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): October 20, 2021

BEIGENE, LTD.
(Exact Name of Registrant as Specified in Charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

c/o Mourant Governance 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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing 13 Ordinary Shares, par value $0.0001 per share	**BGNE**	**The NASDAQ Global Select Market**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited**

*Included in connection with the registration of the American Depositary Shares with the Securities and Exchange Commission. The ordinary shares are not registered or listed for trading in the United States but are listed for trading on The Stock Exchange of Hong Kong Limited.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 7.01. Regulation FD Disclosure.

BeiGene, Ltd. ("BeiGene") expects to announce its financial results for the three and nine months ended September 30, 2021 on Thursday, November 4, 2021 after the close of U.S. financial markets.

Item 8.01. Other Events.

On October 20, 2021, BeiGene and Nanolek, a biopharmaceutical company specializing in the production of import-substituting and innovative drugs in Russia, announced that BRUKINSA® (zanubrutinib) has received approval from the Russia Ministry of Health for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. BeiGene and Nanolek entered into an exclusive distribution agreement for Nanolek to commercialize BRUKINSA in the Russian Federation. 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 and Nanolek Announce Approval in Russia for BRUKINSA® (Zanubrutinib) for Treatment of Patients with Relapsed or Refractory Mantle Cell Lymphoma", issued by BeiGene, Ltd. on October 20, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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SIGNATURE

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.

BEIGENE, LTD.

Date: October 21, 2021

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

Exhibit 99.1

BeiGene and Nanolek Announce Approval in Russia for BRUKINSA® (Zanubrutinib) for Treatment of Patients with Relapsed or Refractory Mantle Cell Lymphoma

This marks the first regulatory approval for BRUKINSA in Russia

BRUKINSA is now approved for the treatment of MCL in ten countries, following the U.S., China, Canada, Australia, and others

BeiGene is committed to rapidly advancing the global registration of BRUKINSA on its own and alongside strategic collaborators

Under an exclusive distribution agreement, Nanolek will commercialize BRUKINSA in Russia

CAMBRIDGE, Mass., BEIJING and MOSCOW -- October 20, 2021 -- BeiGene (NASDAQ: BGNE; HKEX: 06160), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, and Nanolek, a biopharmaceutical company specializing in the production of import-substituting and innovative drugs in Russia, today announced that BRUKINSA® (zanubrutinib) has received approval from the Russia Ministry of Health for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. BeiGene and Nanolek entered into an exclusive distribution agreement for Nanolek to commercialize BRUKINSA in the Russian Federation.

“The registration of BRUKINSA (zanubrutinib), a next-generation BTK inhibitor that demonstrated improved clinical benefit while reducing the frequency of certain off-target side effects in MCL, will give physicians and patients another treatment option. BRUKINSA has the potential to give those impacted by MCL in Russia an improved prognosis and a more tolerable therapeutic option,” commented Irina Vladimirovna Poddubnaya, Professor, Academician of Russian Academy of Sciences (RAS), and Head of Oncology Department at the Russian Medical Academy of Postgraduate Education.

“This approval reinforces BRUKINSA’s potential as a best-in-class BTK inhibitor for the treatment of hematological malignancies, and we are pleased to make it available to MCL patients in Russia,” said Jane Huang, M.D., Chief Medical Officer, Hematology, BeiGene. “We are working to improve outcomes for patients living with cancer, wherever they live, and this year have secured 12 regulatory approvals for BRUKINSA in the United States, Canada, Latin America, and the APAC and EMEA regions.”

“We look forward to collaborating with Nanolek to bring a much needed new treatment option to MCL patients in Russia,” said Vitaly Sokolinsky, Senior Director, New Market Development, Russia, at BeiGene. “Today’s approval in MCL highlights our continued expansion into Russia, greater Europe and beyond as we bring our expertise to new markets around the world.”

“We’re proud of this significant achievement for patients and look forward to contributing to BRUKINSA’s growing global footprint through our strong collaboration with BeiGene,” added Vladimir Khristenko, President of Nanolek. “Together, we are committed to delivering innovative therapies for the benefit of people impacted by cancer in Russia.”

Marketing approval for BRUKINSA for the treatment of MCL in Russia is based on results from two single-arm clinical trials. Across both trials, as assessed by independent review committee (IRC) per 2014 Lugano Classification, BRUKINSA achieved an overall response rate (ORR) of 83.7%, defined as the combined rate of complete responses (CRs) and partial responses (PRs).

Of the 118 patients with MCL who received at least one prior therapy and received BRUKINSA treatment, serious adverse reactions occurred in 36 patients (31%), with the most frequent being pneumonia (11%) and bleeding (5%). Eight patients (7%) discontinued treatment due to adverse reactions in the trials, with the most frequent being pneumonia (3.4%), and one patient (0.8%) experienced an adverse reaction that led to dose reduction.

