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): April 27, 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 2.02. Results of Operations and Financial Condition.

On April 28, 2022, BeiGene, Ltd. (the "Company") filed its 2021 Annual Report for the year ended December 31, 2021 (the "STAR Annual Report") with the Science and Technology Innovation Board (the "STAR Market") of the Shanghai Stock Exchange, which was prepared in accordance with the listing rules of the STAR Market and the applicable securities laws and regulations of the Peoples' Republic of China (the "PRC" and the "PRC Securities Laws").

As required by the PRC Securities Laws, the STAR Annual Report contains additional financial information of the Company regarding the Company's gross profit margin ratio, research and development expenses allocated by key products and other research and development projects, and production, sales and inventory stock units of key products, for the year ended December 31, 2021 (the "Reporting Period"), prepared in accordance with the China Accounting Standards for Business Enterprises – Basic Standard ("CAS") and other applicable PRC accounting rules, guidance and interpretations (together with CAS, "PRC GAAP"). As required by the PRC Securities Laws, the STAR Annual Report also contains financial information of the Company for the Reporting Period prepared in accordance with PRC GAAP. PRC GAAP are different from accounting principles generally accepted in the United States ("U.S. GAAP"). The financial information regarding the Company's research and development expenses allocated by key products and other research and development projects for the Reporting Period and the Company's production, sales and inventory stock units of key products for the Reporting Period prepared in accordance with U.S. GAAP as well as a summary of the material differences between PRC GAAP and U.S. GAAP are attached hereto as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

The STAR Annual Report is available to the public in Chinese language only on the website maintained by the Shanghai Stock Exchange at www.sse.com.cn. The STAR Annual Report and the information contained on the Shanghai Stock Exchange's website are not part of this Current Report on Form 8-K and shall not be deemed filed or furnished by the Company with the U.S. Securities and Exchange Commission, nor shall they be deemed incorporated by reference in any filing by the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Securities Exchange Act of 1934, as amended (the "Exchange Act").

The information in Item 2.02 of this Current Report on Form 8-K and in Exhibit 99.1 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On April 27, 2022, the Company issued a press release announcing that the Independent Data Monitoring Committee (IDMC) determined at a pre-planned interim analysis that RATIONALE 306, a global Phase 3 trial of tislelizumab in combination with chemotherapy, had met the study's primary endpoint of overall survival (OS) in patients with previously untreated advanced or metastatic esophageal squamous cell carcinoma (ESCC). A copy of this press release is attached hereto as Exhibit 99.2, and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Financial Information, furnished herewith
99.2	Press release titled "Global Phase 3 Trial of BeiGene's PD-1 Inhibitor, Tislelizumab, in Combination with Chemotherapy Meets Primary Endpoint in First-Line Advanced Esophageal Squamous Cell Carcinoma" issued by BeiGene, Ltd. on April 27, 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: April 28, 2022

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

Exhibit 99.1

Financial Information

On April 28, 2022, BeiGene, Ltd. (the "Company") filed its 2021 Annual Report for the year ended December 31, 2021 (the "STAR Annual Report") with the Science and Technology Innovation Board (the "STAR Market") of the Shanghai Stock Exchange, which was prepared in accordance with the listing rules of the STAR Market and the applicable securities laws and regulations of the Peoples' Republic of China (the "PRC" and the "PRC Securities Laws"). The STAR Annual Report is available to the public in Chinese language only on the website maintained by the Shanghai Stock Exchange at www.sse.com.cn.

As required by the PRC Securities Laws, the STAR Annual Report contains additional financial information regarding the Company's gross profit margin ratio, research and development expenses allocated by key products and other research and development projects, and production, sales and inventory stock units of key products, for the year ended December 31, 2021 (the "Reporting Period"), prepared in accordance with the China Accounting Standards for Business Enterprises – Basic Standard ("CAS") and other applicable PRC accounting rules, guidance and interpretations (together with CAS, "PRC GAAP"). The key differences between such financial information prepared in accordance with PRC GAAP and those prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for the Reporting Period, which was previously filed with the U.S. Securities and Exchange Commission, are summarized below.

Key Differences between PRC GAAP and U.S. GAAP
Share-based Compensation

Under U.S. GAAP, the Company elects to recognize share-based compensation expenses using the straight-line method for all employee equity awards granted with graded vesting based on service conditions, provided that the amount of compensation cost recognized at any date is at least equal to the portion of the grant-date value of the options that are vested as of that date.

