

**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): February 24, 2023

BEIGENE, LTD.

(Exact Name of Registrant as Specified in Charter)

Cayman Islands
(State or Other Jurisdiction of Incorporation)

001-37686
(Commission File Number)

98-1209416
(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 2.02. Results of Operations and Financial Condition.

On February 27, 2023, BeiGene, Ltd. (the “Company”) announced its financial results for the three months and year ended December 31, 2022. A copy of the press release is attached hereto as Exhibit 99.1 to this Current Report on Form 8-K.

Item 8.01. Other Events.

In its press release dated February 27, 2023, the Company also provided an update on fourth quarter 2022 and recent business highlights and expected milestones for 2023. The information in the press release set forth under the headings “Recent Business Highlights”, “Expected Milestones” and “Forward-Looking Statements” is incorporated by reference into this Item 8.01 of this Current Report on Form 8-K.

On February 24, 2023, the Company announced that the China National Medical Products Administration granted approval for the Company's PD-1 inhibitor, tislelizumab, in combination with fluoropyrimidine and platinum chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma with high PD-L1 expression. 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release titled "BeiGene Reports Fourth Quarter and Full Year 2022 Financial Results", issued by BeiGene, Ltd. on February 27, 2023
99.2	Press release titled "BeiGene Receives 10 th Approval for PD-1 Inhibitor Tislelizumab in China", issued by BeiGene, Ltd. on February 24, 2023
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

The portions of the press releases incorporated by reference into Item 8.01 of this Current Report on Form 8-K are being filed pursuant to such item. The remaining portions of the press release are being furnished pursuant to Item 2.02 of this Current Report on Form 8-K and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended or the Exchange Act, except as expressly set forth by specific reference in such filing.

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: February 27, 2023

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

BeiGene Reports Fourth Quarter and Full Year 2022 Financial Results

- Recorded product revenue of \$339.0 million and \$1.3 billion for the fourth quarter and full year, respectively, increasing 72.3% and 97.9% from the prior-year periods
- BRUKINSA[®] product revenue totaled \$176.1 million and \$564.7 million for the quarter and full year, respectively, increasing 101% and 159% from the prior-year periods
- Tislelizumab product revenue totaled \$102.2 million and \$422.9 million for the quarter and full year, respectively, increasing 88% and 66% from the prior-year periods
- BRUKINSA now approved in the U.S. to treat adult patients with relapsed/refractory (R/R) and first-line chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), and in the EU to treat CLL
 - Presented data from final analysis of the Phase 3 ALPINE trial demonstrating progression-free survival superiority for BRUKINSA versus IMBRUVICA[®] in R/R CLL/SLL as a late breaking abstract at ASH 2022; simultaneously published in *The New England Journal of Medicine*

BASEL, Switzerland; BEIJING; and CAMBRIDGE, Mass. -- February 27, 2023 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today reported financial results for the fourth quarter and full year 2022, recent business highlights, and upcoming milestones.

“We had an outstanding fourth quarter and 2022, with revenues from our two cornerstone medicines, BRUKINSA[®] and tislelizumab, dramatically increasing as our global team continues to bring these innovative therapies to more patients and their caregivers,” said John V. Oyler, Co-Founder, Chairman and Chief Executive Officer at BeiGene. “The final progression-free survival (PFS) analysis of the ALPINE trial demonstrating superior efficacy and a favorable cardiac safety profile compared to IMBRUVICA[®] in relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) and the recent U.S. FDA approval for BRUKINSA in adult patients with CLL/SLL were the most impactful of many recent milestones for our company and a testament to our commitment to following the science.”

“Our fourth quarter results continue to demonstrate BeiGene’s commercial capability as well as our commitment to driving operational and financial excellence,” said Julia Wang, Chief Financial Officer at BeiGene. “With our strong cash position and total product revenue reaching \$1.3 billion in 2022, BeiGene is well positioned to leverage its global scale and financial strength for long-term growth.”

Fourth Quarter and Full Year 2022 Financial Results

Revenue for the fourth quarter and full year 2022 was \$380.1 million and \$1.4 billion, respectively, compared to \$214.0 million and \$1.2 billion in the prior-year periods. The increase in total revenue in the quarter compared to the prior year is primarily attributable to sales of our internally developed products, BRUKINSA and tislelizumab; sales of in-licensed products from Amgen; and collaboration revenue from the Novartis agreements.

