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): April 1, 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))

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 April 1, 2019, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that the Marketing Authorisation Application (the "MAA") for its investigational agent, HTX-011, for postoperative pain, was validated by the European Medicines Agency (the "EMA"), which validation confirms that the submission is complete and starts the EMA's Centralised Procedure, as described in the press release furnished herewith as Exhibit 99.1 (the "Press Release").

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated April 1, 2019

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: April 1, 2019

/s/ David Szekeres

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

Heron Announces European Medicines Agency Validation of Marketing Authorisation Application for HTX-011 for Postoperative Pain Management

SAN DIEGO, Calif. – (PR NEWSWIRE) – April 1, 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 Marketing Authorisation Application (MAA) for its investigational agent, HTX-011, for postoperative pain, was validated by the European Medicines Agency (EMA). Validation of the MAA confirms that the submission is complete and starts the EMA's Centralised Procedure. The EMA granted eligibility to the Centralised Procedure for HTX-011 based on it meeting the criteria of a medicinal product constituting a significant scientific innovation. The Centralised Procedure allows applicants to receive a marketing authorisation that is valid throughout the European Union (EU). With the validation of the MAA, an opinion from the EMA Committee for Medicinal Products for Human Use (CHMP) would be anticipated in the first half of 2020.

HTX-011 is the first and only dual-acting local anesthetic. HTX-011's novel mechanism of action combines bupivacaine with low-dose meloxicam to overcome the challenges of the inflammatory process at the surgical site. HTX-011 has significantly reduced severe pain and the need for opioids better than standard-of-care bupivacaine solution over 72 hours following surgery.

The MAA for HTX-011 is supported by data from 7 completed Phase 2 and Phase 3 studies in more than 1,000 subjects across 5 different surgical models, which are also included in the New Drug Application (NDA) Heron submitted to the U.S. Food and Drug Administration (FDA).

HTX-011 is the only non-opioid pain medication to have been granted Fast Track designation, Breakthrough Therapy designation and Priority Review designation by the FDA. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of April 30, 2019 for the HTX-011 NDA.

"Improved post-operative pain management remains as much an unmet need in Europe as elsewhere," said Professor Richard Langford, Lead Consultant in Pain Medicine, The London Clinic and Chief Medical Officer, St Pancras Clinical Research. "Too many patients still report unacceptable levels of pain after surgery and side effects from opioids, resulting in delayed discharge and recovery and increasing the risk of complications and poorer overall treatment outcomes. Regimens that are easy to use and provide meaningful patient benefit through uninterrupted, effective pain management, particularly in the first few days after surgery, are required. I believe that HTX-011 shows tremendous promise in postoperative pain management and has the potential to change the treatment paradigm for postoperative pain in European practice."

"We are pleased that our MAA for HTX-011 was validated by the EMA," said Kimberly Manhard, Executive Vice President, Drug Development of Heron. "We believe that HTX-011 could have a considerable impact on the lives of patients by significantly reducing the proportion of patients who experience severe pain. We look forward to working closely with the EMA during the review process with the goal of bringing this important product to patients."

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 FDA in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted an NDA to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. The FDA set a PDUFA goal date of April 30, 2019. An MAA for HTX-011 was validated by the 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 HTX-011 NDA as submitted; the timing of the CHMP's review process for HTX-011; whether the EMA 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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