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 25, 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 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 2.02. Results of Operations and Financial Condition.

On February 25, 2022, BeiGene, Ltd. (the "Company") announced its financial results for the three months and year ended December 31, 2021. 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 25, 2022, the Company also provided an update on fourth quarter 2021 and recent business highlights and expected milestones for 2022. 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.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Reports Fourth Quarter and Full Year 2021 Financial Results", issued by BeiGene, Ltd. on February 25, 2022
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

The portions of the press release 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

Exhibit No.	Description
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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 25, 2022

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

BeiGene Reports Fourth Quarter and Full Year 2021 Financial Results

- *Recorded product revenue of $196.8 million and $634.0 million for the fourth quarter and full year, respectively, representing a 96.6% and 105.3% increase from $100.1 million and $308.9 million in the prior year periods*

CAMBRIDGE, Mass. and BEIJING, China, February 25, 2022 -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global biotechnology company focused on developing and commercializing innovative medicines worldwide, today reported financial results for the fourth quarter and full year of 2021, recent business highlights, and anticipated upcoming milestones.

"Last year was transformative for our company, and we have built strategic competitive advantages that will help BeiGene to achieve our mission of making innovative medicines more readily accessible and affordable for all who need them. We have significantly increased the reach of our medicines, as BRUKINSA is now approved in 45 markets, and we now have 16 approved medicines in China, including our sixth approved indication for tislelizumab and five approved Novartis Oncology products in designated regions of China that we plan to promote following the transition from Novartis," said John V. Oyler, Co-Founder, Chairman and Chief Executive Officer of BeiGene. "With exciting momentum for BRUKINSA including acceptance by the FDA and EMA of our supplemental NDAs for CLL, the most common form of adult leukemia, we are building a strong portfolio with cornerstone assets that will support the development of potential future new therapies. In addition, we have expanded our productive collaboration with Novartis by entering into an option, collaboration and license agreement to accelerate our anti-TIGIT antibody, ociperlimab, which is one of the most advanced assets in its class."

Julia Wang, Chief Financial Officer, commented, "We are strongly positioned financially in an environment where the cost of capital is rising for our industry. In 2021, we added over $4 billion to our balance sheet through our public offering and new listing on the STAR market and the upfront payment from our collaboration with Novartis for tislelizumab, plus an additional $300 million in early 2022 for our TIGIT collaboration, that validates the strength of our research and development. Our commercial team is generating substantial product revenue from our internal and partnered medicines, and we expect revenue to continue to grow meaningfully in the year ahead based on approvals achieved and upcoming catalysts. We remain committed to building our internal clinical development and manufacturing capabilities that offer cost advantages and managing our expenses with discipline."

Fourth Quarter and Full Year 2021 Financial Results

Cash, Cash Equivalents, Restricted Cash and Short-Term Investments were $6.62 billion as of December 31, 2021, compared to $3.92 billion as of September 30, 2021, and $4.66 billion as of December 31, 2020. Cash and cash equivalents as of December 31, 2021 do not include the $300 million upfront payment from Novartis for the ociperlimab option, collaboration and license agreement, which was received in January 2022.

- For the fourth quarter of 2021, total cash and short-term investments increased $2.7 billion; cash used in operating activities was $507.8 million; capital expenditures were $115.0 million; and cash provided from financing activities was $3.4 billion, almost entirely due to the net proceeds from the STAR Market offering on December 15, 2021.
- For the full year 2021, total cash and short-term investments increased $2.0 billion; cash used in operating activities was $1.3 billion; capital expenditures were $262.9 million; and cash provided from financing activities was $3.6 billion, primarily due to the net proceeds from the STAR Market offering on December 15, 2021.

Revenue for the fourth quarter and full year 2021 was $214.0 million and $1.2 billion, respectively, compared to $100.1 million and $308.9 million in the prior year periods. The increase in total revenue in the quarter compared to the prior year is attributable to sales of our internally developed products, sales of in-licensed products from Amgen and BMS, as well as collaboration revenue from the Novartis agreements.

