients have an unmet need for a more effective treatment.
- *ABI-H2158 (‘2158), Assembly’s second-generation, more potent core inhibitor candidate*
  - Assembly initiated a multi-center, randomized, placebo-controlled Phase 2 trial to evaluate ‘2158 with entecavir versus placebo with entecavir in treatment naïve HBeAg positive patients with chronic HBV infection.
  - The U.S Food and Drug Administration granted Fast Track designation for ‘2158 for the treatment of chronic HBV Infection.

Microbiome Portfolio

- Assembly presented preclinical data from its immuno-oncology microbiome program in an e-poster at the American Association for Cancer Research (AACR) 2020 Virtual Annual Meeting.
- Assembly will regain worldwide rights to the gastrointestinal programs previously licensed to AbbVie (formerly Allergan pre-acquisition) in the fourth quarter of 2020. The Company is exploring strategic alternatives with respect to its microbiome portfolio.

Corporate Highlights

- In June 2020, William Delaney IV, PhD joined as Chief Scientific Officer, Virology.

Anticipated Milestones and Events

HBV Portfolio

- *'731*
  - Additional interim analyses from Study 211 will be presented at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress, rescheduled to August 27-29, 2020; abstracts were accepted as an oral presentation (HBeAg negative patients) and as a late-breaking poster (HBeAg positive patients).
- *'2158*
  - Phase 1b clinical data on multiple dose cohorts will be presented as a late-breaking poster at EASL.
- The analytical methodologies for Assembly's highly sensitive HBV nucleic acid (DNA and pgRNA) assays will be featured in a poster at EASL.

Upcoming Events and Conferences

- William Blair Biotech Focus Conference: August 6, 2020
- Baird's 2020 Global Healthcare Conference: September 9, 2020

Second Quarter 2020 Financial Results

- **Cash, cash equivalents and marketable securities** were $226.7 million as of June 30, 2020, compared to $249.1 million as of March 31, 2020. This excludes the $40.0 million upfront payment received in July 2020 as part of the collaboration agreement with BeiGene. Including the proceeds from the collaboration, Assembly's cash position is projected to fund operations into the second half of 2022.
- **Revenues** from collaborative research were $39.4 million for the three months ended June 30, 2020 compared to $3.1 million for the same period in 2019. This includes the recognition of deferred revenue and reimbursements incurred under the collaboration agreement with AbbVie (formerly Allergan pre-acquisition) for which AbbVie provided written notice of termination in June 2020. As a result, we recognized the remaining deferred revenue balance of $36.0 million. Assembly will continue to recognize additional collaboration revenue into the fourth quarter of 2020 for reimbursement activities that occur through the 120-day transition period.
- **Research and development expenses** were $23.3 million for the three months ended June 30, 2020, compared to $18.7 million for the same period in 2019. The increase was primarily due to an increase of $3.9 million in research and development expenses related to the HBV program. Research and development expenses include non-cash stock-based compensation expenses of $3.6 million for the three months ended June 30, 2020 and $3.1 million for the same period in 2019.
- **General and administrative expenses** were $9.5 million for the three months ended June 30, 2020 compared to $4.1 million for the same period in 2019. The increase was primarily due to a non-recurring reversal of previously recognized stock-based compensation expense of $3.6 million related to forfeited awards following the departure of one of Assembly's former executive officers in 2019. General and administrative expenses include non-cash stock-based compensation expenses of $3.5 million for the three months ended June 30, 2020 and $(1.1) million for the same period in 2019.
- **Net income (loss) attributable to common stockholders** was $7.5 million, or $0.21 per basic and $0.19 per diluted share, for the three months ended June 30, 2020 compared to $(18.5) million, or $(0.72) per basic and diluted share, for the same period in 2019. This was primarily due to the recognition of the remaining deferred revenue balance as noted above.

About Assembly Biosciences

Assembly Biosciences, Inc. is a clinical-stage biotechnology company developing innovative therapeutics targeting hepatitis B virus (HBV) and diseases associated with the microbiome. The HBV program is focused on advancing a new class of potent, oral core inhibitors that have the potential to increase cure rates for chronically infected patients. The microbiome program is developing novel oral live microbial biotherapeutic candidates with Assembly's fully integrated platform, including a robust process for strain identification and selection, GMP manufacturing expertise and targeted delivery to the lower gastrointestinal tract with the GEMICEL® technology. 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's ability to initiate and complete clinical trials involving its HBV Cure and Microbiome therapeutic product candidates in the currently anticipated timeframes; safety and efficacy data from clinical studies may not warrant further development of Assembly's product candidates; clinical and nonclinical data presented at conferences may not differentiate Assembly's product candidates from other companies' candidates; Assembly may not observe sustained virologic response in patients who stop therapy in Study 211; the timing and ability to implement strategic alternatives with respect to the Microbiome program; Assembly's ability to maintain financial resources necessary to continue its clinical trials and fund business operations; any impact that the spread of the coronavirus and resulting

COVID-19 pandemic may have on Assembly's business and operations, including initiation and continuation of its clinical trials or timing of discussions with regulatory authorities; and other risks identified from time to time in Assembly'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 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's risks and uncertainties are more fully detailed under the heading "Risk Factors" in Assembly'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 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, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current assets		
Cash and cash equivalents	$ 96,709	$ 46,732
Marketable securities	130,005	227,311
Accounts receivable from collaboration	3,315	3,374
Prepaid expenses and other current assets	5,059	5,363
Total current assets	235,088	282,780
Property and equipment, net	2,063	1,830
Operating lease right-of-use (ROU) assets	10,780	11,975
Other assets	5,232	1,684
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 294,801**	**$ 339,907**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,640	$ 1,731
Accrued clinical expenses	4,362	4,826
Other accrued expenses	6,019	8,286
Deferred revenue - short-term	—	6,411
Operating lease liabilities - short-term	3,250	3,186
Total current liabilities	17,271	24,440

Deferred tax liabilities	2,531	2,531
Deferred revenue - long-term	—	30,637
Operating lease liabilities - long-term	7,884	9,082
Total liabilities	**27,686**	**66,690**
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 32,807,519 and 32,558,307 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	33	32
Additional paid-in capital	725,784	712,807
Accumulated other comprehensive income (loss)	104	(201)
Accumulated deficit	(458,806)	(439,421)
Total stockholders' equity	267,115	273,217
Total liabilities and stockholders' equity	**$ 294,801**	**$ 339,907**

ASSEMBLY BIOSCIENCES, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

(In thousands except for share and per share amounts)

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Collaboration revenue	$ 39,376	$ 3,080	$ 43,457	$ 6,966
Operating expenses:				
Research and development	23,327	18,700	46,373	41,405
General and administrative	9,470	4,080	18,199	13,597
Total operating expenses	32,797	22,780	64,572	55,002
Income (loss) from operations	**6,579**	**(19,700)**	**(21,115)**	**(48,036)**
Other income				
Interest and other income, net	691	1,186	1,730	2,463
Total other income	691	1,186	1,730	2,463
Income (loss) before income taxes	**7,270**	**(18,514)**	**(19,385)**	**(45,573)**
Income tax benefit	—	11	—	18
Net income (loss)	**$ 7,270**	**$ (18,503)**	**$ (19,385)**	**$ (45,555)**
Other comprehensive income				
Unrealized gain on marketable securities, net of tax	190	52	305	160
Comprehensive income (loss)	**$ 7,460**	**$ (18,451)**	**$ (19,080)**	**$ (45,395)**
Net income (loss) per share, basic	$ 0.21	$ (0.72)	$ (0.55)	$ (1.77)
Weighted average common shares outstanding, basic	35,307,669	25,740,500	35,229,570	25,690,617
Net income (loss) per share, diluted	$ 0.19	$ (0.72)	$ (0.55)	$ (1.77)

Weighted average common shares outstanding, diluted	37,291,474	25,740,500	35,229,570	25,690,617

Source: Assembly Biosciences, Inc.