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BeiGene, Ltd.
百濟神州有限公司
(incorporated in the Cayman Islands with limited liability)
(Stock Code: 06160)

OVERSEAS REGULATORY ANNOUNCEMENT – FORM 8-K

This announcement is issued pursuant to Rule 13.10B of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

Please refer to the attached for the document which has been published by BeiGene, Ltd. on the website of the U.S. Securities and Exchange Commission on March 8, 2024.

By order of the Board
BeiGene, Ltd.
Mr. John V. Oyler
Chairman

Hong Kong, March 8, 2024

As of the date of this announcement, the Board of Directors of the Company consists of Mr. John V. Oyler as Chairman and Executive Director, Dr. Xiaodong Wang as Non-executive Director, and Dr. Olivier Brandicourt, Dr. Margaret Han Dugan, Mr. Donald W. Glazer, Mr. Michael Goller, Mr. Anthony C. Hooper, Mr. Ranjeev Krishana, Dr. Alessandro Riva, Dr. Corazon (Corsee) D. Sanders and Mr. Qingqing Yi as Independent Non-executive Directors.

**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): March 8, 2024

BEIGENE, LTD.
(Exact Name of Registrant as Specified in Charter)

Cayman Islands
(State or Other Jurisdiction of
Incorporation)

001-37686
(Commission File Number)

98-1209416
(I.R.S. Employer Identification Number)

c/o Maurant 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:

| <u>Title of each class</u> | <u>Trading Symbol(s)</u> | <u>Name of each exchange on which registered</u> |
|-----------------------------------------------------------------------------------------------------------|--------------------------|--------------------------------------------------|
| 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 8.01. Other Events.

On March 8, 2024, BeiGene, Ltd. (“BeiGene”) filed patent infringement suits under the Hatch-Waxman Act against Sandoz Inc. (“Sandoz”) and separately against MSN Pharmaceuticals, Inc. and MSN Laboratories Private Ltd. (collectively “MSN”) in the United States District Court for the District of New Jersey. The patent infringement suits are in response to Sandoz’s and MSN’s notices to BeiGene concerning the filings of Abbreviated New Drug Applications (“ANDAs”) with the U.S. Food and Drug Administration (“FDA”), seeking FDA approval to market a generic version of BRUKINSA[®] (zanubrutinib) along with “Paragraph IV certifications” challenging certain BRUKINSA Orange Book patents for invalidity, unenforceability and/or non-infringement. According to the notices, neither Sandoz nor MSN have challenged BRUKINSA’s composition of matter patent, which remains intact and protects BRUKINSA[®] from generic competition until its expiration in 2034.

BeiGene’s complaints allege that by filing the ANDAs, each of Sandoz and MSN has infringed BRUKISNA’s Orange Book patents included in their respective Paragraph IV certifications, and seek a permanent injunction to prevent Sandoz and MSN from commercializing a generic version of BRUKINSA until the expiration of the asserted patents.

ANDA litigation is common in the U.S. pharmaceutical industry. We may receive additional notices from other generic drug companies and may file additional ANDA lawsuits in the future.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

104 The cover page from this Current Report on Form 8-K, formatted in Inline XBRL

Exhibit Index

| Exhibit No. | Description |
|-------------|-------------------------------------------------------------------------------|
| 104 | The cover page from this Current Report on Form 8-K, formatted in Inline XBRL |

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: March 8, 2024

By: /s/ Chan Lee
Name: Chan Lee
Title: Senior Vice President, General Counsel