- Product revenues totaled $196.8 million and $634.0 million for the fourth quarter and full year 2021, respectively, compared to $100.1 million and $308.9 million in the prior year periods, and were comprised of:
  - Global sales of BRUKINSA of $87.6 million and $218.0 million for the fourth quarter and full year 2021, respectively, compared to $18.3 million and $41.7 million in the prior year periods. Full year 2020 revenue from BRUKINSA reflects sales since its launch in China in June 2020, as well as sales in the United States for the full year;
  - Sales of tislelizumab in China of $54.4 million and $255.1 million for the fourth quarter and full year 2021, respectively, compared to $63.5 million and $163.4 million in the prior year periods. Sales of tislelizumab in the fourth quarter were impacted by 2022 National Reimbursement Drug List (NRDL) price reductions, which resulted in a negative adjustment of $25.4 million as a result of the normal process in China of compensating

distributors for products previously sold at the 2021 price during the quarter that remained in the distribution channel. Full year 2021 sales of tislelizumab included two negative adjustments totaling $45.6 million for distributor channel inventory compensation as a result of inclusion in the March 2021 and January 2022 NRDL lists. Full year 2020 revenue from tislelizumab reflects sales since its launch in China in March 2020;

- Sales of BMS in-licensed products in China of $29.9 million and $89.7 million for the fourth quarter and full year 2021, respectively, compared to $12.6 million and $95.1 million in the prior year periods, respectively; and

- Sales of Amgen in-licensed products in China of $20.3 million and $58.8 million for the fourth quarter and full year 2021, respectively, compared to $5.4 million and $8.5 million in the prior year periods. We began selling Amgen's XGEVA® (*denosumab*) and BLINCYTO® (*blinatumomab*) in July 2020 and August 2021, respectively.

- Collaboration revenue totaled $17.2 million and $542.3 million for the fourth quarter and full year 2021, resulting from the partial recognition of the upfront payments from Novartis of $650.0 million related to the tislelizumab agreement and $300.0 million related to the ociperlimab agreement, which were entered into in the first and fourth quarters of 2021, respectively. We had no collaboration revenue in 2020.

Expenses for the fourth quarter and full year 2021 were $785.7 million and $2.6 billion, respectively, compared to $585.0 million and $2.0 billion in the prior year periods.

- **Cost of Sales** for the fourth quarter and full year 2021 were $48.5 million and $164.9 million, respectively, compared to $21.1 million and $70.7 million in the prior year periods. Cost of sales increased primarily due to increased product sales of tislelizumab, BRUKINSA and XGEVA, as well as sales of BLINCYTO, which commenced in August 2021.

- **R&D Expenses** for the fourth quarter and full year 2021 were $430.5 million and $1.5 billion, respectively, compared to $355.5 million and $1.3 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 external CROs on clinical trials for BRUKINSA, tislelizumab and pamiparib, as well as decreased expense related to upfront fees for in-process R&D. Upfront fees related to in-process R&D for in-licensed assets totaled $30.0 million and $83.5 million in the fourth quarter and full year 2021, respectively, compared to nil and $109.5 million in the prior year periods. Employee share-based compensation expense also contributed to the overall increase in R&D expenses and was $30.6 million and $114.4 million for the fourth quarter and full year 2021, respectively, compared to $23.5 million and $93.0 million in the prior year periods, due to increased headcount and a higher share price.

- **SG&A Expenses** for the fourth quarter and full year 2021 were $306.5 million and $990.1 million, respectively, compared to $208.2 million and $600.2 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, higher professional service fees and higher external commercial expenses, including selling and marketing, market access studies and promotional activities. The overall increase in SG&A expenses was also attributable to higher SG&A-related share-based compensation expense, which was $32.4 million and $126.4 million for the fourth quarter and full year 2021, respectively, compared to $26.0 million and $90.5 million for the prior year periods, due to increased headcount and a higher share price.

- **Net Loss** for the fourth quarter and full year 2021 was $585.7 million and $1.4 billion, or $0.47 and $1.17 per share, respectively, or $6.16 and $15.23 per ADS, respectively, compared to $472.7 million and $1.6 billion, or $0.40 and $1.47 per share, or $5.20 and $19.13 per ADS, respectively, in the prior year periods.

