
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 14, 2015

Heron Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction
of incorporation)

001-33221

(Commission
File Number)

94-2875566

(I.R.S. Employer
Identification No.)

123 Saginaw Drive, Redwood City, California

(Address of principal executive offices)

94063

(Zip Code)

Registrant's telephone number, including area code:

650-366-2626

Not Applicable

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:

- 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))
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Item 8.01 Other Events.

On May 14, 2015, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has accepted the Company's proposal to use the 505(b)(2) development pathway for HTX-019, the Company's proprietary intravenous formulation of aprepitant for the prevention of chemotherapy induced nausea and vomiting, 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 May 14, 2015

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.

May 14, 2015

By: */s/ Esme C. Smith*

Name: Esme C. Smith

Title: VP, General Counsel & Secretary

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 14, 2015

Heron Therapeutics Announces Positive Outcome from Meeting with FDA for HTX-019

REDWOOD CITY, Calif. – May 14, 2015 – Heron Therapeutics, Inc. (NASDAQ: HRTX), announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's proposal to use the 505(b)(2) development pathway for HTX-019, Heron's proprietary intravenous formulation of aprepitant for the prevention of chemotherapy induced nausea and vomiting (CINV).

A 505(b)(2) application allows a portion of the information required for a New Drug Application (NDA) approval, such as safety and efficacy data on the active ingredient, to come from previously completed studies conducted by other parties. This pathway can lead to significantly reduced costs and time required for development compared with a traditional development path.

"We are extremely pleased that the FDA has accepted our proposal to develop and eventually register HTX-019 using the 505(b)(2) pathway," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "Injectable 5-HT₃ and NK₁ receptor antagonists are the backbone of CINV prophylaxis, representing U.S. sales of over 3.6 million units annually. With the potential approval of HTX-019 and 5-HT₃ receptor antagonist SUSTOL[®], our lead development candidate for the treatment of CINV, Heron would be the only company able to market intravenous formulations of both 5-HT₃ and NK₁ receptor antagonists."

About HTX-019 for Chemotherapy Induced Nausea and Vomiting

HTX-019 is a proprietary intravenous formulation of aprepitant, a neurokinin-1 (NK₁) receptor antagonist for the prevention of CINV. NK₁ receptor antagonists are typically used in combination with 5-HT₃ receptor antagonists. At present, the only injectable NK₁ receptor antagonist approved in the U.S. contains polysorbate 80, a surfactant, which may cause hypersensitivity reactions, infusion site reactions or other adverse reactions in some patients. Heron's formulation for HTX-019 does not contain polysorbate 80 and may have a lower incidence of certain types of adverse reactions than reported with the other commercially available injectable NK₁ receptor antagonist. Heron intends to file an NDA for HTX-019 using the 505(b)(2) pathway in the second half of 2016.

About SUSTOL[®] and Chemotherapy Induced Nausea and Vomiting

Heron's lead investigational product candidate, SUSTOL[®] (granisetron injection, extended release), is being developed for the prevention of both acute- and delayed-onset chemotherapy induced nausea and vomiting (CINV) following the administration of moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC) agents. Affecting 70-80% of patients undergoing chemotherapy, CINV is one of the most debilitating side effects of such treatments, often attributed as a leading cause of premature discontinuation of cancer treatment. Injectable 5-hydroxytryptamine type 3 (5-HT₃) receptor antagonists have been shown to be among the most effective and preferred treatments for CINV, however, an unmet medical need exists for patients suffering from CINV during the delayed-onset phase, which typically occurs 1-5 days following administration of chemotherapy agents. For delayed-onset CINV, only one injectable 5-HT₃ receptor antagonist is approved for use following the administration of MEC agents, and none are approved for use following administration of HEC agents. SUSTOL contains the 5-HT₃ receptor antagonist granisetron, selected due to its broad use by physicians based on a well-established record of safety and efficacy. SUSTOL is formulated with the Company's proprietary Biochronomer[®] drug delivery technology and in clinical trials has been shown to maintain therapeutic drug levels of granisetron for up to five days with a single subcutaneous injection.

About HTX-011 for Post-Operative Pain

HTX-011, which utilizes Heron's proprietary Biochronomer drug delivery technology, is a long-acting formulation of the local anesthetic bupivacaine in combination with the anti-inflammatory meloxicam for the prevention of post-operative pain. The effective management of pain with a reduction in the use of opioids remains an important area of unmet medical need, and HTX-011 could potentially provide a differentiated therapeutic profile with advantages compared to currently available pain management options. In a Phase 1 clinical trial, HTX-011 achieved the desired pharmacokinetic profile for both bupivacaine and meloxicam. Therapeutically relevant plasma bupivacaine levels were sustained for 2-3 days in the absence of the large initial peak that can be observed with commercially available formulations. The anesthetic effects of HTX-011 persisted through 96 hours, which closely correlated with plasma bupivacaine concentrations, and HTX-011 was well-tolerated with no serious adverse events.

About HTX-003 for Chronic Pain and Addiction

HTX-003, which utilizes Heron's proprietary Biochronomer drug delivery technology, is a long-acting formulation of buprenorphine for the management of chronic pain and opioid addiction. HTX-003 is designed to maintain therapeutic drug levels of buprenorphine for 30 days following a single subcutaneous injection with a low potential for patient abuse.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company using its proprietary technology and innovative efforts to develop products to address unmet medical needs. The Company's proprietary Biochronomer drug delivery technology is designed to improve the therapeutic profile of injectable pharmaceuticals. The Company's product development efforts focus on identifying current therapies with the potential to be reformulated to expand or extend therapeutic effect or duration of action, minimize drawbacks or

to apply new delivery methods. In addition, we continually evaluate potential development programs, technologies and product candidates that may be complementary to or synergistic with our existing programs and product development goals.

Forward Looking Statements

This news release contains “forward-looking statements” as defined by the Private Securities Litigation Reform Act of 1995. Heron Therapeutics cautions readers that forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include those associated with: the Company’s proposed refiling of its new drug application resubmission for SUSTOL, the potential regulatory approval of SUSTOL and the timing for such approval, if approved at all; the breadth of the scope of regulatory approval for SUSTOL, if approved; the progress in research and development of HTX-019, HTX-011, HTX-003 and our other product candidate programs, including the timing of preclinical activities and clinical studies; safety and efficacy data from our clinical studies that may not warrant further development of our product candidates or may not be sufficient to justify pursuit of commercialization of such product candidates; the launch and acceptance of new products generally; our financial position and our ability to raise additional capital to fund operations if necessary or to pursue additional business opportunities; strategic business alliances we may pursue or the potential acquisition of other products or technologies; and other risks and uncertainties identified in the Company’s filings with the Securities and Exchange Commission. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

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