The recommended dose of BRUKINSA is either 160 mg twice daily or 320 mg once daily, taken orally with or without food. The dose may be adjusted for adverse reactions and reduced for patients with severe hepatic impairment and certain drug interactions.

About Mantle Cell Lymphoma (MCL)

MCL is rare form of non-Hodgkin lymphoma (NHL), representing about 5% of all NHL cases.[1] It develops in the outer edge of a lymph node called the mantle zone.[1] Mantle cell lymphoma occurs more often in men than in women.[1] It is usually diagnosed in people in their early 60s.[1] MCL has a poor prognosis, with a median survival of three to four years, and is often diagnosed at a later stage of disease.[2] In Russia, there are more than 1,000 new cases of MCL diagnosed each year.[3]

About BRUKINSA

BRUKINSA is a small molecule inhibitor of Bruton's tyrosine kinase (BTK) discovered by BeiGene scientists that is currently being evaluated globally in a broad clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies. Because new BTK is continuously synthesized, BRUKINSA was specifically designed to deliver complete and sustained inhibition of the BTK protein by optimizing bioavailability, half-life, and selectivity. With differentiated pharmacokinetics compared to other approved BTK inhibitors, BRUKINSA has been demonstrated to inhibit the proliferation of malignant B cells within a number of disease relevant tissues.

BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021);
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy (China, June 2021)**;
- For the treatment of MCL in adult patients who have received at least one prior therapy (Canada, July 2021);
- For the treatment of MCL in adult patients who have received at least one prior therapy (Chile, July 2021);
- For the treatment of adult patients with MCL who have received at least one previous therapy (Brazil, August 2021);
- For the treatment of adult patients with WM (United States, August 2021);

- For the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen (United States, September 2021)*;
- For the treatment of adult patients with MCL who have received at least one previous therapy (Singapore, October 2021);
- For the treatment of MCL in patients who have received at least one prior therapy (Israel, October 2021);
- For the treatment of adult patients with WM who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy (Australia, October 2021);
- For the treatment of adult patients with MCL who have received at least one prior therapy (Australia, October 2021); and
- For the treatment of adult patients with MCL who have received at least one previous therapy (Russia, October 2021).

To date, more than 30 marketing authorization applications in multiple indications have been submitted in the United States, China, the European Union, and more than 20 other countries or regions.

* This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

** This indication was approved under conditional approval. Complete approval for this indication may be contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

IMPORTANT U.S. SAFETY INFORMATION FOR BRUKINSA (ZANUBRUTINIB)

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher hemorrhage including intracranial and gastrointestinal hemorrhage, hematuria and hemothorax have been reported in 3.4% of patients treated with BRUKINSA monotherapy. Hemorrhage events of any grade occurred in 35% of patients treated with BRUKINSA monotherapy.

Bleeding events have occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Co-administration of BRUKINSA with antiplatelet or anticoagulant medications may further increase the risk of hemorrhage.

Monitor for signs and symptoms of bleeding. Discontinue BRUKINSA if intracranial hemorrhage of any grade occurs. Consider the benefit-risk of withholding BRUKINSA for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Infections

Fatal and serious infections (including bacterial, viral, or fungal) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 27% of patients, most commonly pneumonia. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jiroveci pneumonia and other infections according to standard of care in patients who are at increased risk for infections. Monitor and evaluate patients for fever or other signs and symptoms of infection and treat appropriately.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (26%), thrombocytopenia (11%) and anemia (8%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 13% of patients, and Grade 4 thrombocytopenia occurred in 3.6% of patients.

Monitor complete blood counts regularly during treatment and interrupt treatment, reduce the dose, or discontinue treatment as warranted. Treat using growth factor or transfusions, as needed.

Second Primary Malignancies

Second primary malignancies, including non-skin carcinoma, have occurred in 14% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer, reported in 8% of patients. Other second primary malignancies included malignant solid tumors (4.0%), melanoma (1.7%) and hematologic malignancies (1.2%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Atrial fibrillation and atrial flutter were reported in 3.2% of patients treated with BRUKINSA monotherapy. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher events were reported in 1.1% of patients treated with BRUKINSA monotherapy. Monitor signs and symptoms for atrial fibrillation and atrial flutter and manage as appropriate.

Embryo-Fetal Toxicity

Based on findings in animals, BRUKINSA can cause fetal harm when administered to a pregnant woman. Administration of zanubrutinib to pregnant rats during the period of organogenesis caused embryo-fetal toxicity including malformations at exposures that were 5 times higher than those reported in patients at the recommended dose of 160 mg twice daily. Advise women to avoid becoming pregnant while taking BRUKINSA and for 1 week after the last dose. Advise men to avoid fathering a child during treatment and for 1 week after the last dose.