Recent Business Highlights

Commercial Operations

- Product sales increased 96.6% and 105.3% in the fourth quarter and full year of 2021 compared to the prior year periods, primarily due to increased sales of our internally developed products and in-licensed products from Amgen;

- Global sales of BRUKINSA totaled $87.6 million and $218.0 million in the fourth quarter and full year 2021, representing 378% and 423% increases compared to the prior year periods; U.S. sales of BRUKINSA totaled $55.9 million and $115.7 million in the fourth quarter and full year 2021, representing growth of 539% and 535%, compared to the prior year periods. U.S. sales continued to accelerate in the quarter, driven by continued uptake in mantle cell lymphoma (MCL) and the recent FDA approvals in Waldenström’s macroglobulinemia (WM) and marginal zone lymphoma (MZL). BRUKINSA sales in China totaled $30.6 million and $101.2 million in the fourth

quarter and full year 2021, representing growth of 219% and 331% compared to the prior year periods, driven by a significant increase in all approved indications, including chronic lymphocytic leukemia (CLL). Fourth quarter and full year 2021 sales of BRUKINSA in China were negatively impacted by accrued compensation to distributors of $4.4 million and $7.9 million, respectively, due to price changes related to BRUKINSA's inclusion in the March 2021 and January 2022 NRDL lists;

- Sales of tislelizumab in China totaled $54.4 million and $255.1 million in the fourth quarter and full year 2021, representing a decline of 14% and growth of 56% compared to the prior year periods. In the fourth quarter, 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;

- Continued to build commercial capabilities in designated regions of China referred to as Broad Markets to accommodate increasing medical demand. Our new agreement with Novartis granting us rights to market and promote five Novartis approved and nationally reimbursed oncology products expands our portfolio and enables our commercial team to reach patients in the Broad Markets with these medicines. These products include: TAFINLAR® (dabrafenib), MEKINIST® (trametinib), VOTRIENT® (pazopanib), AFINITOR® (everolimus), and ZYKADIA® (ceritinib);

- Secured NRDL inclusion in China for our eligible medicines, including tislelizumab in first-line non-squamous non-small cell lung cancer (NSCLC), first-line squamous NSCLC and second- or third-line hepatocellular carcinoma (HCC), BRUKINSA in WM, and pamiparib in germline in patients with BRCA (gBRCA) mutation-associated recurrent advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more lines of chemotherapy; and

- Our commercial organization in China continued to demonstrate its ability to bring new products to market, launching QARZIBA and POBEVCY in the fourth quarter.

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 45 markets including the U.S., China, European Union (EU), Great Britain, Canada, and Australia in selected indications and under development for additional approvals globally. The global BRUKINSA development program includes nearly 4,000 subjects enrolled to-date in more than 25 countries and regions.*

- Announced acceptance by the U.S. FDA of a supplemental new drug application for the treatment of adult patients with CLL or small lymphocytic lymphoma (SLL) based on data from two pivotal randomized Phase 3 studies ALPINE (NCT03734016) and SEQUOIA (NCT03336333) presented at the 26th European Hematology Association (EHA2021) Virtual Congress in June 2021 and at the 63rd American Society for Hematology (ASH) Annual Meeting in December 2021, respectively. The Prescription Drug User Fee Act (PDUFA) target action date is October 22, 2022;

- Announced acceptance by the European Medicines Agency of two marketing authorization applications for the treatment of patients with CLL and MZL;

- Received approval in South Korea for the treatment of adult patients with MCL who have received at least one prior therapy, and for the treatment of adult patients with WM who have received at least one prior therapy;

- Received approval in the EU for the treatment of adult patients with WM who have received at least one prior therapy or for the first-line treatment of patients unsuitable for chemo-immunotherapy. The approval is applicable to all 27 EU member states, plus Iceland, Liechtenstein and Norway. BeiGene has begun launching BRUKINSA in the EU;

- Received approvals for WM in Great Britain and Switzerland, and new approvals for MCL in Saudi Arabia and Ecuador, as well as new indication approval for MZL in Canada, and national reimbursement coverage for patients with WM in Israel. There are currently more than 40 marketing authorization applications in multiple indications under review around the world;

- Included in the National Comprehensive Cancer Network® (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines® version 2.2022) for patients with both CLL/SLL as a Category 2A preferred treatment option in the first- and second-line, for patients with and without del(17p)/TP53 mutation. BRUKINSA is not approved in CLL/SLL outside of China; and

- Announced acceptance of supplemental new drug applications (sNDA) in China as a treatment for adult patients with WM, and as a treatment for adult patients with CLL or SLL with breakthrough therapy designation (BTD).

