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 28, 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 September 28, 2020, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that the European Commission has granted a marketing authorization for ZYNRELEF™ (formerly known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults (the "Press Release"). 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 September 28, 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 28, 2020

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

Heron Therapeutics Receives European Commission Authorization for ZYNRELEF™ (HTX-011) for the Treatment of Postoperative Pain

SAN DIEGO, Sept. 28, 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 European Commission has granted a marketing authorization for ZYNRELEF (formerly known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. The marketing authorization follows the European Medicines Agency's (EMA) positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in July 2020. Heron currently expects to make ZYNRELEF available to patients in the European Union (EU) during 2021.

ZYNRELEF is a non-opioid, dual-acting analgesic, utilizing a fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. For approximately 72 hours after ZYNRELEF is applied into the surgical site, ZYNRELEF releases bupivacaine and meloxicam, which are then absorbed into the surrounding tissues. Meloxicam potentiates the effect of bupivacaine, resulting in an increase in analgesia.

The European Commission's authorization of ZYNRELEF is based on the results of Heron's two multi-center, double-blind, active and placebo-controlled Phase 3 studies of ZYNRELEF. The primary endpoint and all 4 key secondary endpoints were met in both Phase 3 studies. ZYNRELEF demonstrated significantly reduced pain and opioid use through 72 hours compared to saline placebo and to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. ZYNRELEF also significantly increased the proportion of patients who required no postoperative opioids. The most common side effect with ZYNRELEF is dizziness.

The European Commission's centralized marketing authorization is valid for the 27 countries that are members of the EU and the United Kingdom. Norway, Iceland and Liechtenstein will make corresponding decisions based on the decision of the European Commission.

"The authorization of ZYNRELEF in the EU is an important milestone for Heron, as well as for the millions of surgical patients in the EU for whom safety, pain relief and recovery are of primary importance," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. "With a novel dual mechanism of action, and single, needle-free application, ZYNRELEF has been clinically shown to better manage severe pain than standard-of-care bupivacaine over 72 hours and we believe that ZYNRELEF adds an effective therapeutic option for the management of postoperative pain for eligible patients."

About ZYNRELEF (Approved in the European Union)

ZYNRELEF, a 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 saline placebo and to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. ZYNRELEF is indicated for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. Efficacy and safety have not been established in major surgeries, including abdominal, vascular and thoracic surgeries. ZYNRELEF should be administered in a setting where trained personal and equipment are available to ensure prompt treatment of any toxic neurological or cardiac effects. ZYNRELEF received authorization from the European Commission in September 2020.

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. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation to HTX-011 and the New Drug Application (NDA) received Priority Review designation. A complete response letter (CRL) was received from the FDA regarding the 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. 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 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.

Investor Relations Contact:

David Szekeres
Chief Legal, Business and Administrative Officer
Heron Therapeutics, Inc.
dszekeres@herontx.com
858-251-4447

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