- Product revenues totaled \$339.0 million and \$1.3 billion for the fourth quarter and full year 2022, respectively, compared to \$196.8 million and \$634.0 million in the prior-year periods, and include:
 - Global sales of BRUKINSA of \$176.1 million and \$564.7 million for the fourth quarter and full year 2022, respectively, compared to \$87.6 million and \$218.0 million in the prior-year periods;
 - Sales of tislelizumab in China of \$102.2 million and \$422.9 million for the fourth quarter and full year 2022, respectively, compared to \$54.4 million and \$255.1 million in the prior-year periods;
 - Sales of Amgen in-licensed products in China of \$27.7 million and \$114.6 million for the fourth quarter and full year 2022, respectively, compared to \$20.3 million and \$58.8 million in the prior-year periods. We began selling Amgen's BLINCYTO[®] (*blinatumomab*) in August 2021. Additionally, prior-year period sales do not include sales of KYPROLIS[®] (*carfilzomib*), which was launched in China in January 2022;
 - Sales of BMS in-licensed products in China of \$21.4 million and \$94.3 million for the fourth quarter and full year 2022, respectively, compared to \$29.9 million and \$89.7 million in the prior-year periods; and
- Collaboration revenue totaled \$41.1 million and \$161.3 million for the fourth quarter and full year 2022, respectively, resulting from the partial recognition of the upfront payments from Novartis related to the tislelizumab and oiperlimab agreements, which were entered into in the first and fourth quarters of 2021. This compared to \$17.2 million and \$542.3 million in the prior-year periods. Full year 2021 collaboration revenue benefited from the timing

of revenue recognition from the upfront license payment from Novartis under the tislelizumab agreement.

Cost of Sales for the fourth quarter and full year 2022 were \$73.5 million and \$286.5 million, respectively, compared to \$48.5 million and \$164.9 million in the prior-year periods. Cost of sales increased primarily due to increased product sales of BRUKINSA and tislelizumab, as well as sales of BLINCYTO, which commenced in August 2021, and KYPROLIS and POBEVCY[®], which commenced in January 2022;

Gross Margin as a percentage of global product sales for the fourth quarter and full year 2022 was 78.3% and 77.2%, respectively, compared to 75.3% and 74.0% in the prior-year periods. The gross margin percentage increased in both the quarter-over-quarter and year-over-year periods primarily due to a proportionally higher sales mix of global BRUKINSA sales compared to other products in our portfolio and compared to lower margin sales of in-licensed products, as well as lower costs per unit for both BRUKINSA and tislelizumab, partially offset by lower average selling prices in China for both BRUKINSA and tislelizumab.

Operating Expenses for the fourth quarter and full year 2022 were \$775.2 million and \$2.9 billion, respectively, compared to \$737.2 million and \$2.5 billion in the prior-year periods.

- **R&D Expenses** for the fourth quarter and full year 2022 were \$446.0 million and \$1.6 billion, respectively, compared to \$430.5 million and \$1.5 billion in the prior-year periods. The increase in R&D expenses was primarily attributable to increases in headcount and costs related to investment in our discovery and development activities, including our continued efforts to internalize research and clinical development activities, partially offset by lower fees paid to clinical research organizations (CROs) for clinical trials. Upfront fees related to in-process R&D for in-licensed assets totaled \$48.7 million and \$68.7 million in the fourth quarter and full year 2022, respectively, compared to \$30.0 million and \$83.5 million in the prior-year periods. Employee share-based compensation expense was \$35.0 million and \$139.3 million for the fourth quarter and full year 2022, respectively, compared to \$30.6 million and \$114.4 million in the prior-year periods; and
- **SG&A Expenses** for the fourth quarter and full year 2022 were \$329.0 million and \$1.3 billion, respectively, compared to \$306.5 million and \$990.1 million in the prior-year periods. The increase in SG&A expenses was primarily attributable to increased headcount, largely related to continued expansion of our commercial teams, and higher external commercial expenses, including market access studies and promotional activities. Employee share-based compensation expense was \$43.2 million and \$163.8 million for the fourth quarter and full year 2022, respectively, compared to \$32.4 million and \$126.4 million for the prior-year periods.

