

Assembly Biosciences Announces Second Quarter 2018 Financial Results

August 8, 2018

- ABI-H0731 Phase 2a Clinical Trials Actively Enrolling Patients; Initial Data Continues to be Anticipated in H1 2019

- Strong Balance Sheet Provides Significant Runway

SAN FRANCISCO and INDIANAPOLIS, Aug. 08, 2018 (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 for the second quarter ended June 30, 2018.

"Based on the positive Phase 1b data for ABI-H0731 that we reported at EASL 2018 in April, we have initiated enrollment in our Phase 2a viral antigen and viral load trials in HBV patients and have raised approximately \$155 million in an oversubscribed public stock offering. This gives us substantial resources to advance our pipeline, including completion of these Phase 2a trials and the introduction of ABI-H2158 into the clinic, which is planned for later this year," said Derek Small, President and Chief Executive Officer. "We also were pleased that ABI-H0731 received Fast Track Designation from the FDA, which allows us to work closely with the agency to bring this new therapeutic candidate to HBV patients as quickly as possible."

Recent Highlights

- Assembly began enrolling patients in two Phase 2a proof of concept studies evaluating ABI-H0731, the Company's lead core inhibitor targeting HBV. Initial data from both studies are expected in the first half of 2019. ABI-H0731 was also granted Fast Track Designation by the U.S. Food and Drug Administration (FDA).
- On July 16, 2018, Assembly announced the closing of an underwritten public offering of 4,600,000 shares of common stock at a public offering price of \$36.00 per share, which includes the full exercise of the underwriters' option to purchase additional shares. Net proceeds to Assembly from this offering were approximately \$155 million.
- Assembly hosted its first Research and Development Day in New York on June 20, 2018. Two key opinion leaders highlighted the need for new and curative treatments for the millions of patients living with HBV. Company management also presented the development plans for ABI-H0731 and the second generation core inhibitor candidate, ABI-H2158. The presentation and recorded replay of the event can be accessed in the Investors section of the Company's website.

Anticipated Milestones and Events

- ABI-H0731
 - Initial Phase 2a data expected in the first half of 2019
- ABI-H2158
 - Phase 1a clinical trial initiation in healthy volunteers expected in the fourth quarter of 2018
- Upcoming events
 - Baird Global Healthcare Conference in New York, September 5-6, 2018
 - Morgan Stanley Global Healthcare Conference in New York, September 12-14, 2018

Second Quarter Financial Results

- Cash, cash equivalents and marketable securities were approximately \$94.9 million as of June 30, 2018 compared to approximately \$109.2 million as of March 31, 2018. As of July 16, 2018, Assembly's pro forma cash balance is approximately \$250 million which includes net proceeds from the offering of approximately \$155.4 million.
- **Revenues** consisting of revenue from collaborative research were approximately \$3.2 million for the three months ended June 30, 2018, compared to approximately \$2.4 million for the same period in 2017. The increase in revenue was due to an increase in Allergan-related activities and expense reimbursement.

- Research and development expenses, excluding stock-based compensation expense, were approximately \$14.2 million for the three months ended June 30, 2018, compared to approximately \$10.9 million for the same period in 2017. This increase was primarily due to an increase of approximately \$3.1 million in research and development expenses related to the HBV program. Stock-based compensation expense was approximately \$3.7 million for the three months ended June 30, 2018, compared to approximately \$1.2 million for the same period in 2017.
- General and administrative expenses, excluding stock-based compensation expense, were approximately \$4.6 million for the three months ended June 30, 2018, compared to approximately \$3.0 million for the same period in 2017. This increase was primarily due to increased headcount across the organization. Stock-based compensation expense was approximately \$7.9 million for the three months ended June 30, 2018, as compared to \$0.8 million for the same period in 2017. This increase was primarily due to a \$4.3 million one-time non-cash expense related to the departure and transition to consultant of a former officer of Assembly and \$3.5 million of expenses related to non-cash, stock-based compensation grants and employee incentive programs including the 2018 Employee Stock Purchase Plan.
- Net loss attributable to common stockholders was approximately \$26.7 million, or \$1.30 per basic and diluted share, for the three months ended June 30, 2018, compared to approximately \$13.5 million, or \$0.78 per basic and diluted share for the same period in 2017. This increase was primarily due to an increase in research and development expenses related to the HBV program, and expenses related to non-cash, stock-based compensation, employee incentive programs and increased headcount across the organization.

