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 9, 2019**

BEIGENE, LTD.
(Exact name of registrant as specified in its charter)

Cayman Islands	**001-37686**	**98-1209416**
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

c/o Mourant Ozannes Corporate 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 8.01 Other Events.

On April 9, 2019, BeiGene, Ltd. (the "Company") issued a joint press release with BioAlta, LLC announcing that the two companies have entered into a global co-development and collaboration agreement for the development, manufacturing and commercialization of BioAlta's investigational Conditionally Active Biologic CTLA-4 antibody (BA3071). The full text of this press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits .

Exhibit No.	Description
99.1	Press Release titled "BioAlta and BeiGene Form Worldwide Collaboration to Develop and Commercialize Novel Conditionally Active Biologic CTLA-4 Therapy" issued on April 9, 2019

Exhibit Index

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SIGNATURES

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.

Date: April 10, 2019

BEIGENE, LTD.

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

BIOATLA AND BEIGENE FORM WORLDWIDE COLLABORATION TO DEVELOP AND COMMERCIALIZE NOVEL CONDITIONALLY ACTIVE BIOLOGIC CTLA-4 THERAPY

Plan to pursue development as a monotherapy and in combination with BeiGene's investigational anti-PD-1 antibody, tislelizumab

San Diego, CA; Beijing, China and Cambridge, MA, – April 9, 2019 – BioAtla ®, LLC, a global clinical-stage biotechnology company focused on the development of Conditionally Active Biologic (CAB) protein therapeutics, and BeiGene, Ltd. (Nasdaq: BGNE; HKEX: 06160), a commercial-stage biopharmaceutical company focused on developing and commercializing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, today announced that the two companies have entered into a global co-development and collaboration agreement for the development, manufacturing and commercialization of BioAtla's investigational CAB CTLA-4 antibody (BA3071). BA3071 is a novel, CTLA-4 inhibitor that is designed to be conditionally activated in the tumor microenvironment in order to reduce systemic toxicity and potentially enable safer combinations with checkpoint inhibitors such as BeiGene's investigational anti-PD-1 antibody, tislelizumab, a humanized IgG4 anti–PD-1 monoclonal antibody specifically designed to minimize binding to FcγR on macrophages.

Under the terms of the collaboration, BioAtla will co-develop the CAB-CTLA-4 antibody to defined early clinical objectives and BeiGene will then lead the parties' joint efforts to develop the product candidate and be responsible for global regulatory filings and commercialization. Subject to the terms of the agreement, BeiGene will hold a co-exclusive license with BioAtla to develop and manufacture the product candidate globally and an exclusive license to commercialize the product candidate globally. BeiGene will be responsible for all costs of development, manufacturing and commercialization in Asia (ex-Japan), Australia and New Zealand, and the parties will share development and manufacturing costs and commercial profits and losses upon specified terms in the rest of the world. BioAtla will receive an upfront payment of $20 million and a milestone payment upon reaching the defined early clinical objectives. BioAtla is also eligible to receive up to $249 million in subsequent development and regulatory milestones globally and commercial milestones in the BeiGene territory, together with tiered royalties on sales in the BeiGene territory. Additional terms of the agreement were not disclosed.

"BeiGene is a recognized leader in China-inclusive global clinical development, with broad oncology clinical programs, which include tislelizumab," said Scott Smith, President of BioAtla. "This collaboration complements our strategy of building our pipeline of innovative CAB oncology candidates, advancing combination product therapies, and effectively addressing markets with strong growth potential and high unmet medical need."

"BioAtla has developed an exciting proprietary protein discovery and expression platform to generate CABs, which in turn have been applied to BA3071, a novel, investigational CTLA-4 inhibitor that is designed to be conditionally activated in the tumor microenvironment," commented Dr. Lai Wang, Senior Vice President, Asia Pacific Clinical Development, Global Research, Clinical Operations and Biometrics, for BeiGene. "The unique nature of BA3071 provides an exciting opportunity to combine this CTLA-4 antibody with our anti-PD-1 antibody, tislelizumab. We look forward to working with BioAtla through proof-of-concept, followed by global development of this potentially unique cancer therapy as a single agent or in combination with other therapies."

"We believe that our collaboration with BeiGene will accelerate the global development and potential commercialization of BA3071 and advance the prospects and potential of safer and more effective combination therapies for the treatment of several cancer indications," stated Jay M. Short, Ph.D., Chairman, CEO and co-founder of BioAtla. "The application of BioAtla's CAB technology to CTLA-4 inhibition may offer greater potency and safety, thereby improving this important cancer therapy and

expanding its potential applications.”

About BA3071

BA3071 is a novel, investigational conditionally active CTLA-4 inhibitor. The first investigational new drug (IND) filing is currently planned for mid-2019. Subject to regulatory clearance of the IND, a Phase 1/2 multi-center, open-label study designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity and antitumor activity of BA3071 alone and in combination with BeiGene’s tislelizumab, an investigational anti-PD-1 inhibitor, is anticipated to start in the second half of 2019.

The cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) is an inhibitory receptor expressed on T cells. The CTLA-4 pathway is a key immune checkpoint pathway that provides a downregulating signal to T cells. The blockade of CTLA-4 is intended to induce an antitumor immune response by promoting the activation and proliferation of tumor-specific T cells. Although inhibition of CTLA-4 has been shown to significantly improve antitumor response, it may also lead to immune attack of healthy cells. To minimize on-target off-tumor toxicity, BioAtla has applied its proprietary CAB technology with the intent to activate binding to the CTLA-4 receptor only on T cells in the tumor microenvironment.

