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): **September 28, 2017**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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 September 28, 2017, BeiGene, Ltd. issued a press release announcing preliminary data from the dose-verification portion of the ongoing Phase 1/2 trial of its investigational anti-PD-1 antibody BGB-A317 in Chinese patients with advanced solid tumors, presented at the 20th Annual Meeting of the Chinese Society of Clinical Oncology (CSCO) in Xiamen, China. 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 issued on September 28, 2017

Exhibit Index

Exhibit No.	Description
99.1	Press Release issued on September 28, 2017

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: September 29, 2017

BEIGENE, LTD.

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

BeiGene

BeiGene, Ltd.

BeiGene Presents Preliminary Phase 1 Data for BGB-A317 in Chinese Patients with Advanced Tumors at the 20 th Annual Meeting of CSCO

CAMBRIDGE , Mass. and BEIJING, China, Sept. 28, 2017 (GLOBE NEWSWIRE) -- BeiGene, Ltd. (NASDAQ:BGNE), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly targeted and immuno-oncology drugs for the treatment of cancer, today presented preliminary data from the dose-verification portion of the ongoing Phase 1/2 trial of its investigational anti-PD-1 antibody BGB-A317 in Chinese patients with advanced solid tumors at the 20 th Annual Meeting of the Chinese Society of Clinical Oncology (CSCO) in Xiamen, China. The preliminary data suggest that BGB-A317 was generally well tolerated and exhibited preliminary evidence of anti-tumor activity in a Chinese study population with advanced solid tumors. BeiGene and Celgene Corporation have a global strategic collaboration for BGB-A317 for solid tumors; BeiGene retains exclusive rights to BGB-A317 in China.

“BGB-A317 was generally well tolerated and showed preliminary activity in a heavily pretreated study population with advanced solid tumors. At the time of the data cut-off, no dose-limiting toxicities were observed. The pharmacokinetic profile in Chinese patients was consistent with that reported in global trials of BGB-A317 at the registrational dose,” commented Professor Lin Shen of the Peking University Cancer Hospital and Beijing Institute for Cancer Research, Beijing, China, the lead author of the abstract.

“This dose-verification trial is an important step as we advance BGB-A317 along China’s domestic innovative drug development pathway. Two registrational trials of BGB-A317, in urothelial cancer and classical Hodgkin lymphoma, are currently ongoing in China. The Celgene partnership allows us to increase our investment in BGB-A317, and we intend to initiate Phase 3 trials supporting approval in China for

each of the four most common tumors in the country including lung, stomach, liver, and esophageal cancers, with the initial studies expected to start in the fourth quarter of 2017 or first quarter of 2018," commented Amy Peterson, MD, Chief Medical Officer, Immuno-oncology at BeiGene.

Summary of Results from the Ongoing Phase 1/2 Trial

The multi-center Phase 1/2 trial of BGB-A317 consists of a Phase 1 dose-verification portion and a Phase 2 portion of indication expansion in disease-specific cohorts. Data presented at CSCO include patients enrolled in the Phase 1 portion of this study, who received BGB-A317 at 200 mg once every three weeks (Q3W).

As of June 16, 2017, 20 patients had enrolled in the trial. The median duration of therapy in these patients was 53 days (range 21–171 days).

Adverse events (AEs) assessed by the investigator to be related to treatment occurred in 19 patients (95%). The most common treatment-related AEs (TRAEs) were related to changes in clinical laboratory value; TRAEs occurring in 15% or more of patients included increased blood bilirubin (45%), anemia (35%), proteinuria (30%), increased aspartate transferase (AST) (25%), increased alanine transferase (ALT) (20%), leukopenia (15%), neutropenia (15%), pyrexia (15%), and vomiting (15%). All of the TRAE cases were grades 1 or 2 except for one case each of grade 3 increased blood bilirubin, leukopenia, and neutropenia. Increased AST (25%) and ALT (20%) were the most common AEs that were potentially immune related.

At the time of the data cutoff, 11 patients had at least one post-baseline imaging assessment, and three patients had at least two imaging assessments. The efficacy-evaluable population (measurable disease at baseline and at least one post-baseline tumor assessment, or progression or death) consisted of 12 patients, including three patients with microsatellite-instability-high (MSI-high) colorectal cancer (CRC), two patients with gastric cancer (GC), two patients with

hepatocellular carcinoma (HCC), two patients with urothelial cancer (UC), two patients with melanoma, and one patient with gastrointestinal stromal tumor (GIST). Partial responses (PR) were observed in one patient with UC (confirmed) and one with GC (unconfirmed). Stable disease was observed in two patients with melanoma and one with MSI-high CRC. In the remaining eight patients who were not evaluable as of the data cutoff, a third unconfirmed PR was observed in a patient with esophageal cancer 11 days after the data cutoff. At the time of the data cutoff, 15 patients remained on treatment.

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. It is differentiated from the currently approved PD-1 antibodies in an engineered Fc region, which is believed to minimize potentially negative interactions with other immune cells. BGB-A317 is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers. BeiGene and Celgene Corporation have a global strategic collaboration for BGB-A317 for solid tumors.

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 700 employees in China, the United States, and Australia, 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 ABRAXANE ® (nanoparticle albumin–bound paclitaxel), REVLIMID ® (lenalidomide), and VIDAZA ® (azacitidine) in China under a license from Celgene Corporation. [i]

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 encouraging clinical data of BGB-A317 and our and Celgene's future development plans for BGB-A317, including the initiation of Phase 3 trials supporting approval in China and the timing of initial studies for such trials. 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 and manufacturing; 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

Lucy Li, Ph.D.
+1 781-801-1800
ir@beigene.com
media@beigene.com

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