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): August 20, 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 7.01 Regulation FD Disclosure.

On August 20, 2019, Heron Therapeutics, Inc. issued a press release announcing that the results from the pivotal Phase 3 EPOCH 2 herniorrhaphy study of the investigational agent HTX-011 have been published online by the *Hernia* journal, 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 August 20, 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: August 20, 2019

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

Exhibit 99.1

Heron Therapeutics Announces Publication of Results from EPOCH 2, a Phase 3 Study of HTX-011 in Patients Undergoing Hernia Repair Surgery

SAN DIEGO, Calif. – (PR NEWSWIRE) – August 20, 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 results from EPOCH 2, a Phase 3 study of the investigational agent HTX-011 in open inguinal hernia repair surgery with mesh, have been published in the journal, *Hernia*, in an article entitled "HTX-011 reduced pain intensity and opioid consumption versus bupivacaine HCl in herniorrhaphy: results from the phase 3 EPOCH 2 study." HTX-011 achieved all primary and key secondary endpoints in EPOCH 2, demonstrating statistically significant reductions in both pain intensity and the use of opioid rescue medications following surgery and an increase in the proportion of patients who were opioid-free.

HTX-011 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. Heron has completed two pivotal Phase 3 studies of HTX-011: EPOCH 1 in bunionectomy, which is a study of a bony tissue surgical model, and EPOCH 2 in hernia repair, which is a study of a soft tissue surgical model.

In EPOCH 2, all primary and key secondary endpoints were achieved. HTX-011 provided superior and sustained pain reduction compared to placebo and bupivacaine solution through the critical 72-hour postoperative window, when pain is often most severe. Significant reductions in pain occurred both early (in the first 8 through 24 hours) and were sustained from 24 through 72 hours. In addition to reductions in average pain intensity scores, HTX-011 significantly reduced the proportion of patients experiencing severe pain through 72 hours compared to placebo and bupivacaine solution. Significant reductions in pain were consistent with the significant decrease in total opioid consumption and the significant increase in opioid-free patients receiving HTX-011, both through 72 hours and as compared to placebo and bupivacaine solution. HTX-011 was well tolerated, with a safety profile comparable to placebo and bupivacaine solution.

"Despite the many risks of opioid use, most patients undergoing hernia repair surgery are prescribed opioids after surgery," said Sonia Ramamoorthy, M.D., Chief of Colorectal Surgery at UC San Diego Health. "These data suggest HTX-011 can significantly reduce postoperative pain, including severe pain, and help patients reduce and even avoid the need for opioids. For the approximately 800,000 inguinal hernia repairs done in the United States each year, exposing fewer patients to opioids and discharging the majority of them without opioids could have a positive impact on the country's high rate of opioid dependency."

The *Hernia* article can be found here.

About EPOCH 2

EPOCH 2 was a randomized, placebo- and active-controlled, double-blind, pivotal Phase 3 clinical study evaluating the efficacy and safety of locally administered HTX-011 at 300 mg/9 mg bupivacaine/meloxicam compared to placebo and the standard dose of bupivacaine solution (75 mg) for postoperative pain control following hernia repair surgery in 418 patients. All primary and key secondary endpoints were achieved:

- There was a 23% reduction in pain intensity as measured by the Area Under the Curve (AUC) 0–72 when comparing HTX-011 to placebo ($p<0.001$).
- There was a 21% reduction in pain intensity as measured by AUC 0–72 when comparing HTX-011 to the current standard-of-care, bupivacaine solution ($p<0.001$).
- Over 72 hours post-surgery, patients receiving HTX-011 consumed 38% less opioids than patients receiving placebo ($p<0.001$) and 25% less opioids than patients receiving bupivacaine solution ($p=0.024$).
- 51% of patients receiving HTX-011 required no opioid medication for 72 hours post-surgery compared to only 22% receiving placebo ($p<0.001$) and 40% receiving bupivacaine solution ($p=0.049$). These results parallel the significantly reduced incidence of severe pain in patients receiving HTX-011 compared to both placebo (40% reduction; $p<0.001$) and bupivacaine solution (19% reduction; $p=0.037$).
- Among the HTX-011-treated patients who were opioid-free through 72 hours post-surgery, more than 84% remained opioid-free through day 28.
- HTX-011 was well tolerated, with a safety profile comparable to placebo and bupivacaine solution.

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 management 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. HTX-011 has been shown to reduce pain significantly better than placebo or bupivacaine solution in five diverse surgical models: hernia repair, abdominoplasty, bunionectomy, total knee arthroplasty and breast augmentation. 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 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. 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 Committtee 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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