

**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): December 18, 2023

Heron Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33221
(Commission
File Number)

94-2875566
(I.R.S. Employer
Identification No.)

4242 Campus Point Court, Suite 200, San Diego, CA
(Address of principal executive offices)

92121
(Zip Code)

Registrant's telephone number, including area code (858) 251-4400

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 (see General Instruction A.2. below):

- 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(s)	Name of each exchange on which registered
Common Stock, par value \$0.01 per share	HRTX	The Nasdaq Capital 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 December 18, 2023, Heron Therapeutics, Inc. (the “Company”) received a paragraph IV certification notice (the “Notice”) from Mylan Pharmaceuticals Inc. (“Mylan”) advising that Mylan filed with the U.S. Food and Drug Administration (“FDA”) an Abbreviated New Drug Application (“ANDA”), seeking approval to manufacture, use or sell a generic version of the Company’s product APONVIE® (aprepitant) in the United States prior to the expiration of U.S. Patents Nos. 9,561,229; 9,808,465; 9,974,742; 9,974,793; 9,974,794; 10,500,208; 10,624,850; 10,953,018; 11,173,118 and 11,744,800 (the “Challenged Patents”), which are listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations*, otherwise known as the “Orange Book” and each of which expire September 18, 2035. The Notice alleges that the Challenged Patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of the generic product described in the ANDA. The Company is currently reviewing the Notice and intends to vigorously defend and enforce its intellectual property rights protecting APONVIE®. As of the date of this filing, the Company is not aware of any other ANDA filers.

In accordance with the Hatch-Waxman Act, because APONVIE® is a new chemical entity, should the Company file a patent infringement lawsuit within 45 days of receipt of the Notice, the FDA cannot approve Mylan’s ANDA any earlier than 7.5 years from the approval of the APONVIE® NDA unless a District Court finds that all of the asserted claims of the patents-in-suit are invalid, unenforceable and/or not infringed.

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: December 22, 2023

Heron Therapeutics, Inc.

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer