# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, D.C. 20549**

# FORM 8-K

## CURRENT REPORT

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): July 17, 2020**

# Assembly Biosciences, Inc.

**(Exact name of Registrant as Specified in Its Charter)**

| **Delaware** | **001-35005** | **20-8729264** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **331 Oyster Point Blvd., Fourth Floor South San Francisco, California** | **94080** |
| **(Address of Principal Executive Offices)** | **(Zip Code)** |

**Registrant's Telephone Number, Including Area Code: (833) 509-4583**

**Not Applicable**
**(Former Name or Former Address, if Changed Since Last Report)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| **Common Stock, par value $0.001** | **ASMB** | **The Nasdaq Global Select Market** |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 1.01 Entry into a Material Definitive Agreement.**

On July 17, 2020, Assembly Biosciences, Inc. (the "Company") entered into a Collaboration Agreement (the "Collaboration Agreement") with BeiGene, Ltd. ("BeiGene") to develop, manufacture and commercialize the Company's novel core inhibitor product candidates ABI-H0731, ABI-H2158 and ABI-H3733 (the "Licensed Compounds"). Pursuant to the Collaboration Agreement, the Company has agreed to grant BeiGene an exclusive, royalty-bearing license to develop and commercialize products containing the Licensed Compounds ("Licensed Products") in the People's Republic of China, Hong Kong, Taiwan and Macau (the "Territory").

Pursuant to the terms of the Collaboration Agreement, BeiGene has agreed to pay the Company an upfront payment of $40 million, and the Company is eligible to receive up to approximately $500 million in milestone payments, comprised of up to $114 million in development and regulatory and $385 million in net sales milestone payments. In addition, the Company is eligible to receive tiered royalties at percentages ranging from the mid-teens to the low 30s of net sales.

BeiGene has agreed to pay all development and regulatory costs up to an aggregate of $45 million in the Territory for the Licensed Products. Following this initial investment, development costs for the Territory will be shared equally by BeiGene and the Company.

Under the Collaboration Agreement, BeiGene and the Company will collaborate on development activities with respect to the Licensed Compounds in accordance with mutually agreed upon development plans. BeiGene will have the exclusive right to commercialize the Licensed Products in the Territory. The Company retains all research, development and commercialization rights to the Licensed Compounds outside of the Territory. BeiGene is required to use commercially reasonable efforts to develop, obtain regulatory and reimbursement approval, market, promote, sell or distribute the Licensed Products in the Territory.

The Collaboration Agreement also contains a standstill provision pursuant to which BeiGene has agreed that, for two years following the effective date of the Collaboration Agreement, neither BeiGene nor any of its affiliates will, among other things, directly or indirectly: acquire the Company's outstanding voting securities; propose or consummate any merger, consolidation or other business combination; seek to have called any meeting of the Company's stockholders; solicit proxies or consents with respect to any of the Company's voting securities; seek representation on the Company's board of directors or management team; or publicly disclose any written or oral intention, plan or arrangement inconsistent with the foregoing. The standstill restrictions are subject to certain exceptions as provided in the Collaboration Agreement.

The Collaboration Agreement also contains provisions such as representations and warranties of the parties, terms as to governance of the collaboration, commercialization and regulatory responsibilities of the parties, and manufacturing and supply, including potential adjustments in the event supply costs exceed certain levels. In addition, during the term of the Collaboration Agreement, neither party will commercialize any competing products in the Territory.

If, after ABI-H2158 and ABI-H3733 reach the end of Phase 2 clinical trials, BeiGene and the Company are unable to mutually agree on the terms of a Phase 3 global study, BeiGene may elect to terminate the Collaboration Agreement solely as it relates to that compound, as applicable. Such a termination would result in the Company regaining all rights to the applicable compound in the Territory. In addition, BeiGene may terminate the Collaboration Agreement for convenience at any time upon 90 days' advance written notice to the Company. The Collaboration Agreement also contains customary provisions for termination by either party, including in the event of breach of the Collaboration Agreement, subject to cure.

The foregoing summary of the Collaboration Agreement is qualified in its entirety by reference to the Collaboration Agreement, which the Company intends to file as an exhibit to its Quarterly Report on Form 10-Q for the period ended September 30, 2020.

