

BeiGene, Ltd.
Form 8-K
July 06, 2017

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): **July 5, 2017**

BEIGENE, LTD.

(Exact name of registrant as specified in its charter)

Cayman Islands
(State or other jurisdiction
of incorporation)

001-37686
(Commission File Number)

98-1209416
(I.R.S. Employer Identification No.)

c/o Maurant Ozannes Corporate Services (Cayman) Limited

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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

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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.

Summary

On July 5, 2017, BeiGene, Ltd. (*BeiGene* or the *Company*) announced a strategic collaboration with Celgene Corporation (*Celgene*) pursuant to which Celgene will have the exclusive right to develop and commercialize BeiGene's investigational anti-programmed cell death protein 1 (*PD-1*) inhibitor, BGB-A317, in patients with solid tumor cancers in the United States, Europe, Japan and the rest of world outside Asia. The parties will also collaborate on up to eight registrational studies for BGB-A317 in solid tumors, including studies currently being planned by BeiGene. BeiGene will retain exclusive rights for the development and commercialization of BGB-A317 for hematological cancers globally and for solid tumors in China and the rest of Asia, other than Japan. Upon closing, BeiGene will receive \$263 million in upfront license fees and a \$150 million equity investment from Celgene at a 35% premium, and will be eligible to receive up to \$980 million in development, regulatory and sales milestone payments and royalties in the low-double digit to mid-twenty percentages on any future sales of BGB-A317, based on specified terms.

In connection with the PD-1 collaboration, the parties also announced that BeiGene will acquire Celgene's commercial operations and sales force in China, excluding Hong Kong, Macau and Taiwan, and gain an exclusive license in that territory to commercialize Celgene's approved cancer therapies, ABRAXANE®, REVLIMID®, and VIDAZA®, and its investigational agent CC-122 in clinical development (the *Celgene Products*).

The transactions have been approved by the boards of directors of both companies and are expected to close in the third quarter of 2017, subject to the expiration or termination of applicable waiting periods under all applicable antitrust laws and satisfaction of other customary closing conditions.

The principal agreements for the transactions are further summarized below.

Exclusive License and Collaboration Agreement

On July 5, 2017, BeiGene entered into an Exclusive License and Collaboration Agreement with Celgene and its wholly-owned subsidiary, Celgene Switzerland LLC (*Celgene Switzerland*), pursuant to which the Company has agreed to grant the Celgene parties an exclusive right to develop and commercialize BGB-A317 in all fields of treatment, other than hematology, in the United States, Europe, Japan and the rest of world other than Asia (the *PD-1 License Agreement*).

Pursuant to the terms of the PD-1 License Agreement, the Celgene parties will make upfront payments to the Company of \$263 million. The Company may also receive up to \$980 million in potential development, regulatory and sales milestone payments and tiered royalties based on percentages of annual net sales, depending on specified terms, in the low double digit to mid-twenties, with customary reductions in specified circumstances. Royalties are payable on a licensed product-by-product and country-by-country basis until the latest of the expiration of the last valid patent claim, the expiration of regulatory exclusivity or 12 years after the first commercial sale of such licensed product in the country of sale.

Each party has the right to develop and commercialize BGB-A317 in their respective fields and territories, and have also agreed to collaborate through a joint steering committee comprised of an equal number of representatives from each party on, among other things, the conduct of up to eight global registrational clinical trials (Basket Studies). Each Basket Study will be conducted and funded by either the Company or Celgene in accordance with a mutually agreed development plan and study design. For any Basket Studies conducted and funded by the Company, Celgene has the right to opt into such program, at which time it will reimburse the Company for agreed upon development costs based on a multiple of such costs that varies according to the stage of development at which Celgene opts into the program. Celgene has committed to use commercially reasonable efforts to develop at least one licensed product and to seek specified regulatory approvals, and to spend at least \$100 million on development for the Basket Studies led by Celgene, subject to specified conditions. In addition, BeiGene retains the right to develop BGB-A317 in combination therapies with its portfolio compounds, and Celgene has a right of first negotiation for BGB-A317 in the hematology field and in BeiGene s territory, subject to specified conditions.

The PD-1 License Agreement contains customary representations, warranties and covenants by the Company and Celgene. Unless earlier terminated, the agreement will expire on a licensed product-by-product and country-by-country basis upon the expiration of the royalty term in such country for such licensed product. The agreement may be terminated by Celgene upon 30 days' prior written notice, or by either party upon the other party's bankruptcy or uncured material breach.

The PD-1 License Agreement is subject to the closing of the other transactions described in this Current Report on Form 8-K, and the expiration or termination of applicable waiting periods under all applicable antitrust laws.

Share Subscription Agreement

In connection with the PD-1 License Agreement, on July 5, 2017, the Company also entered into a Share Subscription Agreement (the "Share Subscription Agreement") with Celgene Switzerland pursuant to which the Company will issue and sell to Celgene Switzerland \$150 million worth of the Company's ordinary shares, par value \$0.0001 per share, consisting of 32,746,416 ordinary shares, or approximately 5.9% of the Company's outstanding shares as of the date of the agreement, at a price per share equal to \$4.58, or \$59.55 per American Depositary Share ("ADS"), which represents a 35% premium over the 11-day volume weighted average price of the Company's ADSs on The NASDAQ Global Select Market during the period from June 16, 2017 through June 30, 2017.

Pursuant to the Share Subscription Agreement, Celgene has agreed to a lock-up for one year, a standstill, and a voting agreement for the duration of the standstill period, all under specified circumstances and as set forth in the agreement. Celgene will also have specified registration rights in the event the purchased shares are not eligible for sale under Rule 144 upon expiration of the lock-up.

The Share Subscription Agreement contains customary representations and warranties and may be terminated at any time prior to closing by (i) mutual written consent of the parties; (ii) upon written notice by either party before December 31, 2017 if the closing has not been consummated by that date; (iii) either party if certain closing conditions are not met; or (iv) by either party upon the other party's uncured material breach of the Share Subscription Agreement.

The closing of the share purchase is subject to the effectiveness of the PD-1 License Agreement, customary closing conditions, and the expiration or termination of applicable waiting periods under all applicable antitrust laws.

The offer and sale of the shares to be issued pursuant to the Share Subscription Agreement will be made in a private placement in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), for transactions by an issuer not involving a public offering, and/or Regulation D under the Securities Act. All certificates evidencing the shares will bear a standard restrictive legend under the Securities Act.

The foregoing summary description of the Share Subscription Agreement does not purport to be complete and is subject to, and qualified in its entirety by, the full text of the Share Subscription Agreement, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K, and which is incorporated herein by reference.

Celgene China Agreements

On July 5, 2017, the Company and a wholly-owned subsidiary of Celgene, Celgene Logistics Sàrl (Celgene Logistics), entered into a License and Supply Agreement (the China License Agreement), pursuant to which the Company will be granted the right to exclusively distribute and promote the Celgene Products in China, excluding Hong Kong, Macau and Taiwan (the Commercial Territory). In addition, if Celgene decides to commercialize a new oncology product through a third party in the Commercial Territory during the first five years of the term, the Company has a right of first negotiation to obtain the right to commercialize the product, subject to certain conditions.

The term of the China License Agreement is 10 years and may be terminated by either party upon written notice in the event of uncured material breach or bankruptcy of the other party, or if the underlying regulatory approvals for

the covered products are revoked. Celgene Logistics also has the right to terminate the agreement with respect to REVLIMID® at any time upon written notice to the Company.

The China License Agreement contains customary representations and warranties and confidentiality and mutual indemnification provisions, and is subject to the closing of the acquisition transaction described below.

On July 5, 2017, a wholly owned subsidiary of the Company, BeiGene (Hong Kong) Co., Ltd., acquired 100% of the equity interests of Celgene Pharmaceutical (Shanghai) Co., Ltd. (Celgene Shanghai), a wholly foreign-owned subsidiary of Celgene Holdings East Corporation established under the laws of China, for an undisclosed cash payment. Celgene Shanghai is in the business of, among other things, providing marketing and promotional services in connection with certain pharmaceutical products manufactured by its affiliates. Prior to closing, Celgene Shanghai will separate certain business functions, including regulatory and drug safety, that will continue to support the business acquired by BeiGene. The acquisition is subject to customary closing conditions, including receipt of governmental approvals.

* * *

The foregoing descriptions of the terms of the PD-1 License Agreement and the China License Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such agreements, which the Company intends to file as exhibits 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 various agreements (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 various agreements would likely change after the execution date of such agreements, 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 various agreements 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.

Item 3.02 Unregistered Sales of Equity Securities.

The disclosure set forth under Item 1.01 under the caption Share Subscription Agreement is incorporated by reference into this Item 3.02.

Item 7.01 Regulation FD Disclosure.

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On July 5, 2017, the Company issued a joint press release with Celgene announcing the above-described transactions. 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 Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section 11 and 12(a)(2) of the Securities Act of 1933, as amended.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

| Exhibit No. | Description |
|-------------|--|
| 10.1 | Share Subscription Agreement, dated July 5, 2017, by and between Celgene Switzerland LLC and the Company |
| 99.1 | Press Release issued on July 5, 2017, furnished herewith |

Forward Looking Statements

This Current Report on Form 8-K and the materials furnished herewith contain forward-looking information about BeiGene within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein and therein which do not describe historical facts, including, among others, statements regarding each party's respective performance of its obligations under the various agreements, including with respect to funding additional clinical trials and conducting commercialization activities; anticipated clinical development plans and costs; expected timing for the closing of the transactions under the various agreements; the timing and amounts of future milestone and royalty payments; and those statements in the materials furnished herewith that are designated as forward-looking statements are forward-looking statements which involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements.

Such risks and uncertainties include, among others, (1) the possibility that the closing conditions set forth in the various agreements, including, those related to antitrust clearance, will not be met and that the parties will be unable to consummate the proposed transactions; (2) the possibility that BeiGene will not realize the expected benefits of the transactions, including the anticipated market opportunity; (3) the possibility that significant safety problems could arise with respect to product candidates; (4) uncertainties relating to the manufacture and commercialization; (5) uncertainties relating to patents and proprietary rights; (6) that the cost of the transaction to BeiGene will be more than planned and/or will not provide the intended positive financial results; (7) that BeiGene or Celgene will fail to fully perform their respective obligations under the various agreements; and (8) other risks identified in BeiGene's Securities and Exchange Commission (SEC) filings, including its Annual Report on Form 10-K for the year ended December 31, 2016, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017 and subsequent filings with the SEC. 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.

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: July 6, 2017

BEIGENE, LTD.

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

Exhibit Index

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