Net Loss for the fourth quarter of 2022 was \$445.3 million, or \$0.33 per share and \$4.29 per ADS, compared to \$590.7 million, or \$0.48 per share and \$6.22 per ADS in the prior year period. The decrease in net loss is primarily attributable to improved operating leverage due to growing product revenues exceeding operating expense growth. The company expects this trend to continue into 2023. Net loss for full year 2022 was \$2.0 billion, or \$1.49 per share and \$19.43 per ADS, compared to \$1.5 billion, or \$1.21 per share and \$15.71 per ADS in the prior-year period. Net loss for 2022 was unfavorably impacted by other non-operating expenses of \$223.9 million, primarily related to foreign exchange losses resulting from the strengthening of the U.S. dollar and the revaluation impact of foreign currencies held in U.S. functional currency subsidiaries. Net loss for the full year 2021 was positively impacted by the timing of revenue recognition related to the Novartis tislelizumab collaboration agreement. The company recognized \$484.6 million in the full year 2021 of the \$650.0 million upfront payment received.

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were \$4.5 billion as of December 31, 2022, compared to \$6.6 billion as of December 31, 2021.

- In fourth quarter of 2022, cash used in operating activities was \$318.2 million, primarily due to our net loss of \$445.3 million, offset by non-cash charges of \$127.3 million; capital expenditures were \$121.4 million; and cash used in financing activities was \$110.4 million;
In the fourth quarter of the prior year, cash used in operating activities was \$507.8 million, primarily due to our net loss of \$590.7 million, offset by non-cash charges of \$92.7 million; capital expenditures were \$115.0 million; and cash provided by financing activities was \$3.4 billion, primarily due to the STAR Market offering in December of 2021; and
- For the full year 2022, cash used in operating activities was \$1.5 billion, primarily due to our net loss of \$2.0 billion, inclusive of \$223.9 million of other losses due primarily to the strengthening of the U.S. dollar and the related revaluation of foreign currencies held by U.S. functional currency subsidiaries, non-cash charges of \$374.8 million and a decrease in our net operating assets and liabilities of \$132.4 million.

For the full year 2021, cash used in operating activities was \$1.3 billion, primarily due to our net loss of \$1.5 billion and an increase in our net operating assets and liabilities of \$118.3 million, partially offset by non-cash charges of \$277.4 million; capital expenditures were \$262.9 million; and cash provided by financing activities was \$3.6 billion, primarily due to the net proceeds from the STAR Market offering in December of 2021.

Recent Business Highlights

Commercial Operations

- Product sales increased 72.3% and 97.9% in the fourth quarter and full year of 2022, respectively, compared to the prior-year periods, primarily due to increased sales of our internally developed products, as well as increased sales of in-licensed products from Amgen and Bio-Thera;
- Global sales of BRUKINSA totaled \$176.1 million and \$564.7 million in the fourth quarter and full year 2022, representing growth of 101% and 159%, respectively, compared to the prior-year periods; U.S. sales of BRUKINSA totaled \$125.3 million and \$389.7 million in the fourth quarter and full year 2022, respectively, representing growth of 124% and 237%, compared to the prior-year periods. U.S. sales growth continued in the quarter, driven again by increasing uptake in mantle cell lymphoma (MCL), Waldenström’s macroglobulinemia (WM), and marginal zone lymphoma (MZL). BRUKINSA sales in China totaled \$40.9 million and \$150.3 million in the fourth quarter and full year 2022, respectively, representing growth of 33% and 49% compared to the prior-year periods, driven by increases in all approved indications;
- Sales of tislelizumab in China totaled \$102.2 million and \$422.9 million in the fourth quarter and full year 2022, respectively, representing growth of 88% and 66% compared to the prior-year periods. Continued increase in new patient demand from broader reimbursement and further expansion of our salesforce and hospital listings continued to drive increased market penetration and market share for tislelizumab;
- Secured National Reimbursement Drug List (NRDL) inclusion of four additional indications in China, with nine approved tislelizumab indications now included. New indications covered as of March 1, 2023, are for:
 - Certain adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC);
 - Adult patients with advanced unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, and certain patients with advanced colorectal cancer (CRC);
 - Adult patients with locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) who have progressed after or are intolerant of prior first-line standard chemotherapy; and
 - As a first-line treatment for patients with recurrent or metastatic nasopharyngeal cancer (NPC); and
- KYPROLIS was included in the NRDL for the first time for the treatment of adult patients with R/R multiple myeloma who have received at least two prior therapies, including a proteasome inhibitor and an immunomodulatory agent. XGEVA[®] was successfully renewed for NRDL inclusion for the treatment of patients with giant cell tumor of the bone (GCTB) that is unresectable or where surgical resection is likely to result in severe morbidity.

