Assembly Biosciences Reports Fourth Quarter and Year End 2018 Financial Results

February 28, 2019

SAN FRANCISCO, Feb. 28, 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 fourth quarter and year ended December 31, 2018.

"Assembly has achieved many significant milestones over the past year across both our HBV and microbiome programs," stated Derek Small, President and Chief Executive Officer of Assembly Biosciences. "Our HBV pipeline has matured to include three chemically-distinct core protein inhibitor candidates, two of which are in clinical studies, and all of which were discovered by our research team with the goal of increasing cure rates for HBV patients. We expect to report patient data throughout the year from our ongoing Phase 2a studies of ABI-H0731, as well as provide updates on our Phase 1 studies of ABI-H2158 and the progress of our third core inhibitor ABI-H3733 towards initiation of clinical studies."

Mr. Small further commented, "In addition, we are pleased to announce the initiation of a Phase 1b study of ABI-M201, the first clinical candidate from our collaboration with Allergan, in patients with mildly to moderately active ulcerative colitis. M201 is the first live biotherapeutic product (LBP) containing a rationally derived consortium of bacteria to be evaluated in patients. The M201 program is an example of the fully integrated platform Assembly has developed in-house to make rationally designed LBPs from strain isolation through CMC drug manufacture to targeted delivery in a proprietary oral capsule. Throughout 2019, we expect to leverage these capabilities to bring forward additional therapeutic candidates for other important disease indications."

Fourth Quarter 2018 and Recent Highlights

- Assembly presented final results of the Phase 1b study of ABI-H0731 at the AASLD Annual Meeting in San Francisco in November 2018. Data showed that 731 was well tolerated, with substantial reductions in both HBV DNA and RNA, distinguishing it from standard of care nucleos(t)ide therapy. The presentation was designated a "Best of AASLD 2018" selection.

- In November 2018, Assembly initiated a Phase 1a study of ABI-H2158 and selected ABI-H3733 as its third core inhibitor candidate for development.

- In January 2019, Assembly completed enrollment of two 24-week Phase 2a studies evaluating ABI-H0731, the Company's lead HBV core inhibitor. The *ABI-H0731-201* "viral antigen" proof-of-concept study enrolled both HBeAg positive and negative patients whose viral load was already suppressed on active nucleos(t)ide ('Nuc') therapy. The *ABI-H0731-202* "viral load" kinetic study enrolled treatment-naïve HBeAg positive patients and is designed to evaluate the *de novo* combination of ABI-H0731 and 'Nuc' therapy (entecavir) to 'Nuc' monotherapy alone. Patients from both studies have the option to roll-over into a 12-month open label extension study, *ABI-H0731-211,* and receive a combination of ABI-H0731 with ongoing 'Nuc' therapy.

- In February 2019, Assembly and Allergan initiated a Phase 1b study of ABI-M201 (M201) in patients with mildly to moderately active ulcerative colitis (UC). M201 is the first oral live biotherapeutic product (LBP) to enter clinical development under the collaboration, and consists of a rationally designed consortium of gut commensal bacteria specifically selected for functional attributes relevant in the treatment of UC. M201 will be delivered orally, utilizing Assembly's Gemicel ® capsule-in-capsule delivery system designed for targeted two-stage delivery into the lower gastrointestinal tract. The Phase 1b study is a randomized, double-blind, and placebo-controlled trial to evaluate safety, efficacy and exploratory endpoints.

Anticipated Milestones and Events

HBV Program

- Annual Meeting of the European Association for the Study of Liver Disease (EASL) in Vienna, Austria, April 10-14, 2019 – Regular submission acceptances:
  - Oral presentation, "Preclinical profile of HBV core protein inhibitor, ABI-H3733, a potent inhibitor of cccDNA generation

in HBV infected cells".
  ○ Poster presentation, "Rapid turnover of HBV cccDNA in nucleoside-treated chronic hepatitis B patients during drug resistance emergence and breakthrough".

- ABI-H0731
  ○ Initial data from Phase 2a combination studies in HBV patients expected in Q2 2019.
  ○ Final six month data from Phase 2a combination studies expected in H2 2019.

- ABI-H2158
  ○ Initiation of Phase 1b study in HBV patients expected in Q2 2019.

- ABI-H3733
  ○ Preclinical profile to be featured in oral presentation at EASL 2019.

Microbiome Program

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

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

Fourth Quarter 2018 and Year End Financial Results

- **Cash, cash equivalents and marketable securities** were approximately $218.1 million as of December 31, 2018 compared to approximately $233.9 million as of the three months ended September 30, 2018 and approximately $123.3 million as of the year ended December 31, 2017.

- **Revenues** consisting of revenue from collaborative research were approximately $3.7 million for the three months ended December 31, 2018 compared to $3.3 million for the same period in 2017 and approximately $14.8 million for the year ended December 31, 2018 compared to approximately $9.0 million in 2017. The increase was related to an increase in Allergan-related activities and expense reimbursement.

