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 10, 2022

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 September 10, 2022, BeiGene, Ltd. ("BeiGene") presented updates from its solid tumor development program for cornerstone PD-1 antibody tislelizumab at the European Society for Medical Oncology Congress 2022 in Paris. 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 Data Presentations at ESMO 2022 Including Late-Breaking Oral Presentation for Tislelizumab in First-Line Unresectable Hepatocellular Cancer" issued by BeiGene, Ltd. on September 10, 2022
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: September 15, 2022

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

Exhibit 99.1

BeiGene Announces Data Presentations at ESMO 2022 Including Late-Breaking Oral Presentation for Tislelizumab in First-Line Unresectable Hepatocellular Cancer

Tislelizumab demonstrated non-inferiority for overall survival and favorable safety profile versus sorafenib in global Phase 3 trial

Additional poster presentations show breadth of tislelizumab global clinical development program as single-agent treatment and in combination

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING – September 10, 2022 - BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global, science-driven biotechnology company focused on developing innovative and affordable medicines to improve treatment outcomes and access for patients worldwide, shared updates from its solid tumor development program for cornerstone PD-1 antibody tislelizumab at the European Society for Medical Oncology (ESMO) Congress 2022 in Paris.

Results from the Phase 3 RATIONALE 301 trial of tislelizumab versus sorafenib as first-line treatment in patients with unresectable hepatocellular carcinoma were accepted as a late-breaking abstract (LBA36) and presented at an oral session on Saturday, September 10. In the final analysis of 674 patients enrolled from Asia, Europe, and U.S., RATIONALE 301 met its primary endpoint of overall survival (OS) non-inferiority, with a median OS of 15.9 months for tislelizumab compared with an OS of 14.1 months for sorafenib (HR: 0.85 [95.003% CI: 0.712, 1.019]); superiority was subsequently tested, which was not met. OS data were consistent across all pre-specified subgroups, including regions.

In the RATIONALE 301 trial, tislelizumab was associated with a higher objective response rate (ORR) (14.3% vs. 5.4%) and more durable responses (median duration of response (DoR) 36.1 months vs. 11.0 months) compared with sorafenib. Median progression-free survival (PFS) for tislelizumab versus sorafenib was 2.1 months vs. 3.4 months respectively; HR: 1.11 [95% CI: 0.92, 1.33].

The safety profiles for tislelizumab and sorafenib treatments were consistent with previous studies, and tislelizumab demonstrated a comparatively favorable profile versus sorafenib with lower incidence rates of grade >3 adverse events (AEs) and AEs leading to discontinuation (48.2% vs 65.4% and 10.9% vs 18.5% respectively). AEs leading to death were low across both tislelizumab (4.4%) and sorafenib (5.2%) arm.

“The RATIONALE 301 study results confirm a durable overall survival benefit of single agent tislelizumab and we are pleased that the safety profile for tislelizumab is consistent with previous studies. While targeted therapies can be an important treatment modality for advanced hepatocellular cancer, the safety and tolerability profile remain an important consideration,” said Mark Lanasa, M.D., Ph.D., Chief Medical Officer, Solid Tumors, at BeiGene. “We’re pleased to share the data at ESMO today and to engage with leading oncology researchers about our expansive clinical development program for tislelizumab in solid tumors.”

In addition to the late-breaking Phase 3 RATIONALE 301 results, BeiGene shared posters demonstrating a consistent response for tislelizumab across pre-specified subgroups in a Phase 3 trial and indications of anti-tumor activity and tolerable safety profile in a Phase 1 trial with tislelizumab in combination with chemotherapy and investigational anti-TIGIT antibody ociperlimab:

- Abstract 1031P – **RATIONALE 303 (NCT03358875):** Tislelizumab demonstrated favorable OS, PFS, DoR, and ORR compared with docetaxel, regardless of subgroup, in a prespecified analysis of Asian versus non-Asian patients in the global RATIONALE 303 study of tislelizumab versus docetaxel as second- or third-line therapy in previously treated patients with locally advanced non-small cell lung cancer (NSCLC) Lower rates of treatment-emergent adverse events were reported for tislelizumab versus docetaxel (41.1% vs 75.2% of Asian patients and 45.9% vs 72.9% of non-Asian patients, respectively).

