Assembly Biosciences Announces First Quarter 2018 Financial Results

May 7, 2018

INDIANAPOLIS and SAN FRANCISCO, May 07, 2018 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (NASDAQ:ASMB), a clinical-stage biotechnology company advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and novel oral synthetic live biotherapeutics for disorders associated with the microbiome, today reported financial results for the first quarter ended March 31, 2018.

“Thanks to the strength of our science, product platforms and our talented and growing team, we’ve had a very strong start to 2018 and are on target to continue to execute on our plan to achieve our goals this year and beyond,” said Derek Small, president and chief executive officer. “Last month at the European Association for the Study of the Liver (EASL) conference, we reported positive interim Phase 1b data for ABI-H0731 our lead Core protein Allosteric Modifier (CpAM), and we are excited to be hosting our first investor and analyst day in June where we will be sharing details about our upcoming two Phase 2a studies. Our microbiome program also continues to make significant progress internally and in collaboration with Allergan.”

Recent Highlights

- For Assembly’s lead CpAM, ABI-H0731 targeting HBV, the Company presented interim Phase 1a and 1b data at the EASL meeting in Paris. The data demonstrated excellent antiviral potency across multiple dosing cohorts, with maximal viral load declines of up to 4.0 $\log_{10}$ IU/mL and a favorable safety profile.
- Assembly expects to initiate two Phase 2a studies of ABI-H0731 this summer in HBV patients. The first study will enroll patients already on standard of care nucleos(t)ide therapy that have fully suppressed viral loads. This six-month study is designed to demonstrate that adjunctive ABI-H0731 therapy can inhibit the generation of cccDNA molecules by showing a decline in several surrogate markers of cccDNA. The second Phase 2a study will enroll treatment naïve patients and is designed to compare the antiviral effectiveness of standard of care entecavir therapy alone to entecavir in combination with ABI-H0731 over six months. Initial data from both studies is expected in the first half of 2019.
- Assembly will also initiate a Phase 1a study in healthy volunteers on its second generation CpAM, ABI-H2158, to profile safety and pharmacokinetic properties in the fourth quarter of 2018.
- Assembly expanded its leadership team with accomplished individuals who bring critical skills and experience that will help enable our continued growth and pipeline advancement.
    - In March, Graham Cooper joined Assembly as chief financial officer and chief operating officer. Mr. Cooper served most recently as chief financial officer of Receptos, where he helped to take the company public and grow the organization to support an ambitious clinical development program ahead of its acquisition by Celgene in 2015.
    - In April, Jackie Papkoff, PhD joined Assembly as senior vice president, chief scientific officer of the microbiome program. Dr. Papkoff has worked in pharma and biotech for over 20 years, most recently as senior vice president, research of Evelo Biosciences.
    - In December 2017 and March 2018, respectively, Assembly appointed Sue Mahony, PhD and Helen S. Kim to its Board of Directors. Dr. Mahony’s career spans 28 years in diverse leadership roles in sales, marketing, clinical development, human resources and general management. Dr. Mahony currently serves as president, Lilly Oncology and a member of the company’s Executive Committee. Ms. Kim has over 27 years of experience in leadership roles in biotechnology and most recently served as executive vice president of business development at Kite Pharma, where she led all business and corporate development initiatives until its sale to Gilead in 2017.

Upcoming Milestones and Events

- ABI-H0731
    - Two Phase 2a studies in HBV patients, expected to initiate summer 2018
    - Initial Phase 2a data expected in the first half of 2019

- ABI-2158
    - Phase 1a clinical trial initiation in healthy volunteers expected in the fourth quarter of 2018

- Conferences and Events

- Jefferies Healthcare Conference in New York on June 6, 2018 at 10:00 a.m. ET
- R&D Day in New York on June 20, 2018

First Quarter Financial Results

- **Cash, cash equivalents and marketable securities** were approximately $109.2 million as of March 31, 2018 compared to approximately $123.3 million, which included $3.3 million of long-term marketable securities, as of December 31, 2017.

- **Revenues** consisting of revenue from collaborative research were approximately $3.6 million for the three months ended March 31, 2018, compared to approximately $0.7 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** were approximately $14.5 million for the three months ended March 31, 2018, compared to approximately $10.6 million for the same period in 2017. This increase was primarily due to increases in headcount across both the HBV and microbiome programs and ramp-up in HBV program expenses related to the expected Phase 2a clinical studies to be initiated in summer 2018.