Regulatory Progress and Development Programs

BRUKINSA[®] (zanubrutinib), a small molecule inhibitor of Bruton’s tyrosine kinase (BTK) designed to maximize BTK occupancy and minimize off-target effects, approved in more than 65 markets including the U.S., China, European Union (EU), Great Britain, Canada, Australia, South Korea and Switzerland in selected indications and under development for additional approvals globally. The global BRUKINSA development program includes more than 4,800 subjects enrolled to-date in 29 countries and regions.

- In January 2023, announced U.S. FDA approval for the treatment of adult patients with R/R and first-line CLL/SLL;
- Announced European Commission (EC) approval for the treatment of adult patients with treatment-naïve (TN) or R/R CLL;
- Presented results from a final analysis of the Phase 3 ALPINE trial demonstrating superior PFS versus IMBRUVICA[®] in adult patients with R/R CLL/SLL, as assessed by an independent review committee (IRC) and investigator, as part of a late breaking abstract session at the 64th American Hematology Society (ASH) Annual Meeting, with simultaneous publication in *The New England Journal of Medicine*;

- Presented other key data from the BRUKINSA clinical development programs at ASH 2022, including an oral presentation of results from the MAGNOLIA trial in MZL and a poster with updated results in acalabrutinib-intolerant patients with B-cell malignancies;
- Announced approvals in Brazil for the treatment of adult patients with WM and adult patients with R/R MZL who have received at least one anti-CD20-based regimen;
- Received marketing authorization by the Medicines and Healthcare products Regulatory Agency (MHRA) in Great Britain for the treatment of adult patients with CLL, and those with MZL who have received at least one prior anti-CD20-based therapy; and
- Expanded BRUKINSA's registration program globally, including 34 launches in 20 markets since January 1, 2022.

Tislelizumab, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in 10 indications and under development for additional approvals globally. The global tislelizumab clinical development program includes more than 11,800 subjects enrolled to-date in 31 countries and regions.

- Announced China National Medical Products Administration (NMPA) approval of BLA application for tislelizumab in combination with chemotherapy as a first-line treatment for patients with locally advanced unresectable or metastatic G/GEJ adenocarcinoma with high PD-L1 expression, which is the tenth approved indication in China for tislelizumab;
- Announced acceptance by the NMPA of a supplemental biologics license application (sBLA) in patients with first-line unresectable or metastatic hepatocellular carcinoma (HCC);
- Filed new drug application for tislelizumab in Brazil seeking marketing authorization for use in first- and second-line NSCLC and second-line esophageal cancer, marking BeiGene's first application for tislelizumab in Latin America; and
- Presented results from the RATIONALE-301 (NCT03412773), RATIONALE-305 (NCT03777657) and RATIONALE-306 (NCT03783442) trials at the 2023 ASCO Gastrointestinal Cancers Symposium, including positive interim overall survival (OS) data for a combination of tislelizumab and chemotherapy in first-line gastric or gastroesophageal junction (G/GEJ) cancer patients whose tumors express PD-L1.

Ociperlimab (BGB-A1217), an investigational anti-TIGIT monoclonal antibody with competent Fc function. The global ociperlimab development program includes 17 countries and regions, and more than 1,600 subjects have been enrolled.

- Presented Phase 1 clinical data for checkpoint inhibitor-experienced advanced NSCLC and extensive-stage small cell lung cancer (SCLC) (NCT04047862) at ESMO-IO 2022.

BGB-11417, an investigational highly selective and highly potent inhibitor of BCL-2, being developed as monotherapy or in combination with zanubrutinib +/- obinutuzumab in B-cell malignancies, in combination with azacytidine in AML and MDS and as monotherapy and in combination with dexamethasone and in combination with carfilzomib in multiple myeloma. The global BGB-11417 development program includes six countries and regions, and more than 350 subjects have been enrolled.

- Presented Phase 1 clinical data for non-Hodgkin's lymphoma, CLL, acute myeloid leukemia (AML) and multiple myeloma (MM) (NCT04883957, NCT04277637, NCT04771130, and NCT04973605) at ASH 2022.