- **Research and development expenses,** excluding stock-based compensation expense, were approximately $18.1 million for the three months ended December 31, 2018 compared to approximately $8.9 million in 2017 and approximately $60.9 million for the year ended December 31, 2018 compared to approximately $38.8 million in 2017. The year end increase was primarily due to an increase of approximately $18.3 million in research and development expenses related to the HBV program and an increase of approximately $3.9 million in research and development expenses related to the microbiome program. Stock-based compensation expense was approximately $3.1 million for the three months ended December 31, 2018 compared to approximately $1.7 million for the same period in 2017 and approximately $11.8 million for the year ended December 31, 2018 as compared to $5.4 million in 2017.

- **General and administrative expenses,** excluding stock-based compensation expense, were approximately $6.3 million for the three months ended December 31, 2018 compared to $3.9 million for the same period in 2017, and approximately $18.1 million for the year ended December 31, 2018 as compared to approximately $13.8 million in 2017. The increase was primarily due to increased headcount across the organization. Stock-based compensation expense was approximately $3.7 million for the three months ended December 31, 2018 compared to approximately $1.1 million for the same period in 2017 and approximately $16.7 million for the year ended December 31, 2018 as compared to approximately $3.2 million in 2017. This increase was primarily due to 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 $26.1 million, or $1.03 per basic and diluted share, for the three months ended December 31, 2018 compared to approximately $3.0 million, or $0.16 per basic and diluted share, for the same period in 2017. For the year ended December 31, 2018, net loss was approximately $90.8 million, or $3.98 per basic and diluted share compared to approximately $42.6 million, or $2.41 per basic and diluted share, for the year ended December 31, 2017. 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, increased headcount across the organization and a one-time income tax benefit in 2017.

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, ABI-H2158 and ABI-H3733 and live biotherapeutic product candidate ABI-M201, Assembly's development programs, the initiation, progress and results of Assembly's ongoing and planned clinical studies and the timing of these events. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "plan," "upcoming," "anticipated," "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 Annual Report on Form 10-K for the year ended December 31, 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.

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Assembly Biosciences, Inc.
Condensed Consolidated Balance Sheets

	As of December 31, 2018	2017
ASSETS		
Current assets		
Cash and cash equivalents	$ 41,471	$ 82,033
Marketable securities, at fair value	176,609	37,914
Accounts receivable from collaboration	2,430	2,274
Prepaid expenses and other current assets	1,992	898
Total current assets	222,502	123,119
Long-term assets		
Marketable securities, at fair value	-	3,347
Property, plant and equipment, net	557	860
Other assets	3,348	340
Indefinite-lived intangible asset	29,000	29,000
Goodwill	12,638	12,638
Total long-term assets	45,543	46,185
Total assets	**$ 268,045**	**$ 169,304**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,693	$ 2,124
Accrued expenses	9,679	6,139
Deferred revenue - short-term	5,100	5,229
Total current liabilities	18,472	13,492
Long-term liabilities		
Deferred rent	108	-
Deferred tax liabilities	3,252	2,136
Deferred revenue - long-term	35,560	40,556
Total long-term liabilities	38,920	42,692
Total liabilities	**57,392**	**56,184**
Commitments and contingencies		
Stockholders' equity		

Preferred stock, $0.001 par value; 5,000,000 shares authorized; 0 shares issued and outstanding	-	-
Common stock, $0.001 par value; 100,000,000 and 50,000,000 shares authorized as of December 31, 2018 and December 31, 2017; 25,495,425 and 20,137,974 shares issued and outstanding as of December 31, 2018 and December 31, 2017, respectively	25	20
Additional paid-in capital	552,762	364,528
Accumulated other comprehensive loss	(347)	(392)
Accumulated deficit	(341,787)	(251,036)
Total stockholders' equity	210,653	113,120
Total liabilities and stockholders' equity	**$ 268,045**	**$ 169,304**

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

	Year Ended December 31,		
	2018	**2017**	**2016**
Collaboration revenue	$ 14,804	$ 9,019	$ -
Operating expenses:			
Research and development	72,741	44,225	33,093
General and administrative	34,798	17,021	12,185
Total operating expenses	107,539	61,246	45,278
Loss from operations	**(92,735)**	**(52,227)**	**(45,278)**
Other income (expenses)			
Interest and other income	3,083	983	1,539
Realized loss from marketable securities	-	(615)	(1,140)
Total other income	3,083	368	399
Loss before income taxes	**(89,652)**	**(51,859)**	**(44,879)**
Income tax (expenses) benefit	(1,099)	9,050	618
Net loss	**$ (90,751)**	**$ (42,809)**	**$ (44,261)**
Other comprehensive (loss) income			
Unrealized gain (loss) on marketable securities, net of tax	45	209	221
Comprehensive loss	**$ (90,706)**	**$ (42,600)**	**$ (44,040)**
Net loss per share, basic and diluted	$ (3.98)	$ (2.41)	$ (2.57)
Weighted average common shares outstanding, basic and diluted	22,801,644	17,750,380	17,226,245

Source: Assembly Biosciences, Inc.