Tislelizumab*, a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages; approved in China in selected indications and under development for additional approvals globally. The global tislelizumab clinical development program includes more than 9,000 subjects enrolled to-date in more than 35 countries and regions.*

- Received approval in China in a sixth indication, for second- or third-line treatment of locally advanced or metastatic NSCLC;
- Announced positive findings from the global Phase 3 RATIONALE 305 trial (NCT03777657) versus placebo in combination with chemotherapy as a first-line treatment for patients with locally advanced, unresectable or metastatic gastric or gastroesophageal junction (G/GEJ) adenocarcinoma with PD-L1 expression. At the interim analysis, tislelizumab in combination with chemotherapy met the primary endpoint of overall survival (OS) in patients with PD-L1 expression, with additional follow-up needed to assess OS benefits in the intention-to-treat (ITT) population. The safety profile of tislelizumab was consistent with that observed in previous trials, with no new safety signals identified with the addition of chemotherapy; and
- Presented results from the Phase 3 RATIONALE 309 trial (NCT03924986) of tislelizumab in first-line patients with nasopharyngeal cancer at the European Society for Medical Oncology Immuno-Oncology Congress 2021. The trial significantly prolonged progression-free survival for patients and demonstrated a safety profile consistent with known risks of each treatment agent.

Ociperlimab (BGB-A1217), *an investigational anti-TIGIT monoclonal antibody with competent Fc function. The global ociperlimab development program includes approximately 800 subjects enrolled to-date in 25 countries and regions.*

- Announced an option, collaboration, and license agreement with Novartis to develop, manufacture and commercialize ociperlimab in North America, Europe, and Japan. BeiGene received an upfront payment of $300 million and granted Novartis an exclusive time-based option until late 2023 under which BeiGene would receive an additional payment of $600 or $700 million upon exercise of the option, subject to receipt of required antitrust approval. During the option period, Novartis will conduct and fund additional global clinical trials of ociperlimab in combination with tislelizumab in selected tumor types; and
- Initiated patient enrollment in BeiGene's global Phase 2 AdvanTIG-205 trial (NCT05014815) in frontline stage IV NSCLC.

Early Stage Programs

- Continued to advance our early stage clinical pipeline of internally-developed product candidates at dose escalation stage, including BGB-A445 (an investigational non-ligand competing OX40 monoclonal antibody as monotherapy or in combination with tislelizumab in solid tumors), BGB-15025 (an investigational hematopoietic progenitor kinase 1 (HPK1) inhibitor as monotherapy or in combination with tislelizumab in solid tumors), and BGB-10188 (an investigational PI3Kδ inhibitor as monotherapy or in combination with BRUKINSA in hematology malignancies, or in combination with tislelizumab in solid tumors); and
- Initiated the first Phase 1 clinical trial (NCT05093270) of BGB-23339, a potent, allosteric investigational tyrosine kinase 2 (TYK2) inhibitor being developed for inflammation and immunology.

Collaboration with Amgen

- Launched KYPROLIS® (carfilzomib) for injection, a next-generation proteasome inhibitor, in China for patients with R/R multiple myeloma.

Other Collaboration Programs

- Received approval and launched POBEVCY® (a biosimilar to bevacizumab) in China, licensed from Bio-Thera Solutions, Ltd., for the treatment of patients with advanced, metastatic or recurrent NSCLC and metastatic colorectal cancer;

- Received approval in China of SYLVANT® (siltuximab for injection), licensed from EUSA Pharma (UK), Ltd., for the treatment of adult patients with multicentric Castleman disease (MCD) who are human immunodeficiency virus (HIV) negative and human herpes virus-8 (HHV-8) negative, also known as idiopathic MCD (iMCD);
- Launched QARZIBA® (dinutuximab beta) in China, a targeted immunotherapy licensed from EUSA Pharma, for the treatment of high-risk neuroblastoma in patients aged 12 months and above who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as patients with a history of R/R neuroblastoma with or without residual disease; and
- Entered a worldwide license and collaboration agreement with Nanjing Leads Biolabs, Co., Ltd. (Leads Biolabs), for research, development and manufacturing rights and exclusive commercialization rights outside of China to LBL-007, a novel investigational antibody targeting the LAG-3 pathway.