**Item 8.01 Other Events.**

On July 20, 2020, BeiGene and the Company issued a joint press release announcing the execution of the Collaboration Agreement, a copy of which is filed herewith as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit Number | Description |
|---|---|
| 99.1 | Joint Press Release of BeiGene, Ltd. and Assembly Biosciences, Inc., dated July 20, 2020. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Assembly Biosciences, Inc.

Date: July 20, 2020

By: /s/ Jason A. Okazaki
Jason A. Okazaki
Chief Legal and Business Officer

**Assembly Biosciences and BeiGene Announce License and Collaboration Agreement in China for Assembly's Portfolio of Three Clinical-Stage Core Inhibitors for Chronic Hepatitis B Infection**

*-- BeiGene acquires exclusive development and commercialization rights to ABI-H0731, ABI-H2158, and ABI-H3733 in China --*
*-- Assembly receives $40 million upfront payment and is eligible to receive up to $500 million in potential development, regulatory, and sales milestone payments plus royalties on product sales --*
*-- Assembly to host webcast and conference call today at 8:30 am ET --*

SOUTH SAN FRANCISCO, Calif., BEIJING, China and CAMBRIDGE, Mass., July 20, 2020 (GLOBE NEWSWIRE) -- Assembly Biosciences, Inc. (Nasdaq: ASMB) and BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), today announced that the companies have entered into a collaboration in China for Assembly's portfolio of three clinical-stage core inhibitor candidates for the treatment of patients with chronic hepatitis B virus (HBV) infection.

Under the terms of the agreement, Assembly has granted BeiGene exclusive rights to develop and commercialize ABI-H0731, ABI-H2158 and ABI-H3733 in China, including Hong Kong, Macau, and Taiwan. ABI-H0731 and ABI-H2158 are both in ongoing Phase 2 clinical trials and ABI-H3733 is in Phase 1 development. BeiGene will be responsible for development, regulatory submissions, and commercialization in China. Assembly retains full worldwide rights outside of the partnered territory for the Company's HBV portfolio.

Assembly will receive an upfront cash payment of $40 million and is eligible to receive up to approximately $500 million in potential development, regulatory and net sales milestone payments pending successful development and commercialization of the licensed candidates. In addition, Assembly is eligible to receive tiered royalties of net sales. BeiGene will contribute initial funding for clinical development in China, after which the development costs for the territory will be shared equally by the parties.

"This collaboration with Assembly expands our portfolio beyond oncology to liver diseases, which are highly prevalent and represent a high unmet need in China," said John Oyler, Co-Founder, Chairman and Chief Executive Officer of BeiGene. "We are thrilled to collaborate with the Assembly team that has industry-leading expertise in this area to advance novel treatments for hepatitis B, with the ultimate goal of developing a cure. Since one-third of the world's individuals living with chronic hepatitis B are in China, we are committed to leveraging our capabilities to further develop these novel therapies for patients with HBV infection."

“Our goal for China has been to find a strong, trustworthy partner with a proven track record, and we are excited to collaborate with the experienced team at BeiGene, a premier scientific partner in our industry,” said John McHutchison, AO, MD, Chief Executive Officer and President of Assembly Biosciences. “BeiGene has world-class operations in China, enabling us to accelerate the clinical development and commercialization of our core inhibitors for this important market as well as globally. With up to 90 million individuals infected with HBV in China and given the significant unmet medical need, we and BeiGene are committed to advancing our novel core inhibitors for patients living with this chronic disease.”

Assembly currently projects its $249 million in cash at March 31, 2020, together with these additional near-term sources of funding, will extend its funding of operations into the second half of 2022.

Goldman Sachs & Co. LLC is acting as exclusive financial advisor to Assembly Biosciences.

**Assembly’s Webcast and Conference Call Today**
Management from Assembly Biosciences will host a webcast and conference call today at 5:30 am PT / 8:30 am ET. The live audio webcast with accompanying slides may be accessed through the “Events & Presentations” page in the “Investors” section of Assembly’s website at https://investor.assemblybio.com/events-presentations. Alternatively, participants may dial (866) 438-0453 (domestic) or (409) 220-9366 (international) and refer to conference ID 4380778. Call participants are encouraged to connect at 5:15 am PT / 8:15 am ET to ensure a timely connection to the call or to utilize the webcast link for listen-only access.

The archived webcast will be available on Assembly’s website beginning approximately two hours after the event and will be archived and available for replay for at least 30 days after the event.