BGB-A445, an investigational non-ligand competing OX40 monoclonal antibody, being developed as monotherapy or in combination with tislelizumab.

- Initiated patient dosing in a Phase 2 basket trial as monotherapy and in combination with tislelizumab in melanoma, renal cell cancer (RCC) and bladder cancer (NCT05661955).

Early-Stage Programs

- Continued to advance our early-stage clinical pipeline of internally developed product candidates at dose escalation stage, including:
 - BGB-B167: an investigational first-in-class CEA x 4-1BB bispecific antibody, as a monotherapy and in combination with tislelizumab in patients with selected CEA-expressing advanced or metastatic solid tumors, including colorectal cancer (CRC);

- BGB-A425: an investigational TIM-3 antibody, in combination with tislelizumab in patients with head and neck squamous cell carcinoma (HNSCC), NSCLC and RCC;
- BGB-15025: an investigational, first-in-class hematopoietic progenitor kinase 1 (HPK1) inhibitor as monotherapy or in combination with tislelizumab in solid tumors;
- BGB-16673: an investigational Chimeric Degradation Activating Compound (CDAC), targeting BTK protein degradation as monotherapy in B cell malignancies;
- BGB-24714: an investigational Second Mitochondrial-derived Activator of Caspase, or SMAC, mimetic as monotherapy or in combination with paclitaxel in advanced solid tumors;
- BGB-10188: an investigational PI3K δ inhibitor as monotherapy or in combination with BRUKINSA in hematology malignancies, or in combination with tislelizumab in solid tumors; and
- BGB-23339: a potent, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor.

Collaboration Programs

- In collaboration with Zymeworks, announced positive topline results for a Phase 2b clinical trial of zanidatamab in advanced or metastatic HER2-amplified biliary tract cancers (NCT04466891); and
- In collaboration with Mirati, initiated patient enrollment for a Phase 2 clinical trial of sitravatinib in combination with tislelizumab in locally advanced unresectable or metastatic ESCC that progressed on or after anti-PD-(L)1 antibody therapy (NCT05461794).

Manufacturing Operations

- Construction continues on the U.S. flagship manufacturing and clinical R&D facility at the Princeton West Innovation Campus in Hopewell, N.J. The property has more than one million square feet total of developable real estate, allowing for future expansion;
- Completed expansion and Good Manufacturing Practices (GMP) certification of our state-of-the-art biologics facility in Guangzhou, China, bringing total capacity to 54,000 liters with an additional expansion of 10,000 liters expected in the second quarter of 2023; and
- Continued construction on our new small molecule manufacturing campus in Suzhou, China. Phase 1 of construction is expected to add more than 559,000 square feet and expand production capacity to 600 million tablets/capsules, and to be completed in 2023. Once completed, qualified and approved, the total production capacity is expected to increase our small molecule manufacturing capability in China by up to 10 times current capacity.

Corporate Developments

- Announced the launch of the *Talk About It: Cancer and Mental Health* program, designed to elevate the important intersection of mental health and cancer care to help improve health outcomes for cancer patients.

Expected Milestones

BRUKINSA

- Submit supplemental New Drug Applications (sNDA) in the U.S. and EU in the first half of 2023 for PFS superiority versus IMBRUVICA in R/R CLL/SLL, as demonstrated in the Phase 3 ALPINE trial;
 - Continue to support NMPA review of sNDA for first-line CLL/SLL and WM in China, with a decision expected in the first half of 2023;
 - Continue to support Health Canada and Australian Therapeutic Goods Administration (TGA) reviews of sNDAs for CLL, with decisions expected in 2023; and
 - Continue to expand BRUKINSA's registration program globally in new geographies and indications.
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Tislelizumab

