
**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 5, 2017**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-37686
(Commission File Number)

98-1209416
(I.R.S. Employer Identification No.)

**c/o Maurant 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 July 5, 2017, BeiGene, Ltd. (the “Company”) issued a press release announcing the dosing of the first patient in a pivotal clinical trial of BGB-A317, an investigational humanized monoclonal antibody, in China designed to investigate the efficacy and safety of BGB-A317 in patients with previously treated, PD-L1-positive, locally advanced or metastatic urothelial cancer. The full text of the Company’s 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on July 5, 2017
	* * *
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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: July 5, 2017

BEIGENE, LTD.

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

Exhibit Index

Exhibit No.	Description
99.1	Press Release issued on July 5, 2017



BeiGene, Ltd.

BeiGene Initiates Pivotal Trial of PD-1 Antibody BGB-A317 in China in Patients with Urothelial Cancer

BEIJING, China, and CAMBRIDGE, Mass., July 5, 2017 (GLOBE NEWSWIRE) — BeiGene, Ltd. (NASDAQ:BGNE), a clinical-stage biopharmaceutical company developing molecularly targeted and immuno-oncology drugs for the treatment of cancer, today announced that the first patient was dosed in a pivotal clinical trial in China of BGB-A317, an investigational anti-PD-1 antibody, in patients with urothelial cancer (UC), more commonly known as bladder cancer. The trial will evaluate BGB-A317 in Chinese patients with previously treated, PD-L1-positive, locally advanced or metastatic UC. BGB-A317 is also being evaluated in a pivotal trial in China in patients with relapsed or refractory classical Hodgkin lymphoma.

“It is estimated that the annual incidence of bladder cancer in China is between 55,000 and 80,000(1),(2). Chemotherapy-refractory bladder cancer patients in China have very limited treatment options and poor outcomes. This patient population is just one example of the unmet need for innovative cancer therapies, including PD-1 inhibitors. For this reason, we are committed to developing BGB-A317 broadly and look forward to initiating additional registrational trials of this agent in China,” commented John V. Oyler, Founder, Chief Executive Officer, and Chairman.

“This trial will examine BGB-A317’s efficacy and safety in patients with PD-L1-expressing bladder cancer, who we believe may be more likely to benefit from a PD-1 inhibitor. We plan to expand the development program for BGB-A317 in China and other geographies, both as monotherapy and in combination,” commented Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology.

The Phase II single-arm, multi-center trial is designed to investigate the efficacy and safety of BGB-A317 in patients with previously treated, PD-L1-positive, locally advanced or metastatic UC. The trial’s primary endpoint is the overall response rate (ORR) according to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST V1.1),

as assessed by independent review. Secondary endpoints include ORR as assessed by investigators, duration of response, disease control rate, progression-free survival, overall survival, safety, and tolerability. Professor Dingwei Ye of the Fudan University Shanghai Cancer Center is the lead principal investigator of the trial.

About BGB-A317

BGB-A317 is an investigational humanized monoclonal antibody that belongs to a class of immuno-oncology agents known as immune checkpoint inhibitors. It is designed to bind to PD-1, a cell surface receptor that plays an important role in downregulating the immune system by preventing the activation of T-cells. BGB-A317 has high affinity and specificity for PD-1, and we believe it is differentiated from the currently approved PD-1 antibodies, as the ability to bind to Fc gamma receptors has been specifically engineered out. BGB-A317 is being developed as a monotherapy and in combination with other therapies for the treatment of various cancers.

About BeiGene

BeiGene is a global, clinical-stage, research-based biotechnology company focused on molecularly targeted and immuno-oncology cancer therapeutics. With a team of over 400 employees in China, the United States, and Australia, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for the treatment of cancer. BeiGene is working to create combination solutions aimed at having both a meaningful and lasting impact on cancer patients.

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 advancement of, and anticipated clinical development and regulatory milestones and plans related to BGB-A317. 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; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; BeiGene's ability to achieve market acceptance in the medical community necessary for commercial success; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct preclinical studies and clinical trials; 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-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.

Investor/Media Contact

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(1) GLOBOCAN 2012: China (2012) Estimated Cancer Incidence, All Ages: Both Sexes. http://globocan.iarc.fr/old/summary_table_pop-html.asp?selection=39160&title=China&sex=0&type=0&window=1&sort=0&submit=%C2%A0Execute. Accessed June 9, 2017.

(2) Chen, et al. Cancer Statistics in China, 2015. *CA Cancer J Clin* . 2016; 66(2):115—32.
