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 8, 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 8, 2017, BeiGene, Ltd. (the "Company") issued a press release announcing preliminary clinical data from the ongoing Phase 1/2 clinical trial of its investigational PARP inhibitor BGB-290 in patients with advanced solid tumors, presented at the European Society for Medical Oncology 2017 Congress in Madrid, Spain ("ESMO"). 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 September 11, 2017, the Company issued a press release announcing preliminary data from multiple disease-specific subgroups in the ongoing Phase 1a/1b trial of its investigational anti-PD-1 antibody BGB-A317 in patients with advanced solid tumors, presented at ESMO. 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 issued on September 8, 2017
99.2	Press Release issued on September 11, 2017

Exhibit Index

Exhibit No.	Description
99.1	Press Release issued on September 8, 2017
99.2	Press Release issued on September 11, 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 11, 2017

BEIGENE, LTD.

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

BeiGene, Ltd.

BeiGene Presents Preliminary Phase 1/2 Clinical Data on PARP Inhibitor BGB-290 in Patients with Advanced Solid Tumors at the European Society for Medical Oncology 2017 Congress

CAMBRIDGE, Mass. and BEIJING, China, Sept. 08, 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 announced preliminary clinical data from an ongoing Phase 1/2 trial of its investigational PARP inhibitor BGB-290 in patients with advanced solid tumors at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain. The data are on display in a poster and are scheduled to be further reviewed during a poster discussion session. The clinical data suggest that BGB-290 was generally well tolerated in patients with advanced solid tumors, with an overall response rate of 33% in 39 evaluable patients with epithelial ovarian cancer (EOC) or other associated tumors and 43% in 23 patients with mutant BRCA status.

“BGB-290 continues to demonstrate promising anti-tumor activity in preliminary data from the Phase 1/2 trial. Objective responses were observed, with three patients achieving a complete response among 39 evaluable patients with epithelial ovarian or associated cancers,” said Jason Lickliter, MBBS FRACP, Chief Medical Officer of Nucleus Network, Melbourne, Australia and coordinating principal investigator of the trial.

“BGB-290 was generally well tolerated, and all observed treatment-related adverse events were grade 3 or lower in severity. In addition to the trial from which data were presented at ESMO, we continue to enroll patients in our Phase 1 monotherapy trial in China and our global Phase 1 trial in combination with BGB-A317, our PD-1 antibody. We also recently initiated two global combination trials of BGB-290 with temozolomide

in solid tumors and with radiation and/or temozolomide in glioblastoma, respectively. We look forward to moving BGB-290 into late-stage development," commented Amy Peterson, MD, Chief Medical Officer, Immuno-oncology at BeiGene.

Summary of Results from an Ongoing Phase 1/2 Trial

The multi-center, open-label Phase 1/2 trial of BGB-290 is being conducted in Australia in patients with advanced solid tumors. The Phase 1 dose-escalation and dose-finding component identified the recommended Phase 2 dose to be 60 mg twice daily (BID). Once-daily dosing will also be evaluated. The ongoing Phase 2 component has two parts: the first part is investigating the safety, tolerability, and antitumor activity of BGB-290 in disease-specific dose-expansion cohorts, and the second part is investigating the effects of food on the pharmacokinetic profile of a single dose of BGB-290. Data presented at ESMO include patients from both the Phase 1 and 2 components of the trial.

As of June 1, 2017, 68 patients were enrolled in the trial, with 45 patients in the Phase 1 component, and 23 patients in the Phase 2 component, including eight patients in the food effect sub-study. The median duration of therapy for all patients was 79 days (range 1–926 days). At the time of the data cutoff, 20 patients remained on treatment.

The safety analysis suggested that BGB-290 was generally well tolerated in patients with advanced solid tumors. Adverse events (AEs) assessed to be related to treatment occurred in 78% of patients and were all grade 3 or lower in severity. The most common treatment-related AEs (≥10% of patients) were nausea (56%), fatigue (40%), anemia (25%), vomiting (21%), diarrhea (21%), decreased appetite (15%), and neutropenia or neutrophil count decrease (12%). Serious AEs (SAEs) occurred in 46% of patients, and SAEs considered related to treatment and occurring in more than one patient included two cases each of nausea and anemia. Four patients discontinued treatment due to treatment-emergent AEs. Four patients had a treatment-emergent AE with a fatal

outcome, none were assessed as related to treatment, all were associated with disease progression.

