

**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 1, 2019**

**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
<b>Common Stock, par value \$0.01 per share</b>	<b>HRTX</b>	<b>The Nasdaq Capital Market</b>

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 1, 2019, Heron Therapeutics, Inc. issued a press release announcing that it has resubmitted its New Drug Application to the U.S. Food and Drug Administration for the investigational agent HTX-011, a long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release, dated October 1, 2019</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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## 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 1, 2019

/s/ David Szekeres

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



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

SAN DIEGO, Calif. -- (PR NEWSWIRE) – October 1, 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 it has resubmitted its New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-011, an investigational agent for the management of postoperative pain. The Company anticipates a 6-month review by the FDA.

The NDA for HTX-011 was resubmitted based on the outcome and final minutes of a Type A meeting with the FDA, which was conducted to obtain clarity on the Complete Response Letter (CRL) issued by the FDA in April 2019. The CRL stated that the FDA was unable to approve the NDA in its present form based on the need for additional chemistry, manufacturing and controls and non-clinical information.

“We are pleased to have reached agreement with the FDA on the required information to include in the HTX-011 NDA resubmission to address the CRL,” said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. “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 that can significantly reduce postoperative pain, including severe pain, and help patients significantly reduce the need for opioids.”

### **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. 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.

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**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](http://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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