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): June 29, 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 June 29, 2020, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that it had received a Complete Response Letter from the U.S. Food and Drug Administration on June 26, 2020 for the Company's New Drug Application for the investigational agent HTX-011, a 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 (the "Press Release"). A copy of the Press Release is filed herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated June 29, 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: June 29, 2020

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

Exhibit 99.1

Heron Therapeutics Receives Complete Response Letter for HTX-011 for the Management of Postoperative Pain

- Complete Response Letter Requests Additional Non-Clinical Information -

- No Clinical Safety or Efficacy Issues and No Chemistry, Manufacturing and Controls (CMC) Issues Identified -

- Conference Call and Webcast Today at 9:00 a.m. ET -

SAN DIEGO, June 29, 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 received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) on June 26, 2020 regarding its New Drug Application (NDA) for HTX-011 for the management of postoperative pain.

The CRL stated that the FDA is unable to approve the NDA in its present form based on the need for additional non-clinical information. Based on the complete review of the NDA, the FDA did not identify any clinical safety or efficacy issues or CMC issues. There are four non-clinical issues in the CRL, none of which relate to any observed toxicity. Three relate to confirming exposure of excipients in preclinical reproductive toxicology studies, and the fourth relates to changing the manufacturing release specification of the allowable level of an impurity based on animal toxicology coverage. We do not believe that any of the issues are significant barriers to ultimate approval, as all of the excipients have extensive histories of use in pharmaceuticals and the specification can be revised. The Company will request a Type A meeting to obtain agreement with the Agency on our responses and resubmit the application as quickly as possible.

“We are committed to resolving the non-clinical issues outlined in the CRL with the FDA and resubmitting an NDA as soon as possible to bring this important non-opioid analgesic to patients,” said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron.

Conference Call and Webcast

Heron will host a conference call and webcast today, June 29, 2020, at 9:00 a.m. ET (6:00 a.m. PT). The conference call can be accessed by dialing 877-311-5906 for domestic callers and 281-241-6150 for international callers. Please provide the operator with the passcode 3252267 to join the conference call. The conference call will be available via webcast under the Investor Relations section of Heron's website at www.herontx.com. An archive of today's teleconference and webcast will be available on Heron's website for 60 days following the call.

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 June 26, 2020 relating to non-clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls (CMC) issues were identified. 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; 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:

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