Inhibition of immune checkpoints using anti-programmed cell death-1 (PD-1) or anti-CTLA-4 monoclonal antibodies has revolutionized the management of patients with advanced-stage melanoma and are among the most promising components of treatment approaches for many other cancers. Employing BioAtla’s proprietary CAB technology, BA3071 is designed to improve the efficacy and safety of anti-CTLA-4 therapy, as a monotherapy and in combination with other therapies, by restricting its activation and that of tumor specific T cells to the tumor microenvironment.

About Conditionally Active Biologics (CABs)

Conditionally Active Biologics are proteins generated using BioAtla’s proprietary protein discovery, evolution and expression technologies. These proteins can be monoclonal antibodies, enzymes and other proteins designed with functions dependent on changes in micro physiological conditions (*e.g.* , pH level, oxidation, temperature, pressure, presence of certain ions, hydrophobicity and combinations thereof) both outside and inside cells.

Studies have shown that cancerous tumors create highly specific conditions at their site that are not present in normal tissue. These cancerous microenvironments are primarily a result of the well understood unique glycolytic metabolism associated with cancer cells, referred to as the Warburg Effect in aerobic cancer cells. CAB proteins are designed to deliver their therapeutic payload and/or recruit the immune response in specific and selected locations and conditions within the body and to be active only in the presence of a particular cellular microenvironment. In addition, the activation is designed to be reversible to repeatedly switch ‘on and off’ should the CAB move from a diseased to a normal cellular microenvironment and vice versa. CABs can be developed in a variety of formats, including antibodies, antibody drug conjugates (ADCs), bispecifics, chimeric antigen receptor T-cells (CAR-Ts) and combination therapies.

About Tislelizumab

Tislelizumab (BGB-A317) is an investigational 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 candidate produced from BeiGene’s immuno-oncology biologic program, and is being developed as a monotherapy and in combination with other therapies for the treatment of a broad array of both solid tumor and hematologic cancers.

Clinical trials of tislelizumab include a global Phase 3 clinical trial in patients with second-line non-small cell lung cancer (NSCLC); a global Phase 3 clinical trial in first-line patients with hepatocellular carcinoma (HCC); a global Phase 3 clinical trial in second-line patients with esophageal squamous carcinoma (ESCC); a global Phase 3 clinical trial in first-line patients with gastric cancer (GC); a global Phase 3 clinical trial in first-line patients with ESCC; a global Phase 3 trial in patients with Stage III NSCLC; a global Phase 2 clinical trial in second- or third-line patients with HCC; a global Phase 1 clinical trial in patients with relapsed/refractory (R/R) NK/T-cell lymphomas; and a global Phase 1 clinical trial in patients with solid tumors. In China, BeiGene has completed a pivotal Phase 2 clinical trial in patients with R/R classical Hodgkin’s lymphoma (cHL), and is conducting a Phase 3 clinical trial in first-line patients with non-squamous NSCLC; a Phase 3 clinical trial in first-line patients with squamous NSCLC; a Phase 2 clinical trial in second-line urothelial cancers (UC); and a Phase 2 clinical trial in patients with

MSI-H or dMMR solid tumors.

The new drug application (NDA) in China for R/R cHL has been accepted by the China National Medical Products Administration (NMPA) and granted priority review.
BeiGene and Celgene Corporation have a global strategic collaboration for the development of tislelizumab in solid tumor cancers outside of Asia (except Japan).

About BioAtla, LLC

BioAtla is a global clinical-stage biotechnology company with operations in San Diego, California, and Beijing, China. BioAtla develops novel monoclonal antibody and other protein therapeutic product candidates designed to have more selective targeting, greater efficacy, and more cost-efficient and predictable manufacturing than traditional antibodies. BioAtla has two programs currently in Phase 1/2 clinical testing in the United States, BA3011, a novel conditionally active AXL-targeted antibody-drug conjugate (CAB-AXL-ADC), and BA3021, a novel conditionally active ROR2-targeted antibody-drug conjugate (CAB-ROR2-ADC).

About BeiGene

BeiGene is a global, commercial-stage, research-based biotechnology company focused on molecularly-targeted and immuno-oncology cancer therapeutics. With a team of over 2,200 employees in China, the United
States, Australia and Europe, BeiGene is advancing a pipeline consisting of novel oral small molecules and monoclonal antibodies for cancer. BeiGene is also working to create combination solutions aimed to have both a meaningful and lasting impact on cancer patients. BeiGene markets ABRAXANE ® (nanoparticle albumin–bound paclitaxel), REVLIMID ® (lenalidomide), and VIDAZA (azacitidine) ® in China under a license from Celgene Corporation. [1]

BeiGene Cautionary Note Regarding BeiGene's 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 future research, development and potential commercialization activities under the agreement with BioAtla, potential payments payable to BioAtla, the speed and outcome of drug development plans, the advancement of and anticipated clinical development, regulatory milestones and commercialization of BA3071 and tislelizumab, potential advantages and differentiation of BA3071 and tislelizumab, BioAtla's and BeiGene's development and commercial plans, and other information that is not historical information. 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, 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.

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