- Continue to support NMPA review of BLA applications for tislelizumab in combination with chemotherapy as a first-line treatment in patients with unresectable locally advanced, recurrent or metastatic ESCC, with a decision expected in the first half of 2023; and for tislelizumab as a treatment for first-line hepatocellular carcinoma, with a decision expected in the second half of 2023;
- Continue to support review by regulatory authorities of BeiGene's applications for tislelizumab, including:
 - Australia's TGA review of BLA for tislelizumab in first- and second-line NSCLC and second-line ESCC, with a decision expected in the second half of 2023, as well as New Zealand's Medsafe review of BLA for tislelizumab in first- and second-line NSCLC and second-line ESCC; and
 - South Korea's MFDS review of BLA for tislelizumab in second-line ESCC;
- In collaboration with Novartis, continue to support review of marketing applications, including:
 - Ongoing FDA review of the BLA submission in second-line ESCC, including facilitating the scheduling of required inspections as soon as possible, with a decision expected in 2023;
 - European Medicines Agency (EMA) review of marketing authorization applications for tislelizumab in first- and second-line NSCLC and second-line ESCC, with a decision expected in 2023;
 - MHRA review of tislelizumab for treatment of first- and second-line NSCLC and second-line ESCC in Great Britain;
 - Swissmedic review of marketing authorization applications for tislelizumab in second-line ESCC and second-line NSCLC;
 - Support U.S. FDA regulatory submission by Novartis in 2023 for first-line gastric cancer and first-line unresectable ESCC;
 - Submit BLA to Japan's Pharmaceutical and Medical Devices Agency (PMDA) in 2023 for first- and second-line ESCC; and
- Announce final analysis data from pivotal trials in extensive-stage small cell lung cancer and first-line gastric cancer in 2023.

BGB-11417 (BCL-2)

- Initiate global pivotal trial in first-line CLL in combination with BRUKINSA in the second half of 2023; and
- Announce readouts from ongoing studies.

Ociperlimab (TIGIT)

- Announce readouts for multiple Phase 2 studies in 2023, including:
 - For second-line ESCC in patients whose tumors express PD-(L)1 (NCT04732494);
 - For first-line HCC (NCT04948697);
 - For first-line NSCLC (NCT05014815); and
- Complete enrollment in the Phase 3 AdvanTIG-302 trial in first-line NSCLC in 2023.

BGB-16673 (BTK CDAC)

- Initial data readouts for Phase 1 studies in B cell malignancies (NCT05006716, NCT05294731) in 2023.

BGB-A445 (OX 40)

- Initial data readout for Phase 1 study in solid tumors (NCT04215978) in 2023.
-

BGB-15025 (HPK 1)

- Initiate dose expansion in combination with tislelizumab in solid tumors (NCT04649385) in 2023.

Collaboration Programs

- In collaboration with Leads Biolabs, initiate patient dosing of LBL-007, a novel investigational antibody targeting the LAG-3 pathway, in combination with tislelizumab, in umbrella studies comparing different tislelizumab combination regimens, including with BGB-A445 and ociperlimab (NCT05635708, NCT05577702), in 2023.

COVID-19 Impact and Response

We expect that the worldwide health crisis of COVID-19 will continue to have a negative impact on our operations, including commercial sales, regulatory interactions, inspections, filings, manufacturing, and clinical trial recruitment, participation, and data readouts. There remains uncertainty regarding the future impact of the pandemic both globally and specifically in China due to outbreaks and restrictions and potential impact on clinical, manufacturing and commercial operations. We are striving to minimize delays and disruptions, have put protocols and procedures in place, and continue to execute on our commercial, regulatory, manufacturing, and clinical development goals globally.

Financial Summary
Select Condensed Consolidated Balance Sheet Data (U.S. GAAP)

(Amounts in thousands of U.S. Dollars)

	As of	
	December 31, 2022 (audited)	December 31, 2021 ¹
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	\$ 4,540,288	\$ 6,624,849
Accounts receivable	173,168	483,113
Property and equipment, net	845,946	587,605
Total assets	\$ 6,379,290	\$ 8,535,525
Liabilities and equity:		
Accounts payable	\$ 294,781	\$ 262,400
Accrued expenses and other payables	467,352	558,055
Deferred revenue	255,887	407,703
R&D cost share liability	293,960	390,362
Debt	538,117	629,678
Total liabilities	1,995,935	2,402,962
Total equity	\$ 4,383,355	\$ 6,132,563

Condensed Consolidated Statements of Operations (U.S. GAAP)

