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 3, 2024

Heron Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-33221**	**94-2875566**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

4242 Campus Point Court, Suite 200, San Diego, CA	**92121**
(Address of principal executive offices)	**(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 Regulation FD Disclosure.

As previously disclosed, on June 14, 2022, Heron Therapeutics, Inc. ("Heron" or the "Company") received a Notice Letter (the "Fresenius Kabi Notice") from Fresenius Kabi USA, LLC ("Fresenius Kabi") advising that Fresenius Kabi had submitted an ANDA to the FDA seeking approval to manufacture, use or sell a generic version of CINVANTI in the U.S. prior to the expiration of U.S. Patent 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; and 11,173,118 (the "CINVANTI Patents"), which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). The Fresenius Kabi Notice alleged that the CINVANTI Patents were invalid, unenforceable and/or would not be infringed by the commercial manufacture, use or sale of the generic product described in Fresenius Kabi's ANDA.

On July 27, 2022, the Company filed a complaint for patent infringement of the CINVANTI Patents against Fresenius Kabi and a related entity in the U.S. District Court for the District of Delaware (the "District Court") in response to Fresenius Kabi's ANDA filing (the "Delaware Litigation"). On May 15, 2024, the Court granted partial summary judgment of infringement for the Company and found no indefiniteness of U.S. Patent Nos. 9,561,229 and 9,974,794. On June 24, 2024, the parties completed a four-day bench trial centered on Fresenius's defense of obviousness of claims from U.S. Patent Nos. 9,561,229 and 9,974,794 that cover CINVANTI. Oral argument was held on August 29, 2024.

On December 3, 2024, the District Court issued a ruling in the Delaware Litigation in the Company's favor. The District Court found that the Company's U.S. Patent Nos. 9,561,229 and 9,974,794, which expire in 2035, are valid and would be infringed by Fresenius Kabi's proposed generic product. The District Court also requested that Heron submit a proposed final judgment reflecting the opinion by December 9, 2024. In view of the decision, the effective date of any final approval by the U.S. Food and Drug Administration of Fresenius Kabi's ANDA shall not be a date earlier than September 18, 2035, the expiration date of each of U.S. Patents Nos. 9,561,229 and 9,974,794.

This Current Report on Form 8-K contains forward-looking statements, including, without limitation, statements related to the potential timing for Fresenius Kabi to commercially launch its proposed generic product in the U.S. Forward-looking statements involve risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these risks and uncertainties, which include factors detailed from time to time under the caption "Risk Factors" in the Company's most recent Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and in the Company's other future filings with the Securities and Exchange Commission. The Company undertakes no duty to update these statements other than to the extent required by applicable law.

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.

Heron Therapeutics, Inc.

Date: December 3, 2024

/s/ Ira Duarte
Ira Duarte
Executive Vice President, Chief Financial Officer