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 synthetic biotherapeutic candidates with Assembly's fully integrated platform, including a robust process for strain identification and selection, GMP banking and production, 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 regarding future events, including statements about the clinical and therapeutic potential of core inhibitors, including ABI-H0731 and ABI-H2158, Assembly's development programs, the results of earlier nonclinical and clinical trials being predictive of future clinical trials, the initiation, progress and results of Assembly's ongoing and planned clinical studies and the timing of these events, our estimates and projections regarding expenses, use of cash, cash equivalents and marketable securities, future revenue, capital requirements, adequacy of capital and financing requirements. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "anticipated", "upcoming," "look forward," "will," "expected," and "potential." 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. Actual results or developments may differ materially from those projected or implied in these forward-looking statements. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading "Risk Factors" in Assembly's Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 filed with the Securities and Exchange Commission. 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.

Contacts

Assembly Biosciences, Inc. Investors: Lauren Glaser (415) 521-3828 Iglaser@assemblybio.com

Assembly Biosciences, Inc. Condensed Consolidated Balance Sheets

	June 30, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	\$ 54,192,131	\$ 82,033,209
Marketable securities, at fair value	38,480,105	37,914,482
Accounts receivable from collaboration	2,125,597	2,273,421
Prepaid expenses and other current assets	2,731,385	897,400
Total current assets	97,529,218	123,118,512
Long-term assets		
Marketable securities, at fair value	2,204,103	3,347,213

Property, plant and equipment, net	639,897	860,026
Security deposits	406,735	339,558
Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	44,888,871	46,184,933
Total assets	\$ 142,418,089	\$ 169,303,445

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities		
Accounts payable	\$ 2,538,976	\$ 2,123,939
Accrued expenses	5,079,780	6,139,000
Deferred revenue - short-term	5,512,109	5,229,227
Total current liabilities	13,130,865	13,492,166
Long-term liabilities		
Deferred tax liabilities	2,108,367	2,135,802
Deferred revenue - long-term	38,078,292	40,555,708
Total long-term liabilities	40,186,659	42,691,510
Total liabilities	53,317,524	56,183,676

Commitments and contingencies

Stockholders' equity

Preferred stock, \$0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, \$0.001 par value; 100,000,000 and 50,000,000 shares authorized as of June 30, 2018 and December 31, 2017, respectively; 20,614,498 and 20,137,974 shares issued and outstanding as of June 30, 2018 and December 31, 2017, respectively	20,614	20,138
Additional paid-in capital	383,543,035	364,528,037
Accumulated other comprehensive loss	(372,078)	(392,391)
Accumulated deficit	(294,091,006)	(251,036,015)
Total stockholders' equity	89,100,565	113,119,769
Total liabilities and stockholders' equity	\$ 142,418,089	\$ 169,303,445

Assembly Biosciences, Inc. Condensed Consolidated Statem

Condensed Consolidated Statements of Operations and Comprehensive

Loss (Unaudited)

	Three Months Ended June 30, Six Months Ended June 30		
	2018 2017 2018 2017		
Collaboration revenue	\$ 3,217,865 \$ 2,359,311 \$ 6,782,925 \$ 3,043,680		
Operating expenses:			
Research and development	17,840,128 12,125,021 32,381,302 22,698,760		
General and administrative	12,543,658 3,801,541 18,239,693 7,842,000		
Total operating expenses	30,383,786 15,926,562 50,620,995 30,540,760		
Loss from operations	(27,165,921) (13,567,251) (43,838,070) (27,497,080)	
Other income (expenses)			
Interest and other income	453,016 239,858 899,422 376,342		
Realized loss from marketable securities	(127,234) (340,984) (150,250) (478,232)	
Total other income	325,782 (101,126) 749,172 (101,890)	
Loss before income taxes	(26,840,139) (13,668,377) (43,088,898) (27,598,970))	
Income tax benefit	33,907 69,513 33,907 69,513		
Net loss	\$ (26,806,232) \$ (13,598,864) \$ (43,054,991) \$ (27,529,45	7)	

Other comprehensive (loss) income

Unrealized loss recognized in accumulated other comprehensive loss before reclassification, net of tax benefit of \$29,835, \$57,437, \$29,835 and \$57,437, respectively

(39,962		(31,203		(129,937		(92,359	
(00,002	,	(01,200	,	(120,007)	(02,000)

Reclassification adjustment of unrealized loss included in net loss, net of tax expense of \$36,307, \$183,371, \$36,307 and \$183,371, respectively Comprehensive loss	127,234 \$ (26,718,960) \$	157,613 (13,472,454) \$	150,250 (43,034,678) \$	294,861 (27,326,955)
Net loss per share, basic and diluted	\$ (1.30) \$	(0.78) \$	(2.11) \$	(1.59)
Weighted average common shares outstanding, basic and diluted	20,541,549	17,342,623	20,387,532	17,305,657

Primary Logo

Source: Assembly Biosciences