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): January 11, 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**
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 1.01. Entry into a Material Definitive Agreement.

On January 11, 2021, BeiGene Switzerland GmbH, a wholly-owned indirect subsidiary of BeiGene, Ltd. (collectively, "BeiGene" or the "Company"), entered into a Collaboration and License Agreement (the "Collaboration and License Agreement") with Novartis Pharma AG ("Novartis"), pursuant to which BeiGene will grant Novartis the right to develop, manufacture and commercialize BeiGene's anti-PD-1 antibody tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan (the "Licensed Territory").

Under the Collaboration and License Agreement, BeiGene will receive an upfront cash payment of $650 million from Novartis. Additionally, BeiGene is eligible to receive up to $1.3 billion upon the achievement of regulatory milestones, $250 million upon the achievement of sales milestones, and tiered royalties based on percentages of annual net sales of tislelizumab in the Licensed Territory ranging from the high-teens to high-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 tislelizumab in the country of sale.

Under the Collaboration and License Agreement, BeiGene and Novartis have agreed to jointly develop tislelizumab in the Licensed Territory, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials to explore potential combinations of tislelizumab with other cancer treatments. BeiGene will be responsible for funding the ongoing clinical trials of tislelizumab, and Novartis has agreed to fund any new registrational, bridging, or post-marketing studies in the Licensed Territory. Subject to specified conditions, BeiGene and Novartis have agreed to jointly fund other new clinical trials in the Licensed Territory agreed by the parties, provided that each party will be responsible for funding clinical trials evaluating tislelizumab in combination with its own- or third-party cancer treatments. BeiGene will initially be responsible for supplying tislelizumab to Novartis, with Novartis having the right to conduct manufacturing for its use in the Licensed Territory after successful transfer of the manufacturing process. In addition, BeiGene has an option to co-detail the product in the United States, Canada and Mexico, on an indication-by-indication basis, funded in part by Novartis. Each party retains the worldwide right to commercialize its propriety products in combination with tislelizumab.

The Collaboration and License 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 and License Agreement will expire in its entirety upon the expiration of all applicable royalty terms under the agreement in all countries in the Licensed Territory. BeiGene may terminate the agreement in its entirety upon written notice (i) if Novartis challenges the licensed BeiGene patents, or (ii) if Novartis files a biologics license application for its anti-PD-1 antibody, spartalizumab, in the Licensed Territory, and BeiGene does not elect to include spartalizumab as a licensed product under the Collaboration and License Agreement or Novartis does not divest the product candidate, in which case Novartis would pay BeiGene a specified termination fee. 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 tislelizumab in the Licensed Territory, or by either party upon the other party's bankruptcy or uncured material breach.

The transaction contemplated under the Collaboration and License Agreement is expected to close in the first quarter of 2021, subject to expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

* * *

The foregoing summary description of the Collaboration and License Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Collaboration and License 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 and License 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 and License 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 and License 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 January 11, 2021, the Company issued a press release announcing the above-described transaction. 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 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued on January 11, 2021, furnished herewith.
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 tislelizumab; the parties' commitments and the potential benefits of the collaboration, and the conditions to closing and expected timing for the closing of the transaction. Actual results may differ materially from those indicated in the forward-looking statements as a result of various important factors, including the possibility that the closing conditions set forth in the Collaboration and License Agreement, including, those related to antitrust clearance, will not be met and that the parties will be unable to consummate the proposed transaction; the possibility that BeiGene will not realize the expected benefits of the transaction; the possibility that BeiGene or Novartis will fail to fully perform their respective obligations under the Collaboration and License Agreement; 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 products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and the impact of the COVID-19 pandemic on the Company's clinical development, 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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99.1	Press Release issued on January 11, 2021, furnished herewith.
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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: January 11, 2021

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

Exhibit 99.1

BeiGene Announces Collaboration with Novartis to Develop and Commercialize Anti-PD-1 Antibody Tislelizumab

Novartis to co-develop and commercialize tislelizumab in North America, Japan, EU, and six other European countries

BeiGene to receive $650 million upfront payment and is eligible to receive up to $1.55 billion in potential regulatory and sales milestone payments plus royalties on product sales

BeiGene has the option to co-detail tislelizumab in North America

Both parties have freedom to conduct combination trials globally

CAMBRIDGE, Mass. and BEIJING, China, January 11, 2021 (BUSINESSWIRE) -- BeiGene, Ltd. (NASDAQ: BGNE; HKEX: 06160), a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide, today announced a collaboration and license agreement with Novartis Pharma AG to develop, manufacture and commercialize BeiGene's anti-PD-1 antibody tislelizumab in the United States, Canada, Mexico, member countries of the European Union, United Kingdom, Norway, Switzerland, Iceland, Liechtenstein, Russia, and Japan. The Companies have agreed to jointly develop tislelizumab in these licensed countries, with Novartis responsible for regulatory submissions after a transition period and for commercialization upon regulatory approvals. In addition, both companies may conduct clinical trials globally to explore combinations of tislelizumab with other cancer treatments, and BeiGene has an option to co-detail the product in North America, funded in part by Novartis.

Tislelizumab is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. It is approved and marketed by BeiGene in China in two indications, classical Hodgkin's lymphoma (cHL) following at least two prior therapies and locally advanced or metastatic urothelial carcinoma (UC) with PD-L1 high expression. In addition, three supplemental new drug applications for tislelizumab have been accepted by the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) and are under review. These indications are first-line treatment of patients with advanced squamous non-small cell lung cancer (NSCLC) in combination with chemotherapy, first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, and previously treated unresectable hepatocellular carcinoma.