At the time of the data cutoff, the efficacy-evaluable population per RECIST 1.1 criteria (measurable disease at baseline and at least one post-baseline tumor assessment) included 39 patients with EOC or associated tumors (i.e., fallopian tube or primary peritoneal cancers). Among this group, there were three confirmed complete responses (CRs), 10 confirmed partial responses (PRs), and 21 cases of stable disease (SD). Of the 23 evaluable patients with EOC or other associated tumors known to be BRCA-mutated, there were three CRs, seven PRs, and 10 cases of SD. Complete and partial responses were observed in patients known to be platinum-resistant as well as patients with platinum-sensitive disease.

About BGB-290

BGB-290 is a potent and highly selective inhibitor of PARP1 and PARP2 with pharmacological properties such as brain penetration and PARP–DNA complex trapping demonstrated in preclinical models. BGB-290 is currently in global clinical development as a monotherapy and in combination with other agents for a variety of solid tumor malignancies.

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 600 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 ® (paclitaxel protein-bound particles for injectable suspension) (albumin-bound), 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-290 and our future development plans for BGB-290. 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

i ABRAXANE ®, REVLIMID ®, and VIDAZA ® are registered trademarks of Celgene Corporation.

BeiGene, Ltd.

BeiGene Presents Preliminary Phase 1 Data for BGB-A317 in Multiple Solid Tumors at the ESMO 2017 Congress

CAMBRIDGE , Mass. and BEIJING, China, Sept. 11, 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 multiple disease-specific subgroups in the ongoing Phase 1A/1B trial of its investigational anti-PD-1 antibody BGB-A317 in advanced solid tumors at the European Society for Medical Oncology (ESMO) 2017 Congress in Madrid, Spain. The three posters contained preliminary data from patients with gastric cancer (GC) and esophageal cancer (EC), head and neck squamous cell carcinoma (HNSCC), and ovarian cancer (OC), respectively. The preliminary Phase 1 data suggest that BGB-A317 was generally well tolerated and exhibited preliminary evidence of anti-tumor activity in advanced patients with each of these tumor types. BeiGene recently closed its global strategic collaboration with Celgene Corporation, in which Celgene gained exclusive rights to develop and commercialize BGB-A317 for solid tumors in the United States, Europe, Japan, and the rest of the world outside of Asia, while BeiGene retains rights for solid tumors in Asia (excluding Japan), and for hematological malignancies and internal combinations globally.

“The early data in each of these patient populations are promising, with confirmed partial responses observed in all four cancer types. Adverse events reported in each group were consistent with the overall safety profile observed in the trial and were generally of low severity, manageable, and reversible,” commented Jayesh Desai, MD, FRACP, a medical oncologist at The Royal Melbourne Hospital and Peter MacCallum Cancer Centre in Melbourne, Australia, and coordinating principal investigator of the study.

“We are pleased to provide early data on patients with four different cancer types

enrolled in our global Phase 1 study of BGB-A317. The preliminary safety profile and antitumor activity support continued development of BGB-A317. BGB-A317 is in registrational trials in China for bladder cancer and classical Hodgkin lymphoma. We look forward to working with Celgene as we plan to initiate global registrational trials," commented Amy Peterson, MD, Chief Medical Officer, Immuno-oncology at BeiGene.

Trial Design

The multi-center, open-label Phase 1A/1B trial of BGB-A317 as monotherapy in advanced solid tumors is being conducted in Australia, New Zealand, the United States, Taiwan, and South Korea and consists of a Phase 1A component (dose-escalation, schedule-expansion, and fixed-dose expansion) and a Phase 1B component of indication expansion in disease-specific cohorts, which include GC, EC, HNSCC, and OC cohorts, among others. In the Phase 1A portion, the maximum administered dose was 10 mg/kg once every two weeks (Q2W) and the maximum tolerated dose was not reached. All patients in the Phase 1B portion received BGB-A317 as a 5 mg/kg intravenous infusion once every three weeks (Q3W). The data cutoff date for the presentations at ESMO was June 8, 2017.