(Amounts in thousands of U.S. dollars, except for shares, American Depositary Shares (ADSs), per share and per ADS data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2022	2021 ¹	2022	2021 ¹
	(unaudited)		(audited)	
Revenue:				
Product revenue, net	\$ 339,022	\$ 196,785	\$ 1,254,612	\$ 633,987
Collaboration revenue	41,073	17,194	161,309	542,296
Total revenues	380,095	213,979	1,415,921	1,176,283
Expenses:				
Cost of sales - products	73,522	48,545	286,475	164,906
Research and development	446,023	430,485	1,640,508	1,459,239
Selling, general and administrative	328,984	306,501	1,277,852	990,123
Amortization of intangible assets	188	187	751	750
Total expenses	848,717	785,718	3,205,586	2,615,018
Loss from operations	(468,622)	(571,739)	(1,789,665)	(1,438,735)
Interest (expense) income, net	18,219	(4,482)	52,480	(15,757)
Other (expense) income, net	19,438	(10,583)	(223,852)	15,904
Loss before income taxes	(430,965)	(586,804)	(1,961,037)	(1,438,588)
Income tax expense	14,370	3,874	42,778	19,228
Net loss	(445,335)	(590,678)	(2,003,815)	(1,457,816)
Less: Net loss attributable to noncontrolling interest	—	—	—	—
Net loss attributable to BeiGene, Ltd.	\$ (445,335)	\$ (590,678)	\$ (2,003,815)	\$ (1,457,816)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	\$ (0.33)	\$ (0.48)	\$ (1.49)	\$ (1.21)
Weighted-average shares outstanding, basic and diluted	1,348,916,108	1,235,346,414	1,340,729,572	1,206,210,049
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	\$ (4.29)	\$ (6.22)	\$ (19.43)	\$ (15.71)
Weighted-average ADSs outstanding, basic and diluted	103,762,778	95,026,647	103,133,044	92,785,388

[1] We revised certain prior period financial statements for an error related to the valuation of net deferred tax assets, the impact of which was immaterial to our previously filed financial statements in the first and second quarter of 2022 and the quarterly and annual periods of fiscal 2021 (see "Notes to the Consolidated Financial Statements, Note. 2 Summary of Significant Accounting Policies" and "Note 3. Revision of Prior Period Financial Statements" included in our Annual Report on Form 10-K for the fiscal year ended 2022).

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 9,000 colleagues spans five continents, with administrative offices in Basel; Beijing; and Cambridge, U.S. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at [@BeiGeneGlobal](https://twitter.com/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 clinical data for BeiGene's drug candidates and approvals of its medicines; the conduct of late-stage clinical trials and expected data readouts; additional planned product approvals and launches; the advancement of and anticipated clinical development, regulatory approvals and other milestones and commercialization of BeiGene's medicines and drug candidates; the potential for BRUKINSA to provide clinical benefit to patients with CLL compared with the comparator drug; the success of BeiGene's commercialization efforts and revenue growth; the expected capacities and completion dates for the Company's manufacturing facilities under construction; the impact of the COVID-19 pandemic on the Company's clinical development, regulatory, commercial, manufacturing, and other operations; BeiGene's plans and the expected events and milestones under the captions "Recent Business Highlights" and "Expected Milestones"; and BeiGene's plans, commitments, aspirations and goals under the caption "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, commercialization, 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 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.

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BeiGene Receives 10th Approval for PD-1 Inhibitor Tislelizumab in China

NMPA grants approval for first-line use in combination with chemotherapy in advanced gastric or gastroesophageal junction adenocarcinoma with high PD-L1 expression

BASEL, Switzerland, BEIJING, CAMBRIDGE, Mass. — February 24, 2023 — BeiGene (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company, today announced that the China National Medical Products Administration (NMPA) granted approval for the company's PD-1 inhibitor, tislelizumab, in combination with fluoropyrimidine and platinum chemotherapy, for the first-line treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with high PD-L1 expression.

In China, gastric cancer (GC) has become the third most common cancerⁱ and adenocarcinoma represents the major histologic subtype, comprising over 90% of reported GC cases across the worldⁱⁱ. More than 70% of patients in China are in advanced or late stage when diagnosedⁱⁱⁱ and the previous standard first-line treatment in China for advanced GC, chemotherapy, provided median overall survival (OS) around one year^{iv}. Newer treatments, including immunotherapy, have improved survival in this treatment setting^v.

“Advanced gastric cancer remains a significant cause of cancer-related mortality in China and we are pleased that tislelizumab plus chemotherapy demonstrated a meaningful survival benefit for patients whose tumors express PD-L1 in the RATIONALE 305 study,” said Lai Wang, Ph.D., Global Head of R&D at BeiGene. “We are grateful to the patients, investigators, and experts from across the world who took part in the RATIONALE 305 trial and look forward to bringing another immunotherapy-based treatment option to patients in China.”