"We are excited to collaborate with Novartis to further explore the potential of tislelizumab in multiple combinations and indications. Novartis is a well-recognized leader in oncology with a unique portfolio of cancer treatments and pipeline agents," said John V. Oyler, Co-Founder, CEO, and Chairman of BeiGene. "This important collaboration stands on a strong foundation of tislelizumab's broad global development program, which has delivered two approvals in China, currently spans 15 potentially registration-enabling clinical trials, and has enrolled over 7,700 patients to date, including approximately 2,500 patients in more than 20 countries and regions outside of mainland China. We look forward to working with Novartis to fulfill the global opportunity of this potentially differentiated anti-PD-1 antibody."

Under the agreement BeiGene will receive an upfront cash payment of $650 million from Novartis. BeiGene is eligible to receive up to $1.3 billion upon the achievement of regulatory milestones, $250 million upon the achievement of sales milestones, and royalties on future sales of tislelizumab in the licensed territory. Under the terms of the agreement, BeiGene will be responsible for funding ongoing clinical trials of tislelizumab, Novartis has agreed to fund new registrational, bridging, or post-marketing studies in its territory, and each party will be responsible for funding clinical trials evaluating tislelizumab in combination with its own or third party products. Each party retains the worldwide right to commercialize its propriety products in combination with tislelizumab.

Closing of the transaction is subject to the expiration or early termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

BeiGene Presentation at J.P. Morgan Healthcare Conference

The Company will present at the 39th Annual J.P. Morgan Healthcare Conference on Thursday, January 14 at 5:20 p.m. ET.

A live webcast of the conference call can be accessed from the investors section of BeiGene's website at http://ir.beigene.com or http://hkexir.beigene.com. An archived replay will be available after the event for 90 days.

About Tislelizumab

Tislelizumab (BGB-A317) is a humanized IgG4 anti-PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages. In pre-clinical studies, binding to FcγR 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 globally as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

Tislelizumab received conditional approval from the China NMPA as a treatment for patients with cHL who received at least two prior therapies and for patients with locally advanced or metastatic UC with PD-L1 high expression whose disease progressed during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. Complete approval for these indications may be contingent upon results from ongoing randomized, controlled confirmatory clinical trials.

In addition, three sNDAs for tislelizumab have been accepted by the CDE of the NMPA and are under review, for first-line treatment of patients with advanced squamous NSCLC in combination with chemotherapy, for first-line treatment of patients with advanced non-squamous NSCLC in combination with chemotherapy, and for previously treated unresectable HCC.

Currently, 15 potentially registration-enabling clinical trials are being conducted in China and globally, including 13 Phase 3 trials and two pivotal Phase 2 trials.

Tislelizumab is not approved for use outside of China.

About Tislelizumab Clinical Program

Clinical trials of tislelizumab include:

- Phase 3 trial comparing tislelizumab to salvage chemotherapy in patients with relapsed/refractory classical Hodgkin Lymphoma (NCT04486391);
- Phase 3 trial in patients with locally advanced or metastatic urothelial carcinoma (NCT03967977);
- Phase 3 trial comparing tislelizumab with docetaxel in the second- or third-line setting in patients with NSCLC (NCT03358875);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced squamous NSCLC (NCT03594747);
- Phase 3 trial of tislelizumab in combination with chemotherapy versus chemotherapy as first-line treatment for patients with advanced non-squamous NSCLC (NCT03663205);
- Phase 3 trial of tislelizumab in combination with platinum-based doublet chemotherapy as neoadjuvant treatment for patients with NSCLC (NCT04379635);
- Phase 3 trial of tislelizumab combined with platinum and etoposide versus placebo combined with platinum and etoposide in patients with extensive-stage small cell lung cancer (NCT04005716);
- Phase 3 trial comparing tislelizumab with sorafenib as first-line treatment for patients with hepatocellular carcinoma (HCC; NCT03412773);
- Phase 2 trial in patients with previously treated unresectable HCC (NCT03419897);
- Phase 3 trial comparing tislelizumab with chemotherapy as second-line treatment for patients with advanced esophageal squamous cell carcinoma (ESCC; NCT03430843);
- Phase 3 trial of tislelizumab in combination with chemotherapy as first-line treatment for patients with ESCC (NCT03783442);
- Phase 3 trial of tislelizumab versus placebo in combination with chemoradiotherapy in patients with localized ESCC (NCT03957590);
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment for patients with gastric cancer (NCT03777657);
- Phase 2 trial in patients with MSI-H/dMMR solid tumors (NCT03736889); and
- Phase 3 trial of tislelizumab combined with chemotherapy versus placebo combined with chemotherapy as first-line treatment in patients with nasopharyngeal cancer (NCT03924986).

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 5,000+ employees in China, the United States, Australia, Europe, and elsewhere are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology products: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

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 tislelizumab; the parties' commitments and the potential benefits of the collaboration, and the conditions to closing and expected timing for the closing of the transaction. 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 products and drug candidates, if approved; BeiGene's ability to obtain and maintain protection of intellectual property for its technology and drugs; BeiGene's reliance on third parties to conduct drug development, manufacturing and other services; BeiGene's limited operating history and BeiGene's ability to obtain additional funding for operations and to complete the development and commercialization of its drug candidates; and the impact of the COVID-19 pandemic on the Company's clinical development, 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.

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