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): May 25, 2023

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 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 8.01 Other Events.

On May 25, 2023, BeiGene, Ltd. (the "Company") announced the presentation of new data showcasing the range of the Company's research expertise and the productivity of one of the industry's largest research and development teams at the 2023 American Society of Clinical Oncology in Chicago. These results include data for the Company's cornerstone therapies, BRUKINSA® (zanubrutinib) and tislelizumab, as well as early results for the Company's OX40 agonist and BCL-2 inhibitor. 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 Presentations at the 2023 ASCO Annual Meeting Reinforce Promise Across Oncology Portfolio" issued by BeiGene, Ltd. on May 25, 2023
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

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99.1	Press release titled "BeiGene Presentations at the 2023 ASCO Annual Meeting Reinforce Promise Across Oncology Portfolio" issued by BeiGene, Ltd. on May 25, 2023
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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: May 26, 2023

By: /s/ Chan Lee
Name: Chan Lee
Title: Senior Vice President, General Counsel

Exhibit 99.1

BeiGene Presentations at the 2023 ASCO Annual Meeting Reinforce Promise Across Oncology Portfolio

Highlights from early- and late-stage pipeline include
-- combination data for cornerstone therapies BRUKINSA and tislelizumab
-- early results for OX40 agonist BGB-A445 and BCL-2 inhibitor BGB-11417

BASEL, Switzerland & BEIJING & CAMBRIDGE, Mass. -- May 25, 2023 -- BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced the presentation of new data showcasing the range of BeiGene's research expertise and the productivity of one of the industry's largest research and development teams at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago. These results include data for BeiGene's cornerstone therapies, BRUKINSA® (zanubrutinib) and tislelizumab, as well as early results for BeiGene's OX40 agonist and BCL-2 inhibitor.

"The data presented at ASCO demonstrate the strength of BeiGene's oncology portfolio, from early data supporting the differentiated biological hypotheses for our BCL-2 inhibitor and OX40 agonist and continuing results from the global development programs for our innovative medicines, BRUKINSA and tislelizumab, as monotherapies and in combination regimens," said Lai Wang, Ph.D., Global Head of R&D at BeiGene. "At BeiGene, we believe the patients we serve come first, and we will continue to partner with patients to advance innovative potential best- and first-in-class medicines."

For more information on BeiGene's clinical program and company updates, please visit BeiGene's virtual ASCO booth: www.BeiGeneVirtualExperience.com.

Cornerstone Medicines Continue to Demonstrate Consistent Safety and Efficacy Profile

In a risk factor analysis of RATIONALE-301, a Phase 3 study of tislelizumab vs sorafenib as first-line treatment of unresectable hepatocellular carcinoma, tislelizumab demonstrated numerically longer median overall survival (OS) versus sorafenib in the biomarker subgroups of *ALBI* grade 1 (19.9 months vs. 16.9 months), *PLR* ≤141 (19.4 months vs. 14.5 months), and *NLR* ≤3 (20.9 months vs. 15.2 months), suggesting the potential for prognostic value.

In a European/North American (EU/NA) subgroup analysis of RATIONALE-301, numerically longer median OS, median duration of response, and a higher objective response rate (ORR) were seen with tislelizumab versus sorafenib. Notably, the EU/NA subgroup had a higher rate of patients with non-viral etiology and a slightly lower number of patients with advanced-stage disease (BCLC Stage C) compared with the overall population from RATIONALE-301.

Additionally, incidence of grade ≥3 treatment-emergent adverse events (TEAEs; 46% vs 66%), grade ≥3 treatment-related TEAEs (TRAEs; 17% vs 50%), and TRAEs leading to discontinuation (9% vs 15%) were lower with tislelizumab versus sorafenib in the EU/NA subgroup respectively and similar to incidences observed in the overall study population.

- These results will be presented on Monday, June 5, as poster presentations from 8:00-11:00 a.m. CT. (Abstracts #4082 and #4083).

In an updated analysis of the ROSEWOOD study, BRUKINSA in combination with obinutuzumab demonstrated clinically meaningful activity and manageable safety profile in patients with heavily pretreated relapsed/refractory (R/R) follicular lymphoma (FL). The combination of BRUKINSA and obinutuzumab represents a potentially new therapy for patients with R/R FL.

