

BeiGene, Ltd.
Form 8-K
March 07, 2019

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): March 6, 2019

BEIGENE, LTD.
(Exact name of registrant as specified in its charter)

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| Cayman Islands (State or other jurisdiction of incorporation) | 001-37686 (Commission File Number) | 98-1209416 (I.R.S. Employer Identification No.) |
|---|---------------------------------------|--|

c/o Mourant Ozannes Corporate 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))

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

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 8.01 Other Events.

On March 6, 2019, BeiGene, Ltd. (the “Company”) issued a joint press release with Ambrx Inc. announcing the parties’ entry into a global research and development collaboration to apply Ambrx’ proprietary Expanded Genetic Code platforms to discover novel biologic drug candidates, with BeiGene receiving worldwide rights to develop and commercialize any drug products that arise from the collaboration. 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

99.1 Press Release titled “Ambrx and BeiGene Announce Global Research and Development Collaboration to Develop Next-Generation Biologics” issued on March 6, 2019

Exhibit Index

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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 hereunto duly authorized.

Date: March 7, 2019 BEIGENE, LTD.

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

Exhibit 99.1

Ambrx and BeiGene Announce Global Research and Development Collaboration to Develop Next-Generation Biologics

Ambrx to receive an upfront payment of US\$10 million to apply its proprietary Expanded Genetic Code platforms to discover novel biologic drug candidates in this collaboration with BeiGene and is eligible to receive additional upfront payments for additional research programs together with development and commercial milestone payments and potential royalties on product sales

BeiGene obtains worldwide rights to develop and commercialize any drug products that arise from the collaboration

SAN DIEGO, Calif., CAMBRIDGE, Mass., and BEIJING, China, March 6, 2019 – Ambrx Inc., a clinical-stage biopharmaceutical company focused on the development of innovative protein therapeutics and BeiGene, Ltd. (Nasdaq: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced a global research and development collaboration. Ambrx has developed proprietary Expanded Genetic Code technology platforms designed to allow the efficient incorporation of non-natural amino acids into proteins in both E. Coli (ReCODEPTM) and CHO cells (EuCODEPTM). This technology enables site-specific modification of proteins to create potentially first- and/or best-in-class innovative protein drugs. The collaboration leverages Ambrx’s clinically validated drug discovery technology platforms with BeiGene’s expertise and resources to pursue the development and commercialization of next-generation biologics drugs.

“We are excited to have access to the Ambrx platform technology, which can be used to introduce non-natural amino acids selectively and specifically into a protein at any site, to develop novel biologic compounds. We believe that by incorporating this site-specific conjugation technology, we can further broaden BeiGene’s portfolio of next-generation biologics,” commented John V. Oyler, Founder, CEO, and Chairman of BeiGene. “This collaboration with Ambrx is another example of our commitment to investing in innovative early-stage research – both via our internal resources and capabilities and via collaborations.”

Under the terms of the agreement, Ambrx will receive an upfront payment of US\$10 million to fund the initial discovery and research activities and additional upfront payments of up to US\$19 million if

BeiGene elects to initiate additional programs. Ambrx is eligible to receive potential development, regulatory, and sales-based milestone payments up to an aggregate of \$446 million for all programs, in addition to tiered royalties on future global sales. BeiGene will have worldwide rights to develop and commercialize any drug products resulting from the collaboration.

"BeiGene is an inspiring and fast-growing biotech company. It has extensive experience in developing and commercializing novel medicines for the treatment of cancer, and we are very excited to enter into a broad collaboration with BeiGene," said Feng Tian, Ph.D., newly appointed President and CEO of Ambrx. "We look forward to working together with the BeiGene team to create innovative drugs utilizing the Ambrx technology platforms. We plan to fully leverage the resources and expertise of BeiGene to work to advance novel biologics, which include targeted immuno-oncology drugs, to the global market."

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 2,200 employees in China, the United States, Australia and Europe, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANEP®P (nanoparticle albumin-bound paclitaxel), REVLIMID®P (lenalidomide), and VIDAZAP®P (azacitidine) in China under a license from Celgene Corporation.

About Ambrx

Ambrx Inc. is a clinical stage biopharmaceutical company using an expanded genetic code to create first- and/or best-in-class biotherapeutics, including antibody drug conjugates (ADC), immunomodulating proteins, bispecific antibodies and other therapeutic proteins with improved pharmacologic properties. The company is developing ARX788, potential best-in-class ADC for breast and gastric cancers. Leveraging the Ambrx proprietary technology platforms, Ambrx has collaborations with Bristol-Myers Squibb, Astellas, BeiGene, Elanco and ZMC, with drug products generated using Ambrx technology in different stages of clinical trials. Ambrx is advancing a robust portfolio of product candidates that are optimized for efficacy, safety and ease of use in multiple therapeutic areas. For additional information, visit www.ambrx.comU39T

BeiGene 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 the future research, development and potential commercialization activities under the agreement with Ambrx, potential payments and/or royalties payable to Ambrx, the speed and outcome of drug development plans, and other information that is not historical information. 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 quarterly 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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