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): May 18, 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 8.01 Other Events.

On May 18, 2020, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that it has initiated a Phase 1b/2 clinical study in patients undergoing bunionectomy of HTX-034, Heron's next-generation product for the treatment of postoperative pain (the "Press Release"). The study initiation follows clearance from the U.S. Food and Drug Administration of the Company's Investigational New Drug application for HTX-034 for the treatment of postoperative pain. A copy of the Press Release is filed herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 18, 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: May 18, 2020

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

Heron Therapeutics Announces Initiation of Phase 1b/2 Clinical Study of HTX-034 for the Treatment of Postoperative Pain

SAN DIEGO, May 18, 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 it has initiated a Phase 1b/2 clinical study in patients undergoing bunionectomy of HTX-034, Heron's next-generation product for the treatment of postoperative pain. The study initiation follows clearance from the U.S. Food and Drug Administration (FDA) of Heron's Investigational New Drug application for HTX-034 for the treatment of postoperative pain.

HTX-034, an investigational non-opioid, is a fixed-dose combination, extended-release solution of the local anesthetic bupivacaine, the nonsteroidal anti-inflammatory drug meloxicam and an additional agent that further potentiates the activity of bupivacaine. HTX-034 is formulated in the same proprietary polymer as HTX-011. HTX-034 is designed to provide superior and prolonged analgesia and enhance the activity of the local anesthetic bupivacaine via two different mechanisms. Local administration of HTX-034 in a validated preclinical postoperative pain model resulted in sustained analgesia for 7 days.

The HTX-034 study is a randomized, active-controlled, double-blinded, Phase 1b/2 study in patients undergoing bunionectomy with an osteotomy and internal fixation. The study will evaluate the safety and efficacy of HTX-034 compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. The Phase 1b portion of the study is intended to select the optimal dose for the Phase 2 expansion portion.

"We are excited to progress HTX-034 into a proof-of-concept study in patients undergoing bunionectomy, a highly painful surgery, where we have the opportunity to evaluate the magnitude and duration of analgesia," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "In the same highly predictive animal model where we optimized HTX-011, HTX-034 has shown enhanced analgesic benefit for 7 days after surgery."

About HTX-034 for Postoperative Pain

HTX-034, an investigational non-opioid, is a fixed-dose combination, extended-release solution of the local anesthetic bupivacaine, the nonsteroidal anti-inflammatory drug meloxicam and an additional agent that further potentiates the activity of bupivacaine. HTX-034 is formulated in the same proprietary polymer as HTX-011. By combining two different mechanisms that each enhance the activity of the local anesthetic bupivacaine, HTX-034 is designed to provide superior and prolonged analgesia. Local administration of HTX-034 in a validated preclinical postoperative pain model resulted in sustained analgesia for 7 days.

About HTX-011 for Postoperative Pain

HTX-011, an investigational non-opioid, 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. The Prescription Drug User Fee Act (PDUFA) goal date is June 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. Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status by Health Canada in October 2019 and accepted by Health Canada in November 2019.

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 U.S. Food and Drug Administration (FDA) approves the New Drug Application (NDA) for HTX-011; the timing of the commercial launch of HTX-011; the timing of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) review process for HTX-011; whether the European Commission (EC) authorizes the Marketing Authorisation Application (MAA) for HTX-011; the timing of Health Canada's New Drug Submission (NDS) review process for HTX-011; whether Health Canada issues a Notice of Compliance for the NDS for HTX-011; the timing and results of studies for the HTX-034 development program; 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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