

Item 8.01. Other Events.

On November 14, 2024, BeiGene USA, Inc. and BeiGene Switzerland GmbH (collectively, “BeiGene”), each a subsidiary of BeiGene, Ltd. (the “Company”), entered into a settlement agreement (the “Settlement Agreement”) with MSN Pharmaceuticals, Inc. and MSN Laboratories Private Ltd. (collectively “MSN”) resolving patent litigation related to the Company’s product, BRUKINSA® (zanubrutinib). The patent litigation was brought by BeiGene against MSN in response to MSN’s filing of an Abbreviated New Drug Application (“ANDA”) with the U.S. Food and Drug Administration (“U.S. FDA”), seeking approval to market a generic version of BRUKINSA and challenging certain BRUKINSA Orange Book patents for invalidity, unenforceability and/or non-infringement. The composition of matter patent for BRUKINSA, expiring in April 2034, was not challenged by MSN in the litigation. As a result of the Settlement Agreement, BeiGene granted MSN the right to sell a generic version of BRUKINSA in the United States no earlier than June 15, 2037, subject to potential acceleration or extension under circumstances customary for settlement of this type. Pursuant to the Settlement Agreement, the parties have filed a joint stipulation to dismiss the suit with the court. As required by law, BeiGene and MSN will submit the Settlement Agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice.

BeiGene and Sandoz Inc. (“Sandoz”) have previously filed a joint stipulation to dismiss the patent litigation brought by BeiGene against Sandoz in response to Sandoz’s filing of an ANDA with the U.S. FDA, seeking approval to market a generic version of BRUKINSA and challenging certain BRUKINSA Orange Book patents for invalidity, unenforceability and/or non-infringement. The suit was thereafter dismissed by the United States District Court for the District of New Jersey.

The settlement with MSN and the dismissal of the Sandoz litigation resolve all patent litigation brought by BeiGene against the companies that filed ANDAs seeking approval to market generic versions of BRUKINSA.

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

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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: November 19, 2024

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