Zanidatamab, an investigational bispecific antibody targeting HER2 in late-stage clinical development with Zymeworks Inc.

- Received Breakthrough Therapy Designation from the Center for Drug Evaluation (CDE) of China's National Medical Products Administration (NMPA) for treating patients with biliary tract cancer who have failed prior systemic therapies; and
- Initiated the global Phase 3 HERIZON-GEA-01 clinical trial (NCT05152147) of zanidatamab plus chemotherapy, with or without tislelizumab, versus standard of care (trastuzumab plus chemotherapy), for the first-line treatment of metastatic HER2-positive gastroesophageal adenocarcinoma (GEA).

Corporate Developments

- Completed the public offering and initial listing of our ordinary shares on the Science and Technology Innovation Board (STAR Market) of the Shanghai Stock Exchange under the stock code “688235” with net proceeds of approximately US$3.4 billion;
- Held a grand opening ceremony for the BeiGene Bioisland Innovation Center (BIC) in Guangzhou, China to support scientists and entrepreneurs in accelerating the development of highly differentiated, cutting-edge medical innovations. The BIC is an innovator-centric incubator built on BeiGene’s goal of supporting exploration of new paths to meet patient needs around the world;
- Announced the appointment of Drs. Margaret Dugan and Alessandro Riva to our Board of Directors and the resignation of Sam Su from our Board after almost four years of service; and
- Expanded our Executive Committee with the following new leaders:
  - Mark Lanasa, M.D., Senior Vice President, Chief Medical Officer, Solid Tumor;
  - Kyu-Sung ("Q") Lee, Senior Vice President, Global Head of Technical Operations and Manufacturing
  - Kevin Mannix, Senior Vice President, Investor Relations;
  - Jurij Petrin, Head of New Market Development; and
  - Eva Yin, Chief Commercial Officer, Greater China.

Manufacturing Operations

- Closed on the acquisition of a 42-acre site at the Princeton West Innovation Campus in Hopewell, N.J., which BeiGene plans to develop as a new commercial-stage manufacturing and clinical R&D campus. Construction of the initial phase is expected to commence in 2022. In addition, the property has more than one million square feet of developable real estate for potential future expansion;
- Continued construction on the new small molecule manufacturing campus in Suzhou, China. Phase 1 of construction will bring over 52,000 square meters and 600M solid oral dosage capacity and is expected to be completed in 2023. Once completed, qualified, and approved, the total production capacity is expected to increase BeiGene's small molecule manufacturing capability in China by up to six times the current capacity; and

- Continued construction on the state-of-the-art biologics facility in Guangzhou, China, which currently is approved for 8,000 liters of biologics capacity, with an additional phase of construction to bring total capacity to 64,000 liters expected to be completed and GMP-ready by the end of 2022.

Expected Milestones

BRUKINSA

- Announce updated topline results for the Phase 3 ALPINE trial (NCT03734016) in R/R CLL/SLL in the second quarter of 2022;
- Announce clinical data from the global Phase 2 ROSEWOOD trial (NCT03332017) in R/R follicular lymphoma in 2022;
- Continue to support ongoing FDA review of the sNDA submission for CLL/SLL, which has a PDUFA target action date of October 22, 2022;
- Continue to support the EMA review of new indication applications for CLL and MZL; and
- Continue to expand BRUKINSA's registration program globally in new geographies and indications, including potential launches in 2022 in more than 10 markets.

Tislelizumab

- Receive approvals in China for the three sBLAs currently under review in first-line NPC, second-line ESCC, and second- or third-line MSI-High solid tumors in 2022;
- In collaboration with Novartis, continue to support the ongoing FDA review of the BLA submission in second-line ESCC, which has a PDUFA target action date of July 12, 2022;
- Continue to support additional planned BLA filings by Novartis in first-line NPC in the U.S. and in NSCLC in the U.S. and EU in 2022; and
- Announce topline results from the global Phase 3 clinical trial (NCT03412773) as first-line treatment for patients with HCC in 2022.

