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): December 19, 2021

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 (NASDAQ)**
Ordinary Shares, par value $0.0001 per share*	**06160**	**The Stock Exchange of Hong Kong Limited (HKEx)**
RMB Shares, par value $0.0001 per share**	**688235**	**The Science and Technology Innovation Board of the Shanghai Stock Exchange (STAR)**

*Included in connection with the registration of the American Depositary Shares ("ADSs") 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 HKEx.

**The RMB shares are ordinary shares of the company issued to permitted investors in the People's Republic of China and listed and traded on the STAR in Renminbi. The RMB shares are not listed for trading in the United States or on the HKEx and are not fungible with the ordinary shares listed on the HKEx or the ADSs representing the ordinary shares listed on NASDAQ, and in no event will any RMB shares be able to be converted into the ordinary shares listed on the HKEx or the ADSs listed on NASDAQ, or vice versa.

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 1.01. Entry into a Material Definitive Agreement.

On December 19, 2021, BeiGene Switzerland GmbH, a wholly-owned indirect subsidiary of BeiGene, Ltd. (collectively, "BeiGene" or the "Company"), entered into an Option, Collaboration and License Agreement (the "Collaboration Agreement") with Novartis Pharma AG ("Novartis"), pursuant to which BeiGene has granted Novartis an exclusive time-based option to receive an exclusive license to develop, manufacture and commercialize BeiGene's investigational TIGIT inhibitor ociperlimab in the United States, Canada, Mexico, member countries of the European Union, the United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan (the "Licensed Territory").

Under the Collaboration Agreement, BeiGene will receive an upfront cash payment of $300 million from Novartis and is eligible to receive an additional payment of $600 million or $700 million upon exercise by Novartis of an exclusive time-based option prior to mid-2023 or late-2023, respectively, subject to receipt of required antitrust approval. Additionally, following option exercise, BeiGene is eligible to receive up to $745 million upon the achievement of regulatory approval milestones, $1.15 billion upon the achievement of sales milestones, and tiered royalties based on percentages of annual net sales of ociperlimab in the Licensed Territory ranging from the high-teens to mid-twenties, with customary reductions in specified circumstances. Royalties are payable on a country-by-country basis from the time of the first commercial sale until the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity, or 10 years after the first commercial sale of ociperlimab in the country of sale.

Under the Collaboration Agreement, during the option period, Novartis has agreed to initiate, conduct and fund additional global clinical trials of ociperlimab in combination with tislelizumab in selected tumor types and BeiGene has agreed to expand enrollment in two ongoing trials. Additionally, following the option exercise, the companies have agreed to jointly develop ociperlimab in the Licensed Territory, with Novartis sharing development costs of global trials and responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals in the Licensed Territory. In addition, both companies may conduct clinical trials globally to explore potential combinations of ociperlimab with other cancer treatments. BeiGene will initially be responsible for supplying ociperlimab to Novartis, with Novartis having the right to conduct manufacturing for its use in the Licensed Territory after successful transfer of the manufacturing process. Following approval, BeiGene has agreed to provide 50% of the co-detailing and co-field medical efforts in the United States, and has an option to co-detail up to 25% in Canada and Mexico, in each case funded in part by Novartis. Each party retains the worldwide right to commercialize its proprietary products in combination with ociperlimab, as is the case with tislelizumab under the parties' existing collaboration agreement. BeiGene retains the rights to manufacture and supply a specified percentage of commercial supply of ociperlimab from its planned U.S. manufacturing facility to be built in Hopewell, New Jersey.

The Collaboration Agreement contains customary representations, warranties and covenants by BeiGene and Novartis. Unless earlier terminated, the agreement will expire on a country-by-country basis upon the expiration of the royalty term in such country. The Collaboration Agreement will expire in its entirety upon the expiration of all applicable royalty terms under the agreement in all countries in the Licensed Territory. The agreement may be terminated by Novartis upon 120 days' prior written notice if delivered before first commercial sale or 180 days' prior written notice if delivered following first commercial sale of ociperlimab in the Licensed Territory, or by either party upon the other party's bankruptcy or uncured material breach. BeiGene may terminate the agreement in its entirety upon written notice if Novartis challenges the licensed BeiGene patents. Either party may terminate the agreement in its entirety effective immediately upon written notice to the other party (i) if the option terminates or expires, or (ii) in the event that the license effective date has not occurred within six months after the date of the Hart-Scott-Rodino Antitrust Improvements Act filing, subject to extension.