If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

Adverse reactions

The most common adverse reactions, including laboratory abnormalities, in ≥ 30% of patients who received BRUKINSA (N = 847) included decreased neutrophil count (54%), upper respiratory tract infection (47%), decreased platelet count (41%), hemorrhage (35%), decreased lymphocyte count (31%), rash (31%) and musculoskeletal pain (30%).

Drug Interactions

CYP3A Inhibitors: When BRUKINSA is co-administered with a strong CYP3A inhibitor, reduce BRUKINSA dose to 80 mg once daily. For coadministration with a moderate CYP3A inhibitor, reduce BRUKINSA dose to 80 mg twice daily.

CYP3A Inducers: Avoid coadministration with moderate or strong CYP3A inducers.

Specific Populations

Hepatic Impairment: The recommended dose of BRUKINSA for patients with severe hepatic impairment is 80 mg orally twice daily.

Please see full U.S. Prescribing Information at www.beigene.com/PDF/BRUKINSAUSPI.pdf and Patient Information at www.beigene.com/PDF/BRUKINSAUSPPI.pdf.

BeiGene Oncology

BeiGene is committed to advancing hematology, immuno-oncology and targeted therapies in order to bring impactful and affordable medicines to patients across the globe. We have a growing R&D team of approximately 2,300 colleagues dedicated to advancing more than 90 clinical trials involving more than 13,000 patients and healthy subjects. Our expansive portfolio is directed by a predominantly internalized clinical development team supporting trials in more than 40 countries or regions. We currently market three medicines discovered and developed in our labs: BTK inhibitor BRUKINSA in the United States, China, Canada, Australia and additional international markets; and non-FC-gamma receptor binding anti-PD-1 antibody tislelizumab and PARP inhibitor pamiparib in China. BeiGene has a high quality, innovative science and medicine organization and is a leader in China with a large oncology focused commercial team.

BeiGene also partners with innovative companies who share our goal of developing therapies to address global health needs. We commercialize a range of oncology medicines in China licensed from Amgen and Bristol Myers Squibb. We also plan to address greater areas of unmet need globally through our collaborations including with Amgen, Bio-Thera, EUSA Pharma, Mirati Therapeutics, Seagen, and Zymeworks. BeiGene has also entered into a collaboration with Novartis granting Novartis rights to develop, manufacture, and commercialize tislelizumab in North America, Europe, and Japan.

About BeiGene

BeiGene is a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide. With a broad portfolio of more than 40 clinical candidates, we are expediting development of our diverse pipeline of novel therapeutics through our own capabilities and collaborations. We are committed to radically improving access to medicines for two billion more people by 2030. BeiGene has a growing global team of over 7,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

About Nanolek

Nanolek is a Russian biopharmaceutical company founded in 2011 by Vladimir Khristenko and Mikhail Nekrasov, specializing in the production of import-substituting and innovative drugs, both developed in-house and created with international partners. It is one of the leaders in the production of pediatric vaccines in Russia. A total of 20 medicines are now in the Nanolek’s portfolio, with 35 more at various stages of preparation for release and will hit the market within the next five years. The company's plant in the Kirov region that opened in 2014 was built with an eye on the best international practices and technologies. The production facility is GMP-certified and besides regularly passes quality audits performed by major international pharmaceutical corporations: Nanolek plant produces drugs in cooperation with such companies as Sanofi, Janssen, Merck, and Aspen.

Nanolek supports scientific educational initiatives through active collaboration with RSOH (Russian Society of Oncohematologists). The company contributes to the development of a further educational program for hematologists on future clinical indications: CLL, Waldenström’s macroglobulinemia and marginal zone cell lymphoma. www.nanolek.ru.

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 plans for development and commercialization of BRUKINSA in Russia and other markets, the potential commercial opportunity for BRUKINSA, plans for making BRUKINSA accessible to patients in Russia, the potential for BRUKINSA to be a best-in-class BTK inhibitor and to provide improved clinical benefits to patients, and BeiGene's plans, commitments, aspirations and goals under the headings "BeiGene Oncology" and "About BeiGene". 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 medicines and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its medicines and technology; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited experience in obtaining regulatory approvals and commercializing pharmaceutical products and its ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates and achieve and maintain profitability; the impact of the COVID-19 pandemic on the BeiGene's clinical development, regulatory, commercial, and other operations, 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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2 Philip J. Bierman, James O. Armitage, in Goldman's Cecil Medicine (Twenty Fourth Edition), 2012.

3 https://glavonco.ru/cancer_register/%D0%9F%D0%BE%D0%BC%D0%BE%D1%89%D1%8C%202019.pdf. Accessed October 2021.