Ociperlimab

- Initiate additional pivotal clinical trials in 2022; and
- Announce data from Phase 1 trial (NCT04047862) cohorts in various solid tumor types in the second half of 2022.

Pamiparib

- Report topline results from the Phase 3 trial (NCT03519230) in China of pamiparib as a maintenance treatment in patients with platinum-sensitive recurrent ovarian cancer, in the first half of 2022.

BGB-11417 (BCL-2)

- Activate pivotal trials in 2022.

Early Stage Programs

- Initiate dose expansion in the Phase 1 clinical trial (NCT04215978) of BGB-A445 (OX-40) in patients with advanced solid tumors in the first half of 2022.

COVID-19 Impact and Response

- The Company expects that the worldwide health crisis of COVID-19 will continue to have a negative impact on its operations, including commercial sales, regulatory interactions, inspections, filings, manufacturing, and clinical trial recruitment, participation, and data read outs. There remains uncertainty regarding the future impact of the pandemic globally. The Company is striving to minimize delays and disruptions, and continues to execute on its 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)

(Audited)

	As of	
	December 31, 2021	December 31, 2020
Assets:		
Cash, cash equivalents, restricted cash and short-term investments	$ 6,624,849	$ 4,658,730
Accounts receivable	483,113	60,403
Property and equipment, net	587,605	357,686
Total assets	$ 8,645,949	$ 5,600,757
Liabilities and equity:		
Accounts payable	$ 262,400	$ 231,957
Accrued expenses and other payables	558,055	346,144
Deferred revenue	407,703	—
R&D cost share liability	390,362	502,848
Debt	629,678	518,652
Total liabilities	2,402,962	1,731,514
Total equity	$ 6,242,987	$ 3,869,243

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,	
	2021	2020	2021	2020
	(unaudited)		(audited)	
Revenue:				
Product revenue, net	$ 196,785	$ 100,100	$ 633,987	$ 308,874
Collaboration revenue	17,194	—	542,296	—
Total revenues	213,979	100,100	1,176,283	308,874
Expenses:				
Cost of sales - products	48,545	21,078	164,906	70,657
Research and development [1]	430,485	355,537	1,459,239	1,294,877
Selling, general and administrative	306,501	208,209	990,123	600,176
Amortization of intangible assets	187	188	750	846
Total expenses	785,718	585,012	2,615,018	1,966,556
Loss from operations	(571,739)	(484,912)	(1,438,735)	(1,657,682)
Interest (expense) income, net	(4,482)	(5,186)	(15,757)	1,998
Other (expense) income, net	(10,583)	8,122	15,904	37,490
Loss before income taxes	(586,804)	(481,976)	(1,438,588)	(1,618,194)
Income tax expense (benefit)	(1,151)	(9,327)	(25,234)	(17,671)
Net loss	(585,653)	(472,649)	(1,413,354)	(1,600,523)
Less: Net income (loss) attributable to noncontrolling interest	—	96	—	(3,617)
Net loss attributable to BeiGene, Ltd.	$ (585,653)	$ (472,745)	$ (1,413,354)	$ (1,596,906)
Net loss per share attributable to BeiGene, Ltd., basic and diluted	$ (0.47)	$ (0.40)	$ (1.17)	$ (1.47)
Weighted-average shares outstanding, basic and diluted	1,235,346,414	1,181,005,180	1,206,210,049	1,085,131,783
Net loss per ADS attributable to BeiGene, Ltd., basic and diluted	$ (6.16)	$ (5.20)	$ (15.23)	$ (19.13)
Weighted-average ADSs outstanding, basic and diluted	95,026,647	90,846,552	92,785,388	83,471,676

[1] Research and development expense for the fourth quarter and full year 2021 includes upfront fees related to in-process research and development of in-licensed assets totaling $30.0 million and $83.5 million, respectively, compared to nil and $109.5 million in the prior year periods.

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 8,000 colleagues across five continents. 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 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 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 captions "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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