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 13, 2020

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 Other Events.

On November 13, 2020, Heron Therapeutics, Inc. issued a press release announcing that the New Drug Application was resubmitted to the U.S. Food and Drug Administration for HTX-011, an investigational agent for the management of postoperative pain, as described in the press release filed herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 13, 2020
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.

Heron Therapeutics, Inc.

Date: November 13, 2020

/s/ David Szekeres
David Szekeres
Executive Vice President, Chief Operating Officer

Heron Therapeutics Resubmits New Drug Application to FDA for HTX-011 for the Treatment of Postoperative Pain

SAN DIEGO, Nov. 13, 2020 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced that the New Drug Application (NDA) was resubmitted to the U.S. Food and Drug Administration (FDA) for HTX-011, an investigational agent for the management of postoperative pain.

The NDA for HTX-011 was resubmitted based on the outcome and final minutes of a Type A End-of-Review meeting with the FDA in September, which was conducted to obtain clarity on the information needed to address the Complete Response Letter (CRL) issued by the FDA in June 2020. The CRL stated that the FDA is unable to approve the NDA in its present form based on the need for additional non-clinical information. There are four non-clinical issues in the CRL, three relate to confirming exposure of excipients in preclinical reproductive toxicology studies and the fourth relates to changing the manufacturing release specification of the allowable level of an impurity based on animal toxicology coverage. Since receiving the CRL, Heron generated data showing that peak plasma levels (Cmax) of excipients in reproductive toxicology studies are >50- to >200-fold higher than the levels observed in patients receiving the highest dose of HTX-011. These results provide validation of the previously submitted animal studies. At the Type A End-of-Review meeting in September, the FDA agreed with the change to the manufacturing specification proposed by Heron to address their concern. The FDA indicated at the Type A End-of-Review meeting that the submission will be classified as a Class 2 resubmission, which means that the FDA can take up to 6 months to review the new information included in the NDA resubmission.

“We are pleased to have resubmitted the NDA for HTX-011, which we believe fully addresses the CRL based on advice from the FDA,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “In our resubmission, we provided compelling evidence responding to the issues identified in the CRL that should provide the basis for the approval of the HTX-011 NDA. Heron remains committed to bringing HTX-011 to patients and we look forward to working with the FDA to achieve this goal.”

About HTX-011 for Postoperative Pain (ZYNRELEF™ in the European Union and European Economic Area)

HTX-011, an investigational non-opioid analgesic, is a dual-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. The FDA granted Breakthrough Therapy designation to HTX-011 and the NDA received Priority Review designation. A CRL was received from the FDA regarding the NDA for HTX-011 in June 2020 relating to non-clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls issues were identified. Heron’s New Drug Submission (NDS) for

HTX-011 for the management of postoperative pain was accepted by Health Canada. Heron is working to respond to a list of questions received from Health Canada in July 2020. In September 2020, the European Commission (EC) granted a marketing authorization for ZYNRELEF (also known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. The EC's centralized marketing authorization is valid for the 27 countries that are members of the European Union, and the other countries in the European Economic Area.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents for patients suffering from pain or cancer. For more information, visit www.herontx.com.

Forward-looking Statements

This news release contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. Heron cautions readers that forward-looking statements are based on management's expectations and assumptions as of the date of this news release and are subject to certain risks and uncertainties that could cause actual results to differ materially, including, but not limited to, those associated with: whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011 in the U.S.; the timing of the commercial launch of ZYNRELEF in Europe; the timing of Health Canada's NDS review process for HTX-011; whether Health Canada issues a Notice of Compliance for the NDS for HTX-011; the extent of the impact of the ongoing COVID-19 pandemic on our business; and other risks and uncertainties identified in the Company's filings with the U.S. Securities and Exchange Commission. Forward-looking statements reflect our analysis only on their stated date, and Heron takes no obligation to update or revise these statements except as may be required by law.

Investor Relations Contact:

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