

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 26, 2017

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,
California

92121

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

(858) 251-4400

Not Applicable

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:

- 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))

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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 26, 2017, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has granted Fast Track designation to the Company's investigational agent, HTX-011, for local administration into the surgical site to reduce postoperative pain and the need for opioid analgesics for 72 hours, as 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 26, 2017

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated October 26, 2017

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.

October 26, 2017

By: /s/ David L. Szekeres

Name: David L. Szekeres

*Title: Senior Vice President, General Counsel, Business Development
and Corporate Secretary*

Heron Therapeutics Granted FDA Fast Track Designation for HTX-011 to Reduce Postoperative Pain and the Need for Opioid Analgesics for 72 Hours

*- First Opioid Alternative for Local Administration Into the Surgical Site
Granted Fast Track Designation -*

*- Phase 3 Studies for HTX-011 Ongoing;
NDA Filing Planned for 2018 -*

SAN DIEGO, Calif.— (BUSINESS WIRE) – October 26, 2017— Heron Therapeutics, Inc. (Nasdaq: HRTX) (the Company or Heron), a commercial-stage biotechnology company focused on developing novel best-in-class treatments to address some of the most important unmet patient needs, announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the Company’s investigational agent, HTX-011, for local administration into the surgical site to reduce postoperative pain and the need for opioid analgesics for 72 hours. Fast Track designation is a process designed to facilitate the development and expedite the review of new therapies to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA. Heron recently initiated the HTX-011 Phase 3 program and expects to file an NDA in 2018.

“Fast Track designation of HTX-011 is an important milestone in ongoing efforts to get ahead of the opioid crisis in America with preventative measures,” said Anita Gupta, D.O., Pharm.D., Senior Vice President, Medical Strategy and Government Affairs of Heron. “Over-reliance on postoperative opioids can become the gateway to addiction by exposing opioid naïve patients to potent and addictive narcotics and leaving hundreds of millions of leftover pills hiding in our community’s medicine cabinets. It is encouraging to see the FDA prioritize new options like HTX-011 that can help minimize or prevent exposure to opioids in the postoperative setting. This will be essential to stopping addiction before it begins.”

HTX-011 is the first and only long-acting, extended-release formulation of the anesthetic bupivacaine designed to address both postoperative pain and inflammation in a single administration at the surgical site. HTX-011 leverages meloxicam in our proprietary polymer formulation to potentiate the local anesthetic activity of bupivacaine over 72 hours. In Phase 2 clinical studies, HTX-011 has consistently demonstrated superiority over both placebo and bupivacaine, the current standard-of-care, in all surgical models evaluated and significantly reduced the need for opioids following surgery. The ongoing Phase 3 studies were designed using the following Phase 2 results for HTX-011:

Bunionectomy: HTX-011 60 mg reduced pain through 72 hours significantly better than placebo ($p=0.0003$) and bupivacaine 50 mg ($p=0.0166$)

- HTX-011 significantly increased the proportion of patients that were opioid-free through 72 hours after surgery, as compared to placebo ($p=0.0106$)

Hernia Repair: HTX-011 300 mg reduced pain through 72 hours significantly better than placebo ($p=0.0045$) and bupivacaine 75 mg ($p=0.0427$)

- HTX-011 significantly increased the proportion of patients that were opioid-free through 72 hours after surgery, as compared to placebo ($p=0.0001$) and bupivacaine 75 mg ($p=0.0108$)

“We are very pleased to receive Fast Track designation for HTX-011 and look forward to working closely with the FDA to bring this option to patients,” said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. “HTX-011 is the first opioid alternative for local administration into the surgical site to receive Fast Track designation and demonstrates the FDA’s commitment to addressing the opioid crisis. We expect to report top-line results from our pivotal Phase 3 studies in the first half of 2018 and then file for FDA review in the second half of 2018. Fast Track designation may allow us to expedite our commercial launch of HTX-011.”

About HTX-011 for Postoperative Pain

HTX-011, which utilizes Heron’s proprietary Biochronomer® drug delivery technology, is an investigational, long-acting, extended-release formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam for the prevention of postoperative pain. By delivering sustained levels of both a potent anesthetic and a local anti-inflammatory agent directly to the site of tissue injury, HTX-011 was designed to deliver superior pain relief while reducing the need for systemically administered pain medications such as opioids, which carry the risk of harmful side effects, abuse and addiction. The Phase 2 development program for HTX-011 was designed to target the many patients undergoing a wide range of surgeries who experience significant postoperative pain. Heron has recently initiated the HTX-011 Phase 3 program and expects to file an NDA in 2018.

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 that address some 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 cancer or pain. 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: the timing of completion and results of the Phase 3 studies for HTX-011; the timing of the HTX-011 NDA filing and review; the timing of the HTX-011 commercial launch; and other risks and uncertainties identified in the Company’s filings with the 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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