Demonstrating a commitment to developing rigorous evidence for potential new treatments for rare hematologic malignancies, BeiGene will detail the trial design of its ongoing Phase 3 MAHOGANY study of BRUKINSA plus obinutuzumab versus lenalidomide plus rituximab in R/R FL or marginal zone lymphoma during the Trials in Progress session.

- These posters will be presented on Monday, June 5 from 8:00-11:00 a.m. CT (Abstracts #7545 and #TPS7590).

First-in-Human Results Show Promise for Key Pipeline Assets

BeiGene's investigational BGB-A445 is a novel monoclonal antibody OX40 agonist that does not compete with endogenous OX40 ligand binding. The molecule is being studied as a single agent or in combination with tislelizumab in patients with advanced solid tumors in an ongoing, Phase 1 dose escalation and expansion study.

In first-in-human results presented at ASCO, BGB-A445 monotherapy or in combination with tislelizumab was generally well-tolerated across all doses with no dose-limiting toxicities and demonstrated preliminary antitumor activity in patients with advanced solid tumors.

As further evaluation, the dose expansion phase is currently enrolling patients into non-small cell lung cancer and head and neck squamous cell carcinoma cohorts.

- These results will be presented on Saturday, June 3, as a poster presentation from 8:00 – 11:00 a.m. CT (Abstract #2574).

BGB-11417 is a potent and highly selective BCL-2 inhibitor, and a dose-finding results showed that single agent treatment was well tolerated at all tested doses up to 640 mg/d as monotherapy in B-cell malignancies, with no dose-dependent toxicity increase. BGB-11417 monotherapy also showed promising initial efficacy results in R/R chronic lymphocytic leukemia/small lymphocytic lymphoma, with patients achieving responses at lower dose levels.

- These results will be presented on Monday, June 5, as a poster presentation from 8:00-11:00 a.m. CT (Abstract #7558).

More details on BeiGene's abstracts are available on the ASCO website.

About BRUKINSA® (zanubrutinib)
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 supported by a broad clinical program which includes more than 4,900 subjects in 35 trials across 29 markets. To date, BRUKINSA is approved in more than 65 markets around the world, including the United States, China, the European Union, Great Britain, Canada, Australia, South Korea, and Switzerland.

About Tislelizumab
Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fc-gamma (Fcγ) receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors. In pre-clinical studies, binding to Fcγ receptors on macrophages has been shown to compromise the antitumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.

The global development program for tislelizumab includes more than 12,000 patients and encompasses more than 20 potentially registration-enabling clinical trials in more than 30 countries and regions., More information on the clinical trial program for tislelizumab can be found at: https://www.beigene.com/en-us/science-and-product-portfolio/pipeline.

Tislelizumab is approved in 11 indications in China, including a recent approval for use in combination with chemotherapy, for the treatment of patients with previously untreated advanced or metastatic esophageal squamous cell carcinoma. Tislelizumab is not currently approved for use outside of China.

About BGB-11417
BGB-11417 is a highly potent and selective Bcl-2 inhibitor designed to produce deeper and more sustained target inhibition.

Compared with venetoclax, BGB-11417 exhibited greater potency (>10-fold) and higher target selectivity and showed signs of overcoming treatment resistance in pre-clinical studies and tumor models.[i]

About BGB-A445
BGB-A445 is an investigational agonistic antibody directed to the OX40 antigen. BGB-A445 is a non-ligand competing antibody that does not disrupt OX40 to OX40 ligand engagement. Preclinical experiments showed that BGB-A445 had increasing effectiveness at higher doses versus an antibody that was ligand-competing, which showed falling effectiveness at higher doses.

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

Warnings and Precautions

Hemorrhage

Fatal and serious hemorrhage has 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 3.6% of patients treated with BRUKINSA monotherapy in clinical trials, with fatalities occurring in 0.3% of patients. Bleeding of any grade, excluding purpura and petechiae, occurred in 30% of patients.

