Assembly Biosciences Reports First Quarter 2019 Financial Results and Recent Highlights

May 9, 2019

SAN FRANCISCO, May 09, 2019 (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 first quarter ended March 31, 2019 and provided a business update.

"We are dedicated to increasing cure rates for individuals with chronic HBV and were honored to have data highlighting our deep pipeline of novel core inhibitor candidates featured at The International Liver Congress™ (ILC) last month, including our ABI-H0731 presentation as a 'Best of ILC' selection," said Derek Small, President and Chief Executive Officer. "We showed interim data from the ongoing Phase 2a trials of '731 demonstrating the potential of core inhibitors in combination with Nuc therapy to be the backbone of HBV cure regimens going forward, along with updates on our next generation core inhibitor programs. Additionally, we initiated a Phase 1b trial for our first microbiome clinical program in collaboration with Allergan, with ABI-M201 now being evaluated in ulcerative colitis patients."

Mr. Small continued, "Our progress this year has helped us to attract development veterans to our leadership team to support both of our programs: Steven J. Knox as Senior Vice President Clinical Development and David R. Houck, Ph.D., as Senior Vice President Product Development and Portfolio Management. These additions reflect our continued evolution into a clinical-stage organization across both our HBV and microbiome programs, allowing us to focus our resources on key pipeline priorities and improving our cash runway."

First Quarter 2019 and Recent Highlights

- Interim data from two ongoing Phase 2a trials of ABI-H0731 ('731) in subjects with chronic HBV infection was presented at a late-breaker oral session at ILC, The Annual Meeting of the European Association for the Study of the Liver (EASL) in Vienna, Austria.
  -- '731 in combination with nucleos(t)ide therapy (Nuc) showed a favorable safety profile and the potential to eliminate residual Hepatitis B Virus (DNA), one of the gating factors to potentially reaching cure.
  -- Significant HBV RNA declines were only observed in patients on '731 combination therapy.
  -- In treatment naïve patients, accelerated and significant declines in HBV DNA were observed starting as early as Week 2.
  -- In Nuc-experienced, virally-suppressed patients, HBV DNA reductions below the detectable limits of a high-sensitivity PCR assay were observed only on combination therapy with '731, an unprecedented finding in the field of HBV. One treatment suppressed patient that achieved rapid DNA "target not detected" and RNA decline to below the limit of quantitation also demonstrated a greater than 0.5 $\log_{10}$ decline in HBeAg by Week 24.
  -- To prevent continual new infection and cccDNA formation, elimination of residual viremia will likely be required to increase cure rates.
- Additional data presentations at EASL included:
  -- A Phase 1a study of next-generation core inhibitor ABI-H2158 (2158), which demonstrated that 2158 was well tolerated and trough liver concentrations are projected to achieve exposures in excess of the *in vitro* EC_{50} (334nM) for cccDNA establishment with once daily administration. A Phase 1b study in patients is underway.
  -- Preclinical profile of ABI-H3733, the Company's third core inhibitor, which demonstrated increased potency in blocking cccDNA formation.
  -- Additional data from continuing longitudinal studies demonstrating that cccDNA population turnover can occur in as little as 3-4 months, contrary to historical estimates of up to 14 years. These results suggest relatively rapid turnover of cccDNA pools and/or infected cells and the potential to pursue cure in a defined treatment period with targeted therapeutic regimens
- Strengthened clinical and product development team:
  -- Steven J. Knox joined as Senior Vice President Clinical Development. Mr. Knox is a 30-year clinical development veteran that came to Assembly from Gilead Sciences where he most recently served as Vice President, Clinical Research and was responsible for global development programs in inflammation and viral hepatitis, including for sofosbuvir (Sovaldi®) and sofosbuvir/ledipasvir (Harvoni®), and tenofovir alafenamide (Vemlidy®)[1].
  -- David R. Houck, Ph.D. joined as Senior Vice President Product Development and Portfolio Management. Mr. Houck has more than 35 years of experience in the pharmaceutical and biotechnology industries, from drug discovery through submission of INDs and NDAs for both small molecules and biologics, to manufacturing and quality control with particular experience in anti-infective agents including HCV and HIV.
- Ongoing Phase 1b clinical trial of microbiome candidate M201 for mildly to moderately active ulcerative colitis (UC) at sites in the U.S.

Anticipated Milestones and Events

HBV Program

- ABI-H0731
  -- 24-week data from Phase 2a trials combining ‘731 with Nuc therapy expected in Q4 2019, along with an update on extended treatment of these patients in the open label Study 211.

- ABI-H2158
  -- Phase 1b trial in HBV-infected subjects data expected by Q1 2020.

- ABI-H3733
  -- Phase 1a trial expected to initiate in Q1 2020.

Microbiome Program

- ABI-M201
  -- Ongoing Phase 1b trial in patients with mildly to moderately active UC.

- Microbiome Platform
  -- Leveraging discovery and development capabilities and manufacturing expertise to advance new proprietary candidates for other disease indications.