The approval was based on data from an interim analysis of the global, randomized, double-blind, placebo-controlled RATIONALE 305 trial (NCT03777657) of tislelizumab in combination with chemotherapy in the first-line treatment setting. A total of 997 patients with locally advanced, unresectable or metastatic G/GEJ from 13 countries and regions across the world were enrolled and randomized 1:1 to receive either tislelizumab and chemotherapy or placebo and chemotherapy, including 546 patients with locally advanced unresectable or metastatic G/GEJ adenocarcinoma with high PD-L1 expression.

Xu Ruihua, M.D., Ph.D., Director of Cancer Control Center of Sun Yat-sen University, and the global principal investigator for RATIONALE 305 noted “The prognosis for patients with advanced G/GEJ adenocarcinoma was poor with traditional chemotherapy treatment and we undertook the global Phase 3 RATIONALE 305 trial with the aim to improve outcomes. With approval from the NMPA, we now have another option for our patients and I expect tislelizumab plus chemotherapy will soon become the new standard of care in this treatment setting in China.”

Results of the RATIONALE 305 interim analysis were shared in an oral presentation at the 2023 ASCO Gastrointestinal Cancers Symposium. In patients with G/GEJ adenocarcinoma with high PD-L1 expression, tislelizumab plus chemotherapy demonstrated statistically significant and clinically meaningful improvement in OS versus placebo plus chemotherapy [median OS: 17.2 vs 12.6 months; HR 0.74 (95% CI 0.59, 0.94); P=0.0056] with a manageable safety profile, and no new safety signals were identified^{vi}. The study is continuing as double-blind towards the final OS analysis in the ITT population.

Tislelizumab is currently under review by the U.S. Food and Drug Administration and the European Medicines Agency (EMA) for advanced or metastatic esophageal squamous cell carcinoma after prior chemotherapy. The EMA is also reviewing tislelizumab for advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy, and in combination with chemotherapy for previously untreated advanced or metastatic NSCLC. Tislelizumab is not approved for use outside of China.

About RATIONALE 305 (NCT03777657)

RATIONALE 305 is a randomized, double-blind, placebo-controlled, global Phase 3 trial comparing the efficacy and safety of tislelizumab combined with platinum and fluoropyrimidine chemotherapy and placebo combined with platinum and fluoropyrimidine chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic G/GEJ adenocarcinoma. The primary endpoint of the trial is OS in patients with PD-L1 high population and in ITT population. Secondary endpoints include progression-free survival, overall response rate, duration of response, and safety.

About Tislelizumab

Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to Fc-gamma (Fc γ) receptors on macrophages, helping to aid the body's immune cells to detect and fight tumors. In pre-clinical studies, binding to Fc γ 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.

BeiGene has initiated or completed more than 20 potentially registration-enabling clinical trials in 35 countries and regions, including 17 Phase 3 trials and four pivotal Phase 2 trials. More information on the clinical trial program for tislelizumab can be found at: <https://www.beigene.com/en-us/science-and-product-portfolio/pipeline>.

About BeiGene

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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 survival benefit of tislelizumab plus chemotherapy for patients who tumors express PD-L1; BeiGene's efforts to make tislelizumab more broadly available to patients in China; the potential for tislelizumab plus chemotherapy to become the new standard of care in treatment for patients with advanced G/GEJ adenocarcinoma and the benefits of such treatment for those patients; the future development and regulatory filing and approval of tislelizumab in other markets; 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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^v CDE, <https://www.cde.org.cn/main/xxgk/postmarketpage?acceptidCODE=f1a61b9035381b8816fc888421252aae>;
<https://www.cde.org.cn/main/xxgk/postmarketpage?acceptidCODE=457d62d01a141c8fca2e536b49f16296>

^{vi} Moehler, Markus H., et al. "Rationale 305: Phase 3 study of tislelizumab plus chemotherapy vs placebo plus chemotherapy as first-line treatment (1L) of advanced gastric or gastroesophageal junction adenocarcinoma (GC/GEJC)." *Journal of Clinical Oncology* 41, no. 4_suppl (February 01, 2023) 286-286 DOI: 10.1200/JCO.2023.41.4_suppl.286