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): **August 26, 2018**

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 August 26, 2018, BeiGene, Ltd. (the "Company") issued a press release announcing acceptance by the China Drug Administration (CDA) of a new drug application (NDA) for zanubrutinib, an investigational Bruton's tyrosine kinase (BTK) inhibitor, for the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL). 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 "BeiGene Announces Acceptance of its First New Drug Application for Zanubrutinib in Relapsed/Refractory Mantle Cell Lymphoma by China Drug Administration" issued on August 26, 2018

Exhibit Index

Exhibit No.	Description
99.1	Press Release titled "BeiGene Announces Acceptance of its First New Drug Application for Zanubrutinib in Relapsed/Refractory Mantle Cell Lymphoma by China Drug Administration" issued on August 26, 2018

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: August 27, 2018

BEIGENE, LTD.

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

EXHIBIT 99.1

BeiGene Announces Acceptance of its First New Drug Application for Zanubrutinib in Relapsed/Refractory Mantle Cell Lymphoma by China Drug Administration

BEIJING, China and CAMBRIDGE, Mass., Aug. 26, 2018 (GLOBE NEWSWIRE) -- 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 the acceptance by the China Drug Administration (CDA) of a new drug application (NDA) for zanubrutinib, an investigational Bruton's tyrosine kinase (BTK) inhibitor, for the treatment of patients with relapsed/refractory mantle cell lymphoma (MCL). Zanubrutinib was discovered in BeiGene's research facilities in Beijing, China, and is being developed globally by BeiGene as a monotherapy and in combination with other therapies to treat various hematologic malignancies.

"We are proud of our team, and are appreciative of the clinical investigators and patients in China who made this first regulatory filing for zanubrutinib possible. This is BeiGene's first NDA and is a significant milestone for our company. We look forward to additional regulatory submissions with zanubrutinib and with tislelizumab, our investigational anti-PD-1 antibody," commented John Oyler, co-founder, CEO and Chairman of BeiGene.

"We believe zanubrutinib is a potentially differentiated BTK inhibitor based on the depth and durability of responses observed in clinical trials of zanubrutinib to date. We are hopeful that zanubrutinib, if approved, may represent a valuable and important treatment option for patients in China with MCL," said Dr. Xiaobin Wu, General Manager of China and President of BeiGene, Ltd.

"We are excited that the CDA has accepted our new drug application of zanubrutinib for patients with MCL and that it is being reviewed as a Category 1 new drug submission, which is reserved for medicines that are going through their first worldwide regulatory review in China. We look forward to working with the CDA as it completes its thorough assessment of zanubrutinib," added Wendy Yan, Global Head of Regulatory Affairs at BeiGene.

The NDA is supported by an extensive clinical and non-clinical data package, including the results from an 86-patient single-arm pivotal Phase 2 study in Chinese patients with relapsed or refractory MCL treated with zanubrutinib, dosed at 160 mg orally twice daily. An independent review of response data from this study showed overall response rate (ORR) of 84 percent, including 59 percent of patients who achieved a complete response. With 8.3 months median follow-up, the median duration of response has not been reached, as a majority of the responders remain in a response. The safety profile was consistent with previously reported clinical data for zanubrutinib. Full results of the study are planned to be presented at an upcoming medical conference.

Zanubrutinib is being studied in several clinical trials as part of a broad development program and was recently granted Fast Track Designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with Waldenström macroglobulinemia (WM). BeiGene plans to submit an NDA to the FDA for zanubrutinib as a potential treatment for patients with WM in the first half of 2019 based on results from a global Phase 1 study.

In addition to the global Phase 1 trial of zanubrutinib, it is also being evaluated in a fully-enrolled, global Phase 3 clinical trial in patients with WM comparing zanubrutinib to ibrutinib, the currently approved BTK inhibitor for WM. Zanubrutinib is also being studied in a global Phase 3 clinical trial in patients with previously untreated chronic lymphocytic leukemia (CLL) and a pivotal Phase 2 trial in patients with relapsed/refractory follicular lymphoma in combination with GAZYVA ® (obinutuzumab). In China, BeiGene has completed enrollment in two other pivotal Phase 2 clinical trials of zanubrutinib in patients with CLL and WM, respectively. BeiGene also plans to initiate a Phase 3 trial comparing zanubrutinib to ibrutinib in patients with relapsed/refractory CLL/small lymphocytic lymphoma (SLL). As of August 2018, more than 1,500 patients have been enrolled in the zanubrutinib clinical development program.

About Mantle Cell Lymphoma
Lymphoma is a diverse group of malignancies that originates from B, T or NK cells. Mantle cell lymphoma (MCL) is typically an aggressive form of non-Hodgkin lymphoma (NHL) that arises from B cells originating in the "mantle zone." In 2013, the incidence of lymphoma was 4.2 per 100,000 and the mortality was 2.2 per 100,000 in mainland China [i], making it the eleventh most common cancer and the tenth leading cause of cancer death. [ii] Mantle cell lymphoma usually has a poor prognosis, with a median survival of three to four years, although occasional patients may have an indolent course. [iii] Frequently, mantle cell lymphoma is diagnosed at a later stage of disease.

About Zanubrutinib
Zanubrutinib (BGB-3111) is an investigational small molecule inhibitor of Bruton's tyrosine kinase (BTK) that is currently being evaluated in a broad pivotal clinical program globally and in China as a monotherapy and in combination with other therapies to treat various B cell 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 1,300 employees in China, the United States, Australia and Switzerland, 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. [iv]

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, regulatory milestones and commercialization of zanubrutinib and tislelizumab. 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-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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[i] Chen W, Zheng R, Zhang S, Zeng H, Xia C, Zuo T, et al. Cancer incidence and mortality in China, 2013. Cancer Lett. 2017; 401:63–71

[ii] Chen W, Zheng R, Baade PD, Zhang S, Zeng H, Bray F, et al. Cancer Statistics in China, 2015. CA Cancer J Clin. 2016;66(2):115–32

[iii] Philip J. Bierman, James O. Armitage, in Goldman's Cecil Medicine (Twenty Fourth Edition), 2012

[iv] ABRAXANE ® , REVLIMID ® , and VIDAZA ® are registered trademarks of Celgene Corporation.