



Assembly Biosciences Reports Fourth Quarter and Year End 2019 Financial Results

March 4, 2020

SOUTH SAN FRANCISCO, Calif., March 04, 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 fourth quarter and year ended December 31, 2019.

"We closed out 2019 with exciting Phase 2 data from our HBV core inhibitor program at AASLD, where ABI-H0731 showed superior antiviral activity to nucleos(t)ide therapy alone as well as significant declines in pgRNA that we believe are reflective of decreases in cccDNA levels. With these encouraging findings and input from our investigators, we are finalizing plans to this year begin transitioning patients meeting certain criteria off 731+Nrti therapy in the ongoing extension study, to observe if viral suppression can be sustained," said John McHutchison, AO, MD, Chief Executive Officer and President. "Importantly, we begin 2020 well-resourced to advance our strategy and pipeline. During the fourth quarter we further strengthened our senior leadership team with the appointments of our Chief Financial Officer, our Chief Medical Officer and our Senior Vice President of Regulatory Affairs. With our experienced and dedicated team and a strong balance sheet following our successful December equity offering, we are well positioned to move our lead HBV candidate toward registration studies, to advance our second generation HBV candidate into Phase 2, and to further progress our microbiome program. We are also pleased to note that abstracts from both our HBV and microbiome therapeutic programs will be featured in presentations at medical meetings during the second quarter of 2020."

Fourth Quarter 2019 and Recent Highlights

- At the American Association for the Study of Liver Diseases (AASLD) Annual Meeting in November 2019, Assembly presented final 24-week data from two Phase 2 studies (201 and 202) and interim data from the ongoing Phase 2 long-term extension study (211) of ABI-H0731 (731), as well as interim data from the Phase 1b study of ABI-H2158 (2158).
 - 731 + nucleos(t)ide analogs (Nrti) in HBeAg positive patients with chronic Hepatitis B infection demonstrated favorable longer-term safety and tolerability, greater reductions in HBV DNA and HBV pgRNA than in Nrti alone. Data also showed that significant declines in HBV pgRNA, a primary surrogate marker of cccDNA, were associated with reductions in hepatitis B viral antigens (HBeAg, HBcrAg and HBsAg)
 - Interim data from the ongoing Phase 1b study of 2158 demonstrated potent antiviral activity and tolerability in the initial low dose cohort of 100 mg in HBeAg-positive patients treated for 14 days. The study is ongoing, and the company expects to report data on higher dose cohorts in Q2 2020.
- Abstracts featuring data from Assembly's HBV portfolio have been accepted for presentation at the International Liver Congress (EASL) in London, April 15-19, 2020.
- An abstract featuring preclinical data from Assembly's microbiome therapeutics program focused on ulcerative colitis has been accepted for poster presentation during Digestive Disease Week in Chicago, May 2-5, 2020, and an abstract featuring preclinical data from Assembly's proprietary oncology microbiome therapeutics program has also been accepted for a poster presentation during the American Association for Cancer Research Annual Meeting in San Diego, April 24-29, 2020.
- Assembly strengthened its balance sheet with an underwritten public offering that closed in December 2019 and resulted in net proceeds of \$134.7 million.

Upcoming Milestones

HBV Program

- ABI-H0731
 - Additional interim analyses from study 211 planned in Q2 2020
- ABI-H2158
 - Final Phase 1b data on higher dose cohorts to be reported in Q2 2020.
 - Phase 2 trial expected to initiate in Q2 2020.
- ABI-H3733
 - Phase 1a trial expected to initiate in Q1 2020.

Microbiome Program

- ABI-M201
 - Enrollment is ongoing in a multi-center randomized, placebo-controlled Phase 1b trial in patients with mildly to moderately active ulcerative colitis (UC).
- Microbiome Platform
 - Leveraging Assembly's rational function-based microbial discovery platform and in-house high-quality manufacturing expertise to advance new proprietary live biotherapeutic consortium candidates for oncology and other disease indications.

Fourth Quarter 2019 and Year End Financial Results

- **Cash, cash equivalents and marketable securities** were \$274.0 million as of December 31, 2019, compared to \$156.9 million as of September 30, 2019 and \$218.1 million as of the year ended December 31, 2018. This year end cash position is projected to fund operations into 2022.
- **Revenues** from collaborative research were \$4.8 million for the three months ended December 31, 2019 compared to \$3.7 million for the same period in 2018, and \$16.0 million for the year ended December 31, 2019 compared to \$14.8 million in 2018. The increase was related to an increase in research and development efforts for our microbiome program, including the initiation of a Phase 1b study.
- **Research and development expenses**, excluding stock-based compensation expense, were \$19.6 million for the three months ended December 31, 2019, compared to \$18.1 million for the same period in 2018, and \$74.4 million for the year ended December 31, 2019 compared to \$60.9 million for the year ended December 31, 2018. This increase was primarily due to an increase of \$9.4 million in research and development expenses related to the HBV program and an increase of \$4.1 million in gross research and development expenses related to the microbiome program. Stock-based compensation expense was \$3.1 million for the three months ended December 31, 2019 compared to \$3.1 million for the same period in 2018 and \$11.4 million for the year ended December 31, 2019 as compared to \$11.8 million in 2018.
- **General and administrative expenses**, excluding stock-based compensation expense, were \$7.4 million for the three months ended December 31, 2019 compared to \$6.3 million for the same period in 2018, and \$23.7 million for the year ended December 31, 2019 compared to \$18.1 million in 2018. The increase was primarily due to increased headcount and a one-time expense for severance packages in conjunction with the relocation of the corporate headquarters to South San Francisco. Stock-based compensation expense was \$3.4 million for the three months ended December 31, 2019 compared to \$3.7 million for the same period in 2018 and \$9.2 million for the year ended December 31, 2019 as compared to \$16.7 million in 2018. This decrease was primarily due to a one-time expense incurred in 2018 coupled with the reversal in 2019 of previously recognized 2018 expenses related to the departures of two executive officers in 2018 and 2019, respectively.
- **Net loss attributable to common stockholders** was \$27.1 million, or \$0.99 per basic and diluted share, for the three months ended December 31, 2019 compared to \$26.1 million, or \$1.03 per basic and diluted share, for the same period in 2018. For the year ended December 31, 2019, net loss was \$97.6 million, or \$3.72 per basic and diluted share, compared to \$90.8 million, or \$3.98 per basic and diluted share, for the year ended December 31, 2018.