The foregoing summary description of the Collaboration Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Collaboration Agreement, which the Company intends to file as an exhibit to a subsequent periodic report or on an amendment to this Current Report on Form 8-K.

* * *

The representations and warranties and other statements in the Collaboration Agreement (1) speak only as to the date on which they were made, and may be modified or qualified by confidential schedules or other disclosures, agreements or understandings among the parties, which the parties believe are not required by the securities laws to be publicly disclosed, and (2) may be subject to a different materiality standard than the standard that is applicable to disclosures to investors. Moreover, it was advised that information concerning the subject matter of the representations and warranties and other statements made in the Collaboration Agreement would likely change after the execution date of such agreement, and subsequent information may or may not be fully reflected in the Company's public disclosures. Accordingly, investors should not rely upon representations and warranties and other statements in the Collaboration Agreement as factual characterizations of the actual state of affairs of the Company. Investors should instead look to disclosures contained in the Company's reports under the Securities Exchange Act of 1934, as amended (the "Exchange Act").

Item 7.01. Regulation FD Disclosure.

On December 20, 2021, the Company issued a press release announcing the transactions described in this Current Report on Form 8-K. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and shall not be deemed to be "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 of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing or this Current Report.

Item 8.01. Other Events.

On December 19, 2021, BeiGene Suzhou Co., Ltd., a wholly-owned indirect subsidiary of BeiGene, Ltd. ("BeiGene Suzhou"), entered into a Market Development Agreement (the "Market Development Agreement") with Beijing Novartis Pharma Co., Ltd. ("Novartis Beijing"), pursuant to which BeiGene Suzhou will obtain the right to market and promote five Novartis Beijing approved and nationally reimbursed oncology products for an initial period of seven years in China's broad markets, which include approximately 13,000 hospitals in cities and counties with smaller populations, where roughly 500,000 people with cancer receive their medical care. These products include: TAFINLAR® (dabrafenib), a BRAF inhibitor, and MEKINIST® (trametinib), a MEK inhibitor, both approved for the treatment of melanoma; VOTRIENT® (pazopanib), a VEGFR inhibitor for advanced renal cell carcinoma; AFINITOR® (everolimus), an mTOR inhibitor, for advanced renal cell carcinoma following progression on or after vascular endothelial growth factor (VEGF)-targeted therapy; and ZYKADIA® (ceritinib), an ALK inhibitor approved for ALK+ NSCLC. Under the agreement, BeiGene Suzhou is eligible to receive certain payments calculated based on sales. The agreement may be terminated by either party upon specified circumstances, including upon the other party's bankruptcy or uncured material breach.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release titled "BeiGene Expands Collaboration with Novartis to Develop and Commercialize BeiGene's TIGIT Inhibitor and Market Five Novartis Oncology Medicines in China Broad Markets", issued by BeiGene, Ltd. on December 20, 2021.
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Forward Looking Statements

This Current Report on Form 8-K and the materials furnished herewith contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws, including statements regarding the further advancement of, and anticipated clinical development, regulatory milestones, and commercialization of ociperlimab; and the option exercise by Novartis, the potential payments to be received by BeiGene, the receipt of required antitrust approval, and the parties' commitments and the potential benefits of the ociperlimab collaboration and broad markets agreements. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the possibility that BeiGene will not realize the expected benefits of the transactions; the possibility that BeiGene or Novartis will fail to fully perform their respective obligations under the ociperlimab collaboration and broad markets agreements; 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 the Company's clinical development, regulatory, commercial 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. BeiGene cautions you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. BeiGene disclaims any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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: December 20, 2021

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

Exhibit 99.1

BeiGene Expands Collaboration with Novartis to Develop and Commercialize BeiGene's TIGIT Inhibitor and Market Five Novartis Oncology Medicines in China Broad Markets

Strategic collaboration expected to advance clinical development of ociperlimab in combination with tislelizumab, including initiation and funding by Novartis of additional studies

