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

BEIGENE, LTD.
(Exact Name of Registrant as Specified in Charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

c/o Mourant Governance Services (Cayman) Limited
94 Solaris Avenue, Camana Bay
Grand Cayman KY1-1108
Cayman Islands
(Address of Principal Executive Offices) (Zip Code)

+1 (345) 949-4123
(Registrant's telephone number, including area code)

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**
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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. o

Item 8.01 Other Events.

On July 17, 2020, BeiGene, Ltd. (the “Company” or "BeiGene") issued a press release announcing that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a new drug application (NDA) of BeiGene’s investigational inhibitor of PARP1 and PARP2, pamiparib, for the treatment of patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy. The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On July 20, 2020, BeiGene and Assembly BioSciences, Inc. ("Assembly") issued a joint press release announcing that they 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. The full text of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled “BeiGene Announces Acceptance of a New Drug Application of Pamiparib in Ovarian Cancer in China,” issued on July 17, 2020
99.2	Press Release titled “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,” issued on July 20, 2020
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

EXHIBIT INDEX

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SIGNATURE

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 hereunto duly authorized.

BEIGENE, LTD.

Date: July 21, 2020

By: /s/ Scott A. Samuels
Name: Scott A. Samuels
Title: Senior Vice President, General Counsel

BeiGene Announces Acceptance of a New Drug Application of Pamiparib in Ovarian Cancer in China

BEIJING, China and CAMBRIDGE, Mass., July 17, 2020 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) has accepted a new drug application (NDA) of BeiGene's investigational inhibitor of PARP1 and PARP2, pamiparib, for the treatment of patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy.

"This is our first NDA filing for pamiparib, which was discovered by BeiGene and is being developed as both a monotherapy and in combination with other agents, including our own anti-PD1 antibody, tislelizumab," commented Yong (Ben) Ben, M.D., Chief Medical Officer, Immuno-Oncology at BeiGene. "For patients in China with advanced ovarian cancer, we are hopeful that pamiparib can offer a new treatment option. We look forward to presenting the clinical data that supports the NDA filing and additional results, including Phase 3 data, in the upcoming months."

This NDA is supported by clinical results from a Phase 1/2 trial of pamiparib in patients with advanced ovarian cancer, fallopian cancer, and primary peritoneal cancer or advanced triple negative breast cancer (NCT03333915). The pivotal Phase 2 portion of the trial enrolled 113 patients in China with high-grade epithelial ovarian cancer (including fallopian or primary peritoneal cancer) or high-grade endometrioid epithelial cancer, harboring germline BRCA1/2 mutation, following at least two prior lines of standard chemotherapy. Patients received pamiparib 60 mg orally twice daily and the primary endpoint of the trial is objective response rate (ORR) by RECIST v1.1. Results of this study will be presented at an upcoming medical conference.

About Ovarian Cancer

In China, ovarian cancer is the tenth most common form of cancer among women, with over 50,000 new cases and more than 30,000 deaths in 2018.[1] More than 60 percent of patients are diagnosed with advanced disease.[2] The standard therapy for ovarian cancer consists of surgery followed by postoperative platinum-based chemotherapy. An estimated 70 percent of patients with epithelial ovarian cancer, which accounts for more than 90 percent of all ovarian cancer,[3] who achieve a full remission following first-line therapy will develop recurrent disease.[4]

About Pamiparib

Pamiparib (BGB-290) is an investigational inhibitor of PARP1 and PARP2 which has demonstrated pharmacological properties such as brain penetration and PARP-DNA complex trapping in preclinical models. Discovered by BeiGene scientists, pamiparib is currently in global clinical development as a monotherapy and in combination with other agents for a variety of

solid tumor malignancies. To-date more than 1,200 patients have been enrolled in clinical trials of pamiparib.

A new drug applications (NDA) for pamiparib for patients with ovarian cancer has been accepted by the Center for Drug Evaluation (CDE) of the NMPA.

About the Pamiparib Clinical Program

Clinical trials of pamiparib include:

- Phase 3 trial in China of pamiparib as maintenance versus placebo in patients with platinum-sensitive recurrent ovarian cancer (NCT03519230);
- Phase 2 trial of pamiparib in patients with metastatic castration-resistant prostate cancer with homologous recombination deficiency (NCT03712930);
- Phase 2 trial in China of pamiparib in patients with metastatic HER2-negative breast cancer with BRCA mutation (NCT03575065);
- Phase 2 trial of pamiparib in patients with advanced or inoperable gastric cancer (NCT03427814);
- Phase 1/2 trial in China of pamiparib in patients with advanced ovarian cancer, fallopian cancer, and primary peritoneal cancer or advanced triple negative breast cancer (NCT03333915);
- Phase 1b/2 trial of pamiparib in combination with radiation therapy and/or temozolomide in patients with first-line or recurrent/refractory glioblastoma (NCT03150862);
- Phase 1b trial of pamiparib in combination with temozolomide in patients with locally advanced or metastatic solid tumors (NCT03150810); and
- Phase 1b trial of pamiparib in combination with tislelizumab for a variety of solid tumor malignancies (NCT02660034).

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. Our 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. We currently market two internally-discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan 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 us on Twitter at @BeiGeneUSA.

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 BeiGene's further advancement of, and anticipated clinical development, regulatory milestones and commercialization of pamiparib; the potential for pamiparib to offer a new treatment option for patients with ovarian cancer; and the release of data from clinical trials of pamiparib. 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, as well as those risks more fully discussed in the section entitled "Risk Factors" in BeiGene's most recent annual report on Form 10-K, 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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[1] Globocan 2018; Bray et al 2018

[2] Torre et al 2018

[3] Mutch and Part 2014

[4] McMeekin et al 2004

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 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.

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 438077. 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. Our 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. We currently market two internally-discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan 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 us 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.

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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