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 regarding future events, including statements about the timing of data from our clinical studies involving our HBV and Microbiome therapeutic product candidates, the initiation of clinical studies for our HBV product candidates, the presentation of Microbiome non-clinical data at scientific conferences, adequacy of our financial resources and projected cash runway. Certain forward-looking statements may be identified by reference to a future period or by use of forward-looking terminology such as "expected," "planned," "projected," "upcoming" and "will." 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; whether our cash resources will be sufficient to fund continuing operations for the periods and/or trials. 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, 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.

Contacts

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Balance Sheet
For the Period Ended December 31, 2019

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS

(In thousands except for share amounts and par value)

| | As of December 31, | |
|---|---------------------------|-------------------|
| | 2019 | 2018 |
| ASSETS | | |
| Current assets | | |
| Cash and cash equivalents | \$ 46,732 | \$ 41,471 |
| Marketable securities | 227,311 | 176,609 |
| Accounts receivable from collaboration | 3,374 | 2,430 |
| Prepaid expenses and other current assets | 5,363 | 1,992 |
| Total current assets | 282,780 | 222,502 |
| Property and equipment, net | 1,830 | 557 |
| Operating lease right-of-use assets | 11,975 | — |
| Other assets | 1,684 | 3,348 |
| Indefinite-lived intangible asset | 29,000 | 29,000 |
| Goodwill | 12,638 | 12,638 |
| Total assets | \$ 339,907 | \$ 268,045 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current liabilities | | |
| Accounts payable | \$ 1,731 | \$ 3,693 |
| Accrued clinical expenses | 4,826 | 3,561 |
| Other accrued expenses | 8,286 | 6,118 |
| Deferred revenue - short-term | 6,411 | 5,100 |
| Operating lease liabilities - short-term | 3,186 | — |
| Total current liabilities | 24,440 | 18,472 |
| Deferred rent | — | 108 |
| Deferred tax liabilities | 2,531 | 3,252 |
| Deferred revenue - long-term | 30,637 | 35,560 |
| Operating lease liabilities - long-term | 9,082 | — |
| Total liabilities | 66,690 | 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 December 31, 2019 and 2018; 32,558,307 and 25,495,425 shares issued and outstanding as of December 31, 2019 and 2018, respectively | 32 | 25 |
| Additional paid-in capital | 712,807 | 552,762 |
| Accumulated other comprehensive loss | (201 | (347 |
| Accumulated deficit | (439,421 | (341,787 |
| Total stockholders' equity | 273,217 | 210,653 |
| Total liabilities and stockholders' equity | \$ 339,907 | \$ 268,045 |

Assembly Biosciences, Inc.
Income Statement
For the Period Ended December 31, 2019

ASSEMBLY BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands except for share and per share amounts)

| | Year ended December 31, | | |
|---|--------------------------------|---------------------|---------------------|
| | 2019 | 2018 | 2017 |
| Collaboration revenue | \$ 15,963 | \$ 14,804 | \$ 9,019 |
| Operating expenses: | | | |
| Research and development | 85,757 | 72,741 | 44,225 |
| General and administrative | 32,919 | 34,798 | 17,021 |
| Total operating expenses | 118,676 | 107,539 | 61,246 |
| Loss from operations | (102,713) | (92,735) | (52,227) |
| Other income (expenses) | | | |
| Interest and other income | 4,300 | 3,083 | 983 |
| Other income (expense), net | 5 | — | (615) |
| Total other income | 4,305 | 3,083 | 368 |
| Loss before income taxes | (98,408) | (89,652) | (51,859) |
| Income tax benefit (expense) | 774 | (1,099) | 9,050 |
| Net loss | \$ (97,634) | \$ (90,751) | \$ (42,809) |
| Other comprehensive (loss) income | | | |
| Unrealized gain on marketable securities, net of tax | 146 | 45 | 209 |
| Comprehensive loss | \$ (97,488) | \$ (90,706) | \$ (42,600) |
| Net loss per share, basic and diluted | \$ (3.72) | \$ (3.98) | \$ (2.41) |
| Weighted average common shares outstanding, basic and diluted | 26,258,790 | 22,801,644 | 17,750,380 |



Source: Assembly Biosciences, Inc.