**About Assembly Biosciences’ HBV Core Inhibitor Portfolio**
Assembly’s HBV portfolio includes three clinical-stage small molecule candidates, all of which are HBV core inhibitors that target multiple steps of the HBV lifecycle. In Phase 2 clinical trials, first-generation core inhibitor ABI-H0731 administered with nucleos(t)ide analogue reverse transcriptase inhibitor (NrtI) therapy has been well-tolerated, has shown statistically superior antiviral activity in HBV DNA suppression compared to NrtI therapy alone, and has demonstrated significant declines in pgRNA that may indicate decreased cccDNA levels. In the ongoing Phase 2 open-label extension trial, Assembly is beginning to transition patients off combination therapy, to then monitor for sustained virologic response (SVR).

Assembly’s HBV portfolio also includes two more potent, second-generation candidates, ABI-H2158 in a Phase 2 clinical trial and ABI-H3733 in Phase 1 development.

Clinical data from ABI-H0731 and ABI-H2158 have been selected for presentation at the European Association for the Study of the Liver's (EASL) Digital International Liver Congress, August 27-29, 2020.

**About HBV**
Chronic hepatitis B virus (HBV) infection is a debilitating disease of the liver that afflicts over 250 million people worldwide with up to 90 million people in China, as estimated by the World Health Organization. HBV is a global epidemic that affects more people than hepatitis C virus (HCV) and HIV infection combined—with a higher morbidity and mortality rate. HBV is a leading cause of chronic liver disease and need for liver transplantation, and up to one million people worldwide die every year from HBV-related causes.

The current standard of care for patients with chronic HBV infection is life-long suppressive treatment with medications that reduce, but do not eliminate, the virus, resulting in very low cure rates. There is a significant unmet need for new therapies to treat HBV.

**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.

**About BeiGene**
BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Its 4,100+ employees in China, the United States, Australia, and Europe are committed to expediting the development of a diverse pipeline of novel therapeutics for cancer. BeiGene currently markets two internally-discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. BeiGene also markets or plans to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow BeiGene on Twitter at @BeiGeneUSA.

**Assembly's Forward-Looking Statements**
The information in this press release contains forward-looking statements that are subject to certain risks and uncertainties that could cause actual results to materially differ from those projected or implied. These risks and uncertainties include: Assembly

and BeiGene’s ability to initiate and complete clinical trials for ABI-H0731, ABI-H2158, and ABI-H3733 in the currently anticipated timeframes in China; safety and efficacy data from clinical studies may not warrant further development of Assembly’s core inhibitor product candidates; the products subject to the collaboration may not achieve future milestones or be eligible for royalties; ABI-H0731, ABI-H2158 and ABI-H3733 may not receive regulatory approval under the currently anticipated timelines, or at all; Assembly’s core inhibitor products may not be differentiated from other companies’ candidates; Assembly may not observe sustained virologic response (SVR) in patients who are treated with its core inhibitors; and other risks identified from time to time in Assembly’s reports filed with the U.S. Securities and Exchange Commission (the SEC). All statements other than statements of historical fact are statements that could be deemed forward-looking statements. Readers are cautioned not to rely on these forward-looking statements. 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. More information about the risks and uncertainties faced by Assembly are more fully detailed under the heading “Risk Factors” in Assembly’s filings with the Securities and Exchange Commission, including its most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. Except as required by law, Assembly assumes no obligation to update publicly any forward-looking statements, whether resulting from new information, future events or otherwise.

**BeiGene’s Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding future development and potential commercialization of the licensed product candidates; potential payments payable to Assembly; the potential of the licensed product candidates to treat and possibly achieve SVR in HBV patients; and the parties’ commitments and the potential benefits of the collaboration. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including BeiGene's ability to demonstrate the efficacy and safety of its drug candidates; the clinical results for its drug candidates, which may not support further development or marketing approval; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials and marketing approval; BeiGene's ability to achieve commercial success for its marketed products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene’s limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; the impact of the COVID-19 pandemic on the Company’s clinical development, commercial and other operations, as well as those risks more fully discussed in the section entitled “Risk Factors” in BeiGene’s most recent quarterly report on Form 10-Q, as well as discussions of potential risks, uncertainties, and other important factors in BeiGene's subsequent filings with the U.S. Securities and Exchange Commission. All information

in this press release is as of the date of this press release, and BeiGene undertakes no duty to update such information unless required by law.

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