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): September 16, 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 7.01 Regulation FD Disclosure.

On September 16, 2020, Heron Therapeutics, Inc. issued a press release announcing that the results from EPOCH 2 follow-on study (NCT03695367) of the investigational agent HTX-011 in open inguinal hernia repair surgery with mesh, have been published online by the journal, *Surgery* in an article entitled "Opioid-free recovery following herniorrhaphy with HTX-011 as the foundation of a multimodal analgesic regimen," 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 September 16, 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: September 16, 2020

/s/ David Szekeres
David Szekeres
Chief Legal, Business, and Administrative Officer

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

- Over 90% of Hernia Repair Patients Receiving HTX-011 Required No Opioids to Manage Their Postoperative Pain Through 72 hours After Surgery -

SAN DIEGO, Sept. 16, 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 results from EPOCH 2 follow-on study (NCT03695367) of the investigational agent HTX-011 in open inguinal hernia repair surgery with mesh, have been published online by the journal, *Surgery* in an article entitled "Opioid-free recovery following herniorrhaphy with HTX-011 as the foundation of a multimodal analgesic regimen." In this study, more than 90% of patients receiving HTX-011, along with postoperative over-the-counter (OTC) acetaminophen and ibuprofen, remained opioid-free throughout the 72-hour period following hernia repair surgery. The mean pain intensity never rose above the mild range through 72 hours following surgery.

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 (EPOCH 1 in bunionectomy and EPOCH 2 in hernia repair) 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 well tolerated, with a safety profile comparable to placebo and bupivacaine solution.

"Typically, the first 72 hours after surgery are the most difficult from a pain management perspective and is where patients experience the most severe pain requiring opioids," said Jay Redan, M.D., Chief of Surgery at AdventHealth Celebration. "The EPOCH 2 follow-on study provides important evidence that HTX-011, along with OTC analgesics, can keep patients in the mild pain range, allowing more than 90% to remain opioid-free. The study was able to identify patients who should receive an opioid discharge prescription and has the potential to personalize postoperative pain management so that opioids are only prescribed to those who will need them after discharge. This can help to substantially limit the amount of opioids going home with patients following hernia repair surgery."

The *Surgery* article can be found here.

About the EPOCH 2 Follow-On Study

The EPOCH 2 follow-on study was a multicenter, postoperative pain management study evaluating the efficacy and safety of locally administered HTX-011 300 mg bupivacaine / 9 mg meloxicam via needle-free application into the surgical site in combination with a postoperative non-opioid multimodal analgesia (MMA) regimen of over-the-counter oral acetaminophen and

ibuprofen in 63 patients. The study included two sequential cohorts, with identical procedures and MMA regimens, except that patients in Cohort 2 also received an intraoperative dose of ketorolac (15 mg or 30 mg, based on age, renal function and weight) prior to wound closure. The goal was to increase the proportion of opioid-free patients by combining HTX-011 with a postoperative regimen of readily available, oral analgesics. Key results of the study include the following:

- In total, more than 90% of patients in this study did not require opioids to manage their postoperative pain during the first 72 hours.
- Across all study patients, 87% were opioid-free through Day 10 and 83% were opioid-free throughout the entire 28-day follow-up period of the study.
- Patients in the study who required an opioid during the 72-hour postoperative period could be identified retrospectively with the following algorithm: pain score ≥6 at 2 hours postoperatively or received opioid rescue medication within the first 2 hours postoperatively.
- Mean pain intensity scores were similar between cohorts and never rose above the mild pain range (NRS <4) throughout the 72-hour postoperative period.
- Addition of an intraoperative dose of ketorolac did not provide additional benefit for pain intensity or opioid use.

HTX-011 was well tolerated, and co-administration with non-steroidal anti-inflammatory drugs did not affect the safety of HTX-011.

About HTX-011 for Postoperative Pain

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. HTX-011 was granted Breakthrough Therapy designation and received Priority Review designation. A complete response letter (CRL) was received from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for HTX-011 in June 2020 relating to non-clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls (CMC) issues were identified. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for HTX-011 under the proprietary name ZYNRELEF™ in July 2020. Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status and accepted by Health Canada. Heron is working to respond to a list of questions received from Health Canada in July 2020.

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: the timing of the NDA resubmission to the FDA; 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 European Commission’s (EC) review process for ZYNRELEF; whether the EC authorizes the Marketing Authorisation Application for ZYNRELEF; 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 Coronavirus Disease 2019 (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.

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