Under PRC GAAP, the Company recognizes share-based compensation expense using the accelerated method for all employee equity awards granted with graded vesting.

Excess tax income from the exercise of stock option

Under U.S. GAAP, deferred taxes are calculated based on the cumulative share-based compensation expense recognized in the financial statements and ASC 2016-09 requires all excess tax benefits and tax deficiencies to be recorded as income tax expense or benefit in the statement of operations, rather than in shareholders' equity.

Under PRC GAAP, deferred taxes are calculated based on the estimated tax deduction determined at each reporting date. If the tax deduction exceeds cumulative compensation cost for an individual award, tax benefits on the excess are credited to shareholders' equity. If the tax deduction is less than or equal to cumulative compensation cost for an individual award, tax expenses are recorded in the statement of operations.

Leasing

Under U.S. GAAP, as a lessee, the Company recognizes a lease liability based on the present value of the total remaining lease payments, and a corresponding right-of-use assets under U.S. GAAP. The Company subsequently recognizes operating lease expenses on a straight-line basis over the lease term.

PRC GAAP requires entities to present interest expenses on the lease liability and depreciation on the right-of-use assets separately in the statements of operations. The combination of a straight-line depreciation of the right-of-use assets and the effective interest rate method applied to the lease liability will result in a higher total charge to profit or loss in the initial years of the leases and decreasing expenses during the latter part of the lease term.

Gross Profit Margin Ratio

As required by the PRC Securities Laws, the STAR Annual Report contains financial information regarding gross profit margin ratio by region, which was prepared in accordance with PRC GAAP. The corresponding financial information prepared in accordance with U.S. GAAP is presented below. Amounts reported herein are stated in thousands of U.S. dollars.

	For the year ended December 31, 2021			**For the year ended December 31, 2020**		
By Region	Revenue	COGS	Gross Margin ratio	Revenue	COGS	Gross Margin ratio
China	517,173	162,976	68.5%	290,646	70,388	75.8%
Ex-China	659,110	1,930	99.7%	18,228	269	98.5%
Total	1,176,283	164,906		308,874	70,657	

Research and Development Expenses Allocated by Key Products and Other R&D Projects

As required by the PRC Securities Laws, the STAR Annual Report contains financial information regarding research and development ("R&D") expenses allocated by key products, which was prepared in accordance with PRC GAAP. The corresponding financial information prepared in accordance with U.S. GAAP is presented below. Amounts reported herein are stated in thousands of U.S. dollars.

Pipeline Products/ Projects	Year ended December 31, 2021	Year ended December 31, 2020	Implementation
Zanubrutinib	141,495	154,806	Clinical stage
Tislelizumab	163,986	215,808	Clinical stage
Pamiparib	14,419	28,156	Clinical stage
Ociperlimab (BGB-A1217)	65,102	22,133	Clinical stage
Bcl-2 (BGB-11417)	10,978	4,950	Clinical stage
OX40 (BGB-A445)	2,225	3,010	Clinical stage
Other R&D projects	79,556	73,536	Clinical / preclinical stage
R&D collaboration projects	198,964	226,505	N/A
Subtotal of external R&D expenses	676,725	728,904	
Subtotal of internal R&D expenses	782,514	565,973	
Total	1,459,239	1,294,877	

Production, Sales and Inventory Stock Units of Key Products

As required by the PRC Securities Laws, the STAR Annual Report contains financial information regarding the production, sales and inventory stock units of key products, which was prepared in accordance with PRC GAAP. The corresponding financial information prepared in accordance with U.S. GAAP is presented below.