BeiGene expands commercial portfolio in China broad markets with marketing rights for five Novartis Oncology products

BASEL, CAMBRIDGE, Mass. & BEIJING—(BUSINESS WIRE)—December 20, 2021—BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160; SSE: 688235), a global science-driven biotechnology company, today announced an option, collaboration and license agreement with Novartis Pharma AG to develop, manufacture and commercialize BeiGene's investigational TIGIT inhibitor ociperlimab in North America, Europe, and Japan. In addition, the parties entered into an agreement granting BeiGene rights to market, promote and detail five approved Novartis oncology products, TAFINLAR® (dabrafenib), MEKINIST ® (trametinib), VOTRIENT® (pazopanib), AFINITOR® (everolimus), and ZYKADIA® (ceritinib), across designated regions of China referred to as "broad markets."

Building upon the collaboration between BeiGene and Novartis for anti-PD1 antibody tislelizumab announced in January 2021, BeiGene has granted Novartis an exclusive time-based option under which, upon exercise by Novartis prior to late 2023, the companies have agreed to jointly develop ociperlimab, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals in the licensed territory. During the option period Novartis will conduct and fund additional global clinical trials of ociperlimab in combination with tislelizumab in selected tumor types. In addition, following option exercise, both companies may conduct clinical trials globally to explore combinations of ociperlimab with other cancer treatments. Following approval, BeiGene will co-detail the product in the United States.

Ociperlimab is an investigational potent TIGIT inhibitor with intact Fc function, believed to be critical for the anti-tumor activities of TIGIT antibodies. An immune checkpoint molecule, ociperlimab is currently being investigated in two global Phase 3 clinical trials, the AdvanTIG-301 and AdvanTIG-302 trials, in combination with tislelizumab in NSCLC. To date, approximately 600 subjects have been enrolled across the ociperlimab development program, which includes six global trials in patients with lung cancers, esophageal squamous cell carcinoma, and cervical cancer.

"We are excited to expand our productive collaboration with Novartis to include the development of ociperlimab, one of the most advanced TIGIT inhibitor programs. Building on the work accomplished with Novartis on the tislelizumab program, we are excited to explore additional synergies among our pipelines, and to potentially expedite access to ociperlimab," said John V. Oyler, Co-Founder, CEO, and Chairman of BeiGene. "In addition, our strong science-based commercial team in China, which is now more than 3,100 people, is well positioned to help deliver the five Novartis oncology medicines to the patients who need them across parts of China. This multi-faceted and important collaboration stands on the strong foundation our companies have built together, and our shared commitment to serving patients around the world."

Ociperlimab Option, Collaboration and License Agreement

Under the terms of the agreement, BeiGene will receive an upfront cash payment of $300 million from Novartis along with an additional payment of $600 or $700 million upon exercise by Novartis of an exclusive time-based option prior to mid-2023 or between then and late-2023, subject to receipt of required antitrust approval. In addition, following option exercise, BeiGene is eligible to receive up to $745 million upon the achievement of regulatory approval milestones, $1.15 billion upon the achievement of sales milestones, and royalties on future sales of ociperlimab in the licensed territory. The licensed territory is the same as the tislelizumab collaboration, the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan. Subject to the terms of the agreement, during the option period, Novartis will initiate and fund additional global clinical trials with ociperlimab and BeiGene has agreed to expand enrollment in two ongoing trials. Additionally, following the option exercise, Novartis has agreed to share development costs of global trials. Following approval, BeiGene has agreed to provide 50 percent of the co-detailing and co-field medical efforts in the United States, and has an option to co-detail up to 25 percent in Canada and Mexico, funded in part by Novartis. Each party retains the worldwide right to commercialize its propriety products in combination with ociperlimab, as is the case with tislelizumab under the parties' existing agreement.

Market Development of Novartis Products in China Broad Markets

Under the terms of the market development agreement, BeiGene will obtain the right to market and promote five Novartis approved and nationally reimbursed oncology products in designated regions of China referred to as Broad Markets. These products include:

- TAFINLAR® (dabrafenib), a BRAF inhibitor, and MEKINIST ® (trametinib), a MEK inhibitor, both approved for the treatment of melanoma. This combination is also being investigated for NSCLC indications;
- VOTRIENT® (pazopanib), a VEGFR inhibitor for advanced renal cell carcinoma;
- AFINITOR® (everolimus); an mTOR inhibitor, for advanced renal cell carcinoma following progression on or after vascular endothelial growth factor (VEGF)-targeted therapy; and

- ZYKADIA® (ceritinib), an ALK inhibitor approved for ALK+ NSCLC.