Bleeding has occurred in patients with and without concomitant antiplatelet or anticoagulation therapy. Coadministration 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 infections) and opportunistic infections have occurred in patients with hematological malignancies treated with BRUKINSA monotherapy. Grade 3 or higher infections occurred in 24% of patients, most commonly pneumonia (11%), with fatal infections occurring in 2.9% of patients. Infections due to hepatitis B virus (HBV) reactivation have occurred.

Consider prophylaxis for herpes simplex virus, pneumocystis jirovecii 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 (22%), thrombocytopenia (8%) and anemia (7%) based on laboratory measurements, developed in patients treated with BRUKINSA monotherapy. Grade 4 neutropenia occurred in 11% of patients, and Grade 4 thrombocytopenia occurred in 2.8% 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 13% of patients treated with BRUKINSA monotherapy. The most frequent second primary malignancy was non-melanoma skin cancer reported in 7% of patients. Other second primary malignancies included malignant solid tumors (5%), melanoma (1.2%), and hematologic malignancies (0.5%). Advise patients to use sun protection and monitor patients for the development of second primary malignancies.

Cardiac Arrhythmias

Serious cardiac arrhythmias have occurred in patients treated with BRUKINSA. Atrial fibrillation and atrial flutter were reported in 3.7% of 1550 patients treated with BRUKINSA monotherapy, including Grade 3 or higher cases in 1.7% of patients. Patients with cardiac risk factors, hypertension, and acute infections may be at increased risk. Grade 3 or higher ventricular arrhythmias were reported in 0.2% of patients.

Monitor for signs and symptoms of cardiac arrhythmias (e.g., palpitations, dizziness, syncope, dyspnea, chest discomfort), manage appropriately, and consider the risks and benefits of continued BRUKINSA treatment.

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

In this pooled safety population, the most common adverse reactions, including laboratory abnormalities, in ≥30% of patients who received BRUKINSA (N=1550) included decreased neutrophil count (42%), upper respiratory tract infection (39%), decreased platelet count (34%), hemorrhage (30%), 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 strong or moderate CYP3A inducers. Dose adjustment may be recommended with moderate CYP3A inducers.

Specific Populations

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

INDICATIONS

BRUKINSA is a kinase inhibitor indicated for the treatment of adult patients with:

- Chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)
- Waldenström's macroglobulinemia (WM)
- Mantle cell lymphoma (MCL) who have received at least one prior therapy
- Relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen

The MCL and MZL indications are approved under accelerated approval based on overall response rate. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

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

About BeiGene

BeiGene is a global biotechnology company that is discovering and developing innovative oncology treatments that are more affordable and accessible to cancer patients worldwide. With a broad portfolio, we are expediting development of our diverse pipeline of novel therapeutics through our internal capabilities and collaborations. We are committed to radically improving access to medicines for far more patients who need them. Our growing global team of more than 9,400 colleagues spans five continents, with administrative offices in Beijing, China; Cambridge, U.S.; and Basel, Switzerland. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneGlobal.

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 strength of BeiGene's oncology portfolio; the potential for BeiGene's programs to develop innovative potential best- and first-in-class medicines; the general future of BeiGene's pipeline and programs; BeiGene's advancement, anticipated clinical development, regulatory milestones and commercialization of tislelizumab, BGB-11417, BGB-A445, and zanubrutinib; and BeiGene's plans, commitments, aspirations, and goals under the heading "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; and the impact of the COVID-19 pandemic on BeiGene's clinical development, regulatory, commercial, manufacturing, 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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[i] Nan Hu, Yunhang Guo, Hai Xue, Ye Liu, Yin Guo, Fan Wang, Xiaomin Song, Ying Guo, Shuaishuai Chen, Haipeng Xu, Taichang Zhang, Yanwen Ma, Xuebing Sun, Yuan Hong, Yutong Zhu, Aiying Xu, Zhenzhen Cheng, Haimei Xing, Zhiwei Wang, Xuesong Liu, Lai Wang; Abstract 3077: Preclinical characterization of BGB-11417, a potent and selective Bcl-2 inhibitor with superior antitumor activities in haematological tumor models. *Cancer Res* 15 August 2020; 80 (16_Supplement): 3077. https://doi.org/10.1158/1538-7445.AM2020-3077