Item	Unit	Production or purchase quantity for the year ended December 31, 2021	Sales quantity for the year ended December 31, 2021	Stock quantity as of December 31, 2021
Key products	vials	1,984,300	1,119,800	932,900

Exhibit 99.2

Global Phase 3 Trial of BeiGene's PD-1 Inhibitor, Tislelizumab, in Combination with Chemotherapy Meets Primary Endpoint in First-Line Advanced Esophageal Squamous Cell Carcinoma

- *Statistically significant and clinically meaningful improvement in overall survival achieved for tislelizumab and chemotherapy compared to placebo and chemotherapy*

- *Safety profile for the combination consistent with previous trials*

CAMBRIDGE, Mass. & BASEL, Switzerland & BEIJING-- Apr 27, 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, today announced the Independent Data Monitoring Committee (IDMC) determined at a pre-planned interim analysis that RATIONALE 306, a global Phase 3 trial of tislelizumab in combination with chemotherapy, had met the study's primary endpoint of overall survival (OS) in patients with previously untreated advanced or metastatic esophageal squamous cell carcinoma (ESCC). The safety and tolerability profile for tislelizumab in combination with chemotherapy at this interim analysis was consistent with previous trials and no new safety signals were identified.

"ESCC is a difficult to treat disease that imposes a significant symptom burden on patients. We are encouraged by the survival benefit seen in the tislelizumab and chemotherapy group in RATIONALE 306. We have designed an expansive clinical development program, with a global scope, to investigate tislelizumab as a potential treatment for solid tumors, and it is rewarding to deliver the seventh positive Phase 3 pivotal trial to demonstrate benefit with tislelizumab treatment," said Mark Lanasa, M.D., Chief Medical Officer, Solid Tumors at BeiGene. "Combined with the overall survival benefit seen in RATIONALE 302, the second-line evaluation of tislelizumab versus chemotherapy in ESCC, the results from 306 add to the body of evidence supporting tislelizumab as a potential standard of care for patients suffering from this disease. We are grateful to the more than 1,100 patients with ESCC who chose to participate in these two pivotal Phase 3 studies and look forward to sharing the RATIONALE 306 study results with the community at a future scientific conference."

Tislelizumab is currently under review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for advanced or metastatic ESCC 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. In January 2021, BeiGene announced a collaboration with Novartis to accelerate the clinical development and marketing of tislelizumab in North America, Europe, and Japan.

Tislelizumab is approved by the China National Medical Products Administration (NMPA) as a treatment for eight indications, including a recent approval for use in patients with locally advanced or metastatic ESCC who have disease progression or are intolerant to first-line standard chemotherapy. Tislelizumab is not approved for use outside of China.

About RATIONALE 306

RATIONALE 306 (NCT03783442) is a randomized, placebo-controlled, double-blind, global Phase 3 study to evaluate the efficacy and safety of tislelizumab in combination with chemotherapy as a first-line treatment in patients with advanced or metastatic ESCC. The primary endpoint of the trial is overall survival (OS). Secondary endpoints include progression free survival, overall response rate, and duration of response per RECIST v1.1, as well as health-related quality of life measures and safety.

The trial enrolled 649 patients at research centers across Asia-Pacific, Europe, and North America. Patients were randomized 1:1 to receive either tislelizumab plus chemotherapy or placebo plus chemotherapy.

About Esophageal Squamous Cell Carcinoma

There are two main types of esophageal cancer, based on the cells where cancer develop: squamous cell carcinoma (ESCC) and adenocarcinoma (EAC). ESCC is the most common subtype of esophageal cancer, accounting for more than 85% of esophageal cancers worldwide.[i,ii] Because many patients are diagnosed with ESCC at later stages of disease, management of ESCC is challenging and the overall prognosis remains poor.[iii,iv,v]

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 drug from BeiGene's immuno-oncology biologics program and is being developed internationally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

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

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 2,900 colleagues dedicated to advancing more than 100 clinical trials that have involved more than 14,500 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 the U.S., China, the European Union, Great Britain, Canada, Australia, and additional international markets; 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, including a biologics license application (BLA) under U.S. Food and Drug Administration (FDA) review, 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, 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 plans for development and regulatory filings of tislelizumab in ESCC 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 annual report on Form 10-K 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.

[i] Wang QL, et al. Clin Epidemiol 2018;10:717–728.

[ii] Huang FL, Yu SJ. Asian J Surg 2018;41:210–215.

[iii] American Cancer Society. What is Esophageal Cancer? Available at https://www.cancer.org/cancer/esophagus-cancer/about/what-is-cancer-of-the-esophagus.html. Accessed August 2021.

[iv] Codipilly DC et al. Gastrointest Endosc. 2018 Sep; 88(3): 413–426.

[v] Abnet CC et al. Gastroenterology. 2018 Jan; 154(2): 360–373.

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