The Broad Market territories in China include approximately 13,000 hospitals, in cities and counties with smaller populations, where roughly 500,000 people with cancer in China receive their medical care. BeiGene has significant market penetration in the Broad Markets for its own and in-licensed approved products.

About Ociperlimab

Ociperlimab is an investigational humanized IgG 1 monoclonal antibody discovered and being developed globally by BeiGene. An immune checkpoint molecule, ociperlimab is one of the most advanced anti-TIGIT antibodies in development with intact Fc function. Targeting TIGIT provides a potential mechanism to rescue immune cells (e.g., T cells, NK cells, and dendritic cells) from the immunosuppressive tumor microenvironment, to induce an efficient antitumor immune response. The TIGIT pathway has been understood to cooperate with PD-1 to maximize the suppression of effector tumor infiltrating immune cells as well as to promote resistance to anti-PD-1 therapy. TIGIT represents a promising target with the potential to significantly improve and/or extend the therapeutic benefit of anti-PD-1 therapy to a greater number of patients.

Ociperlimab is currently being investigated in combination with BeiGene's anti-PD-1 antibody, tislelizumab, in multiple ongoing trials, including:

- AdvanTIG-301: Phase 3 trial (NCT04866017) in locally advanced, unresectable non-small cell lung cancer;
- AdvanTIG-302: Phase 3 trial in untreated non-small cell lung cancer (NCT04746924);
- AdvanTIG-202: Phase 2 trial in metastatic cervical cancer (NCT04693234);
- AdvanTIG-203: Phase 2 trial in advanced esophageal squamous cell carcinoma (NCT04732494);
- AdvanTIG-204: Phase 2 trial in untreated limited-stage small cell lung cancer (NCT04952597);
- AdvanTIG-205: Phase 2 trial in untreated metastatic non-small cell lung cancer (NCT05014815);
- AdvanTIG-206: Phase 2 trial in first-line advanced hepatocellular carcinoma (NCT04948697); and
- Phase 1b trial in advanced solid tumors (NCT04047862).

BeiGene's Collaboration with Novartis

In January 2021 BeiGene and Novartis announced a collaboration granting Novartis rights to develop, manufacture, and commercialize BeiGene's anti-PD1 antibody tislelizumab in North America, Europe, and Japan. Since closing the collaboration in February 2021, the companies have accomplished key objectives in their collaboration, including filing the first biologics license application (BLA) for tislelizumab outside of China. The U.S. Food and Drug Administration (FDA) accepted for review the BLA submission for patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic therapy. The Prescription Drug User Fee Act (PDUFA) target action date is July 12, 2022, and the companies are working closely together on launch preparation activities as well as other planned BLA submissions and combination strategies for tislelizumab within each company's product portfolio and pipeline. Building upon that progress and the shared commitment to expanding patient access to new treatments, the companies have entered into a new agreement to collaborate on the development, manufacturing and commercialization of BeiGene's investigational TIGIT inhibitor ociperlimab.

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 team of approximately 2,750 colleagues dedicated to advancing more than 90 ongoing or planned clinical trials (over 70 clinical trials are ongoing) involving more than 14,000 patients and healthy volunteers. 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 United States, China, the EU, 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 collaborations including with Amgen, Mirati Therapeutics, Seagen, and Zymeworks.

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 approximately 8,000 colleagues across five continents. To learn more about BeiGene, please visit www.beigene.com.

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 further advancement of, and anticipated clinical development, regulatory milestones, and commercialization of ociperlimab and tislelizumab; the expected expansion and acceleration of clinical development of ociperlimab; the option exercise by Novartis, the potential payments to be received by BeiGene, the receipt of required antitrust approval, and the parties' commitments and the potential benefits of the ociperlimab collaboration and broad markets agreements; 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; and the impact of the COVID-19 pandemic on the Company's clinical development, regulatory, commercial 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.

BeiGene Investor

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