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): October 28, 2019

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 October 28, 2019, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has accepted its New Drug Application (the "NDA") resubmission for HTX-011, an investigational agent for the management of postoperative pain, as described in the press release furnished herewith as Exhibit 99.1 (the "Press Release"). Additionally, the Company announced in the Press Release that the FDA set a Prescription Drug User Fee Act goal date of March 26, 2020 for the NDA, as further described in the Press Release furnished herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 28, 2019
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: October 28, 2019

/s/ David Szekeres

David Szekeres
Senior Vice President, General Counsel,
Business Development and Corporate Secretary

Exhibit 99.1

Heron Therapeutics Announces FDA Acceptance of New Drug Application Resubmission for HTX-011 for Management of Postoperative Pain

- FDA Sets Prescription Drug User Fee Act (PDUFA) Goal Date of March 26, 2020 -

SAN DIEGO, Calif. -- (PR NEWSWIRE) – October 28, 2019 -- 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 U.S. Food and Drug Administration (FDA) has accepted its New Drug Application (NDA) resubmission for HTX-011, an investigational agent for the management of postoperative pain. The FDA set a PDUFA goal date of March 26, 2020.

“HTX-011 was designated by the FDA as a Breakthrough Therapy for postoperative pain management and has the potential to be an important new pain management option for patients, which has been shown in Phase 3 clinical trials to significantly reduce postoperative pain, including severe pain, and to significantly reduce the need for opioids,” said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. “The recently reported topline results from Study 306 in patients undergoing knee replacement surgery who received HTX-011 as part of a common multimodal analgesic regimen showed that patients maintained an average pain score in the mild range for 72 hours after surgery with only 25% receiving a prescription for opioids upon hospital discharge. These results provide additional evidence that even in large painful surgical procedures HTX-011 can help to reduce both pain and the amount of opioid pills going out into society.”

“There remains a significant need for a new, non-opioid postoperative pain management option that can manage pain through the 72 hours after surgery, when pain is most intense,” said Roy G. Soto, MD, Director of Education and Anesthesiology Residency Program, Beaumont Health System. “The surgical setting is a key place we can have a dramatic impact on the opioid crisis, by reducing the amount of opioids used after surgery and, ultimately, the number of unused pills in our homes and communities.”

About HTX-011 for Postoperative Pain

HTX-011, an investigational agent, 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. HTX-011 was granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted a New Drug Application (NDA) to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A Complete Response Letter (CRL) was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to chemistry, manufacturing and controls and non-clinical information. No issues related to clinical

efficacy or safety were noted. Heron resubmitted an NDA to the FDA for HTX-011 in September 2019 and the FDA set a PDUFA goal date of March 26, 2020. A Marketing Authorisation Application (MAA) for HTX-011 was validated by the European Medicines Agency (EMA) in March 2019 for review under the Centralised Procedure.

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; the timing of the EMA Committee for Medicinal Products for Human Use (CHMP) review process for HTX-011; whether the European Commission authorizes the MAA for HTX-011; 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 and Media Contact:

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