Preliminary Results in GC and EC (Abstract #387P)

The data presented at ESMO were from 83 patients with advanced or metastatic GC (46 patients) or EC (37 patients) treated with BGB-A317 at 2 mg/kg or 5 mg/kg Q2W or Q3W. At the time of the data cutoff, median treatment duration was 45 days (range 4–457 days) for patients with GC and 50 days (range 1–246 days) for patients with EC.

Adverse events (AEs) assessed by the investigator to be related to treatment occurred in 15 patients with GC (33%). Of those, abdominal pain (9%), decreased appetite (9%), fatigue (7%), nausea (7%), and pruritus (4%) were reported in more

than one patient, and all of these cases were grades 1 or 2. AEs assessed to be related to treatment occurred in 15 patients with EC (41%). Of those, fatigue (16%), nausea (8%), decreased appetite (5%), infusion-related reaction (5%), and myalgia (5%) occurred in more than one patient, and all of these cases were grades 1 or 2. Only one patient in each cohort reported a treatment-related AE of grade 3 or higher: grade 3 proteinuria in one patient with GC and grade 3 dermatitis in one patient with EC. Serious AEs (SAEs) considered related to treatment included one case of diarrhea and one case of pyrexia, each occurring in patients with GC. Eight patients (two with GC, six with EC) had a treatment-emergent AE with a fatal outcome, none were assessed as related to treatment.

At the time of the data cutoff, the efficacy-evaluable population (measurable disease at baseline and at least one post-baseline tumor assessment, or progression or death) included 34 GC patients and 31 EC patients. Among GC patients, four achieved a confirmed partial response (PR) and three achieved stable disease (SD) per RECIST 1.1 criteria. Among EC patients, two achieved a confirmed PR and nine achieved SD. Three of the nine patients with EC who achieved SD also achieved an unconfirmed PR, including one who awaits response confirmation. At the time of the data cutoff, 27 patients remained on treatment.

Preliminary Results in HNSCC (Abstract #388P)

The data presented at ESMO were from 18 patients with advanced HNSCC treated with BGB-A317 at 5 mg/kg Q3W. At the time of the data cutoff, median treatment duration was 104 days (range 30–339 days).

AEs assessed by the investigator to be related to treatment occurred in seven patients with HNSCC (39%). Of those, only fatigue (11%, all grade 1 or 2) was reported in more than one patient. One case of grade 3 nausea was the only treatment-related AE of grade 3 or higher in severity. No patient discontinued treatment due to a treatment-related AE, and of the nine deaths reported, none were

considered to be associated with the treatment.

Of the 17 efficacy-evaluable HNSCC patients, three achieved a confirmed PR and six achieved SD. At the time of the data cutoff, three patients remained on treatment.

Preliminary Results in OC (Abstract #389P)

The data presented at ESMO were from 51 patients with advanced or metastatic OC treated with BGB-A317 at different dose levels (0.5 to 10 mg/kg Q2W in dose escalation, 2 or 5 mg/kg Q2W or Q3W or 200 mg Q3W in dose expansion, or 5 mg/kg Q3W in indication expansion). At the time of the data cutoff, median treatment duration was 71 days (range 29–540 days).

AEs assessed by the investigator to be related to treatment occurred in 28 patients (55%). Of those, fatigue (18%), pruritus (10%), rash (10%), diarrhea (10%), lethargy (6%), nausea (6%), abdominal pain (4%), dry eye (4%), dry skin (4%), onychoclasis (4%), and maculo-papular rash (4%) were reported in more than one patient, and all, except one case of grade 3 diarrhea, were grades 1 or 2. Two additional treatment-related AEs of grade 3 or higher included one case each of grade 3 pyrexia and stomatitis. SAEs considered related to treatment occurred in three patients and included one case each of pyrexia, colitis, and mucosal inflammation.

Of the 50 efficacy-evaluable OC patients, two achieved a confirmed PR and 20 achieved SD. At the time of the data cutoff, six 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 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 600 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 ® (azaciditine) 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. 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.

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

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