

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): November 10, 2023



NEUROCRINE BIOSCIENCES, INC.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

0-22705
(Commission
File Number)

33-0525145
(IRS Employer
Identification No.)

12780 El Camino Real,
San Diego, California
(Address of Principal Executive Offices)

92130
(Zip Code)

(858) 617-7600

(Registrant's telephone number, including area code)

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	Name of each exchange on which registered
Common Stock, \$0.001 par value	NBIX	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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 November 10, 2023, Neurocrine Biosciences, Inc. (the “Company”) entered into an agreement (the “Zydus Agreement”) with Zydus Worldwide DMCC, Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Limited (collectively, “Zydus”) resolving patent litigation related to INGREZZA[®], the Company’s medication for the treatment of tardive dyskinesia and chorea associated with Huntington’s disease. The patent litigation was filed by the Company in the United States District Court for the District of Delaware in response to Zydus notifying the Company that they had submitted an Abbreviated New Drug Application (ANDA) to the United States Food and Drug Administration seeking approval to market generic versions of INGREZZA prior to expiration of the Company’s Orange Book listed patents. As a result of the Zydus Agreement, the Company has granted Zydus the right to sell generic versions of INGREZZA in the United States beginning October 1, 2038, or earlier under certain circumstances. As required by law, the Company and Zydus will submit the Zydus Agreement to the United States Federal Trade Commission and the United States Department of Justice.

The Company previously entered into agreements resolving similar patent litigation with each of a) Sandoz Inc. (“Sandoz”), and Crystal Pharmaceutical (Suzhou) Co., Ltd. and Crystal Pharmatech Co., Ltd. (collectively, “Crystal”) (Sandoz and Crystal, collectively, the “Sandoz Parties”; b) Teva Pharmaceuticals, Inc., Teva Pharmaceuticals Development, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, “Teva”); and c) Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, “Lupin”). Pursuant to the terms of the respective agreements with the Sandoz Parties, Teva, Lupin, and Zydus, each of Teva, the Sandoz Parties, Lupin, and Zydus has the right to sell generic versions of INGREZZA in the United States beginning March 1, 2038, or earlier under certain circumstances.

The settlements with Teva, the Sandoz Parties, Lupin and Zydus resolve all patent litigation brought by the Company against the companies that filed ANDAs seeking approval to market generic INGREZZA.

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.

NEUROCRINE BIOSCIENCES, INC.

Dated: November 13, 2023

/s/ Darin M. Lippoldt

Darin M. Lippoldt

Chief Legal Officer