
**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): September 28, 2023

HARMONY BIOSCIENCES HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-39450
(Commission
File Number)

82-2279923
(IRS Employer
Identification No.)

630 W. Germantown Pike, Suite 215
Plymouth Meeting, PA 19462
(Address of principal executive offices) (Zip Code)

(484) 539-9800
(Registrant's telephone number, including area code)

N/A
(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>
Common Stock, \$0.00001 par value per share	HRMY	The Nasdaq Global 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 September 28, 2023, Harmony Biosciences Holdings, Inc. (the "Company") received paragraph IV certification notices (the "Notices") from Novugen Pharma Sdn. Bhd. and Lupin Ltd. (together, the "ANDA Filers") advising that the ANDA Filers had each filed with the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA" and, together, the "ANDAs"), seeking approval to manufacture and sell a generic version of the Company's product WAKIX® (pitolisant) in the United States prior to the expiration of U.S. Patents Nos. 8,486,947 and 8,207,197 (the "Challenged Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book" and which expire September 26, 2029 and March 7, 2030 respectively. The Notices do not challenge U.S. Patent No. 8,354,430 which expires February 6, 2026. The Notices allege that the Challenged Patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of the generic product in the ANDAs. The Company is currently reviewing the Notices and intends to vigorously defend and enforce its intellectual property rights protecting WAKIX. As of the date of this filing, the Company is not aware of any other ANDA filers.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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.

HARMONY BIOSCIENCES HOLDINGS, INC.

Date: October 4, 2023

By: /s/ Christian Ulrich

Christian Ulrich

SVP & General Counsel