- **General and administrative expenses** were approximately $5.7 million for the three months ended March 31, 2018, compared to approximately $4.0 million for the same period in 2017. This increase was primarily due to increases in headcount across the organization.

- **Net loss attributable to common stockholders** was approximately $16.2 million, or $0.80 per basic and dilulted share, for the three months ended March 31, 2018, compared to approximately $13.9 million, or $0.81 per basic and diluted share for the same period in 2017.

About Assembly Biosciences

Assembly Biosciences, Inc. is a clinical-stage public biotechnology company developing two innovative platform programs: an HBV program advancing a new class of oral therapeutics for the treatment of hepatitis B virus (HBV) infection and a microbiome program developing novel oral synthetic live biotherapeutics for disorders associated with the microbiome. Assembly's HBV-cure program is advancing multiple drug candidates with the aim of increasing cure rates in patients with chronic HBV. TAssembly's microbiome program consists of a fully integrated platform that includes a robust strain identification and selection process, methods for strain isolation and growth under current Good Manufacturing Practices and a patented delivery system, GEMICEL®, which allows for targeted oral delivery of live biologic and conventional therapies to the lower gastrointestinal tract. 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 ABI-H0731 and Assembly's development programs, the results of earlier nonclinical studies and clinical trials may not be predictive of future clinical trial results, the initiation, progress and results of Assembly's ongoing and planned clinical studies and the timing of these events and our estimates and projections regarding expenses, use of cash, cash equivalents and marketable securities, future revenue, capital requirements and financing requirements. Certain forward-looking statements may be identified by reference to a future period or periods or by use of forward-looking terminology such as "expected," "anticipated," "designed" or "developing." 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 Annual Report on Form 10-K for the year ended December 31, 2017 and Assembly's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 each 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.

Assembly Biosciences, Inc.
Condensed Consolidated Balance Sheets

	March 31, 2018 (Unaudited)	December 31, 2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 66,926,630	$ 82,033,209
Marketable securities, at fair value	42,232,348	37,914,482
Accounts receivable from collaboration	2,263,556	2,273,421
Prepaid expenses and other current assets	1,803,066	897,400
Total current assets	113,225,600	123,118,512
Long-term assets		
Marketable securities, at fair value	-	3,347,213
Property, plant and equipment, net	731,500	860,026
Security deposits	425,592	339,558

Intangible assets	29,000,000	29,000,000
Goodwill	12,638,136	12,638,136
Total long-term assets	42,795,228	46,184,933
Total assets	**$ 156,020,828**	**$ 169,303,445**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,372,874	$ 2,123,939
Accrued expenses	4,647,472	6,139,000
Deferred revenue - short-term	5,159,587	5,229,227
Total current liabilities	12,179,933	13,492,166
Long-term liabilities		
Deferred tax liabilities	2,135,802	2,135,802
Deferred revenue - long-term	39,323,844	40,555,708
Total long-term liabilities	41,459,646	42,691,510
Total liabilities	**53,639,579**	**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, $0.001 par value; 50,000,000 shares authorized; 20,386,736 and 20,137,974 shares issued and outstanding as of March 31, 2018 and December 31, 2017, respectively	20,387	20,138
Additional paid-in capital	370,104,986	364,528,037
Accumulated other comprehensive loss	(459,350)	(392,391)
Accumulated deficit	(267,284,774)	(251,036,015)
Total stockholders' equity	102,381,249	113,119,769
Total liabilities and stockholders' equity	**$ 156,020,828**	**$ 169,303,445**

Assembly Biosciences, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended March 31,	
	2018	**2017**
Collaboration revenue	$ 3,565,060	$ 684,369
Operating expenses:		
Research and development	14,541,174	10,573,739
General and administrative	5,696,035	4,040,459
Total operating expenses	20,237,209	14,614,198
Loss from operations	**(16,672,149)**	**(13,929,829)**
Other income (expenses)		
Interest and other income	446,406	136,484
Realized loss from marketable securities	(23,016)	(137,248)
Total other income (expense)	423,390	(764)
Net loss	**$ (16,248,759)**	**$ (13,930,593)**
Other comprehensive (loss) income		
Unrealized loss recognized in accumulated other comprehensive loss before reclassification	(89,975)	(61,156)
Reclassification adjustment of unrealized loss included in net loss	23,016	137,248
Comprehensive loss	**$ (16,315,718)**	**$ (13,854,501)**
Net loss per share, basic and diluted	$ (0.80)	$ (0.81)
Weighted average common shares outstanding, basic and diluted	20,231,804	17,268,280

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Source: Assembly Biosciences