Abstract 1017P –**AdvanTIG-105 (NCT04047862):** Ociperlimab and tislelizumab plus chemotherapy demonstrated antitumor activity in cohorts 1 and 2 of this Phase 1b dose-expansion study and the recommended Phase 2 dose showed a manageable safety profile in patients with metastatic squamous and non-squamous NSCLC.

BeiGene also shared posters describing the trial design for ongoing tislelizumab combination clinical trials:

Abstract 1194TiP – **AdvanTIG-205 (NCT05014815):** Phase 2 trial of ociperlimab + tislelizumab + chemotherapy in first line treatment of patients with locally advanced, unresectable, or metastatic NSCLC.

Abstract 1187TiP – **BGB-A317-Sitra-301 (NCT04921358)**: Phase 3 study of tislelizumab with sitravatinib versus chemotherapy in patients with locally advanced/metastatic NSCLC previously treated with chemo and an anti-programmed cell death protein 1/ligand 1 antibody.

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 anti-tumor activity of PD-1 antibodies through activation of antibody-dependent macrophage-mediated killing of T effector cells.

Tislelizumab is the first investigational medicine from BeiGene's immuno-oncology biologics program and is being evaluated in solid tumor and hematologic malignancies, as monotherapy and in combination.

The global tislelizumab clinical development program includes more than 11,000 subjects enrolled to-date in 30 countries and regions. More information on the tislelizumab development program, including clinical trials and regulatory submissions, can be found on the Tislelizumab Fact Sheet in our corporate press kit.

About RATIONALE 301

RATIONALE 301 (NCT03412773) is a global, Phase 3, randomized, open-label study of tislelizumab compared with sorafenib as a first-line treatment in adult patients with unresectable HCC. The primary endpoint of the study is non-inferiority of OS between the two treatment groups. The key secondary endpoint is ORR, as assessed by Blinded Independent Review Committee (BIRC) per RECIST v1.1. Other secondary endpoints include other efficacy assessments such as PFS, DoR, and Time to Progression per BIRC, as well as measures of health-related quality of life, and safety and tolerability.

BeiGene Oncology

BeiGene is committed to advancing best- and first-in-class clinical candidates internally or with like-minded partners to develop impactful and affordable medicines for patients across the globe. We have a growing R&D and medical affairs team of approximately 3,300 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 16,000 subjects. Our expansive portfolio is directed predominantly by our internal colleagues supporting clinical trials in more than 45 countries and regions. Hematology-oncology and solid tumor targeted therapies and immuno-oncology are key focus areas for the Company, with both mono- and combination therapies prioritized in our research and development. BeiGene currently has three approved medicines discovered and developed in our own labs: BTK inhibitor BRUKINSA® in more than 50 markets including the U.S., China, the European Union, Great Britain, Canada, Australia, and South Korea; and the non-FC-gamma receptor binding anti-PD-1 antibody, tislelizumab, as well as the PARP inhibitor, pamiparib, in China.

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, Bristol Myers Squibb, EUSA Pharma and Bio-Thera. We also plan to address greater areas of unmet need globally through our other collaborations including with Mirati Therapeutics, Seagen, and Zymeworks.

In January 2021, BeiGene and Novartis announced a collaboration granting Novartis rights to co-develop, manufacture, and commercialize BeiGene's anti-PD1 antibody, tislelizumab, in North America, Europe, and Japan. Building upon this productive collaboration, BeiGene and Novartis announced an option, collaboration, and license agreement in December 2021 for BeiGene's TIGIT inhibitor, ociperlimab, that is in Phase 3 development. Novartis and BeiGene also entered into a strategic commercial agreement through which BeiGene will promote five approved Novartis Oncology products across designated regions of China.

About BeiGene

BeiGene is a global biotechnology company that is developing and commercializing innovative and affordable oncology medicines to improve treatment outcomes and access for far more 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 8,500 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 BeiGene's advancement of anticipated clinical development, regulatory milestones and commercialization of tislelizumab, ociperlimab and sitravatinib, 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 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.

Investor
Kevin Mannix
+1 240-410-0129
ir@beigene.com

Media
Emily Collins
+1 201-201-4570
media@beigene.com