Upcoming Conferences

- Bank of America Merrill Lynch Health Care Conference 2019 in Las Vegas, May 14-15, 2019.
- Jefferies 2019 Healthcare Conference in New York on June 5, 2019 at 9:00am ET.

First Quarter 2019 Financial Results

- **Cash, cash equivalents and marketable securities** were approximately $193.5 million as of March 31, 2019, compared to approximately $218.1 million as of December 31, 2018. This quarter-end cash position is projected to fund operations into 2021.

- **Revenues** from collaborative research were approximately $3.9 million for the three months ended March 31, 2019 compared to $3.6 million for the same period in 2018.

- **Research and development expenses,** excluding stock-based compensation expense, were approximately $20.0 million for the three months ended March 31, 2019, compared to approximately $12.0 million for the same period in 2018. This increase was primarily due to an increase of approximately $6.4 million in research and development expenses related to the HBV program and an increase of approximately $1.6 million in research and development expenses related to the microbiome program. Stock-based compensation expense was approximately $2.7 million for the three months ended March 31, 2019, compared to approximately $2.5 million for the same period in 2018.

- **General and administrative expenses,** excluding stock-based compensation expense, were approximately $5.7 million for the three months ended March 31, 2019, compared to $4.1 million for the same period in 2018. The increase was primarily due to increases in professional fees, employee-related expenses and facility expenses associated with the Company’s new offices in South San Francisco. Stock-based compensation expense was approximately $3.8 million for the three months ended March 31, 2019, compared to approximately $1.6 million for the same period in 2018.

- **Net loss attributable to common stockholders** was approximately $27.1 million, or $1.05 per basic and diluted share, for the three months ended March 31, 2019, compared to approximately $16.3 million, or $0.80 per basic and diluted share, for the same period in 2018. The increase was primarily due to an increase in research and development expenses related to the HBV program, 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, the timing of the initiation of and the availability of data from our ongoing and planned clinical trials and cash projections. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as “expected,” “may,” “will,” “projected” 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. These risks and uncertainties include, among others: the components, timing, cost and results of clinical trials and other development activities involving our product candidates (including those licensed by Allergan Pharmaceuticals International Limited); the unpredictability of the preclinical and clinical development of our product candidates and of the duration and results of regulatory review of those candidates by the FDA and foreign regulatory authorities; our anticipated capital expenditures and our estimates regarding our capital requirements; and the possible impairment of, or inability to obtain, intellectual property rights and the costs of obtaining such rights from third parties. 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 March 31, 2019 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.

[1]Sovaldi®, Harvoni® and Vemlidy® are registered trademarks of Gilead Sciences, Inc., or its related companies.

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ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
($ in thousands except for share and per share amounts)

	March 31, 2019 (Unaudited)	December 31, 2018
ASSETS		
Current assets		
Cash and cash equivalents	$ 29,107	$ 41,471
Marketable securities	164,429	176,609
Accounts receivable from collaboration	2,987	2,430
Prepaid expenses and other current assets	4,283	1,992
Total current assets	200,806	222,502
Property and equipment, net	2,079	557
Operating lease right-of-use assets	13,063	-
Other assets	1,661	3,348
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total assets	**$ 259,247**	**$ 268,045**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,427	$ 3,693
Accrued expenses	10,141	9,679
Deferred revenue - short-term	9,933	5,100
Operating lease liabilities - short-term	2,704	-
Total current liabilities	25,205	18,472
Deferred rent	-	108
Deferred tax liabilities	3,252	3,252
Deferred revenue - long-term	29,868	35,560
Operating lease liabilities - long-term	10,521	-
Total liabilities	**68,846**	**57,392**
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 March 31, 2019 and December 31, 2018; 25,549,757 and 25,495,425 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	26	25
Additional paid-in capital	559,453	552,762
Accumulated other comprehensive loss	(239)	(347)

Accumulated deficit	(368,839)	(341,787)
Total stockholders' equity	190,401	210,653
Total liabilities and stockholders' equity	**$ 259,247**	**$ 268,045**

ASSEMBLY BIOSCIENCES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
($ in thousands except for share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2019	**2018**
Collaboration revenue	$ 3,885	$ 3,565
Operating expenses:		
Research and development	22,704	14,541
General and administrative	9,517	5,696
Total operating expenses	32,221	20,237
Loss from operations	**(28,336)**	**(16,672)**
Other income (expenses)		
Interest and other income	1,276	446
Other income (expense), net	1	(23)
Total other income	1,277	423
Loss before income taxes	**(27,059)**	**(16,249)**
Income tax benefit	7	-
Net loss	**$ (27,052)**	**$ (16,249)**
Other comprehensive (loss) income		
Unrealized gain (loss) on marketable securities, net of tax	108	(67)
Comprehensive loss	**$ (26,944)**	**$ (16,316)**
Net loss per share, basic and diluted	$ (1.05)	$ (0.80)
Weighted average common shares outstanding, basic and diluted	25,668,798	20,231,804

Source: Assembly Biosciences, Inc.