
**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) August 9, 2016

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 CA
(Address of principal executive offices)

94063
(Zip Code)

Registrant's telephone number, including area code (650) 366-2626

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))
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ITEM 8.01 Other Events.

On August 10, 2016, Heron Therapeutics, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration has approved SUSTOL® (granisetron) extended-release injection for the prevention of chemotherapy-induced nausea and vomiting, as described in the press release furnished herewith as Exhibit 99.1.

A copy of presentation materials discussing SUSTOL, all or a part of which may be used by the Company in investor or scientific presentations from time to time, is furnished as Exhibit 99.2 hereto. The attached materials have also been posted on the Company’s website at www.herontx.com. The Company does not undertake any obligation to update this presentation.

ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated August 10, 2016
99.2	Corporate Presentation, dated August 10, 2016

SIGNATURE

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.

Date: August 10, 2016

Heron Therapeutics, Inc.

/s/ Brian Drazba

Brian Drazba

Vice President, Finance and Chief Financial Officer



Heron Therapeutics Announces U.S. FDA Approval of SUSTOL® (granisetron) Extended-Release Injection for the Prevention of Chemotherapy-Induced Nausea and Vomiting

- SUSTOL is the first extended-release 5-HT₃ receptor antagonist approved for the prevention of acute and delayed nausea and vomiting associated with both moderately emetogenic chemotherapy and anthracycline and cyclophosphamide combination chemotherapy regimens
- A standard of care in the treatment of breast cancer and other cancer types, AC-based regimens are among the most commonly prescribed highly emetogenic chemotherapy regimens as defined by both the National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO)
- U.S. commercial launch of SUSTOL is planned for the fourth quarter of 2016
- Conference call and webcast at 9 a.m. ET today

REDWOOD CITY, Calif. – August 10, 2016 – Heron Therapeutics, Inc. (NASDAQ: HRTX), today announced that the U.S. Food and Drug Administration (FDA) has approved SUSTOL® (granisetron) extended-release injection. SUSTOL is a serotonin-3 (5-HT₃) receptor antagonist indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

SUSTOL is an extended-release, injectable 5-HT₃ receptor antagonist that utilizes Heron's Biochronomer® polymer-based drug delivery technology to maintain therapeutic levels of granisetron for ≥ 5 days, covering both the acute and delayed phases of chemotherapy-induced nausea and vomiting (CINV).

“Despite advances in the management of CINV, up to half of patients receiving chemotherapy can still experience CINV, with delayed CINV being particularly challenging to control,” commented Ralph V. Boccia, MD, FACP, Medical Director, Center for Cancer and Blood Disorders. “In our experience, other 5-HT₃ receptor antagonists, including palonosetron, are generally effective for 48 hours or less. SUSTOL, due to its extended-release profile, represents a novel option that can protect patients from CINV for a full 5 days.”

The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical trials that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (day 1 following chemotherapy) and the delayed phase (days 2-5 following chemotherapy).

"The SUSTOL clinical trial populations and results are highly representative of cancer patients in our real-world clinical practice," said Jeffrey Vacirca, MD, FACP, Chief Executive Officer and Director of Clinical Research, North Shore Hematology Oncology Associates and Vice President, Community Oncology Alliance. "Use of MEC regimens is widespread, and AC-based regimens are among the most commonly prescribed highly emetogenic chemotherapy regimens. The most significant challenge for my breast cancer patients receiving AC is chemotherapy-induced nausea and vomiting. SUSTOL represents a better option to manage this devastating side effect of therapy."

"We would like to thank the investigators, caregivers and most of all the patients who have helped us to achieve this important milestone," commented Barry D. Quart, PharmD, Chief Executive Officer of Heron Therapeutics. "In addition to bringing an important product to patients, we are extremely pleased to have obtained the first approval of a product utilizing Heron's Biochronomer polymer-based drug delivery technology."

"The approval of SUSTOL is a major step in Heron's evolution into a fully-integrated biopharmaceutical company with both development and commercial capabilities," said Robert H. Rosen, President of Heron Therapeutics. "Our focus now turns to ensuring patients have access to this important therapy. We look forward to collaborating with the oncology community to make SUSTOL available in the fourth quarter of this year."

Conference Call and Webcast

Heron Therapeutics will host a conference call and webcast on Wednesday, August 10, 2016 at 9 a.m. ET (6 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 64356010 to join the conference call. A slide presentation accompanying today's press release and conference call may also be found on Heron's website at www.herontx.com under the investor relations section. The conference call will also be available via webcast under the investor relations section of Heron's website. Please connect to Heron's website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. An archive of today's teleconference and webcast will be available on Heron's website for 60 days following the call.

About SUSTOL® (granisetron) extended-release injection

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-HT₃ receptor antagonist that utilizes Heron's Biochronomer® polymer-based drug delivery technology to maintain therapeutic levels of granisetron for ≥5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical trials that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (day 1 following chemotherapy) and the delayed phase (days 2-5 following chemotherapy).

Important Safety Information for SUSTOL

SUSTOL is contraindicated in patients with hypersensitivity to granisetron, any of the components of SUSTOL, or any other 5-HT₃ receptor antagonist.

Injection site reactions (ISRs), including infection, bleeding, pain and tenderness, nodules, swelling, and induration, have occurred with SUSTOL. Monitor for ISRs following SUSTOL injection. Inform patients that some ISRs may occur 2 weeks or more after SUSTOL administration. In patients receiving antiplatelet agents or anticoagulants, consider the increased risk of bruising or severe hematoma prior to the use of SUSTOL.

Monitor for constipation and decreased bowel activity and consider optimizing patients' current bowel regimens used for managing preexisting constipation. Instruct patients to seek immediate medical care if signs and symptoms of ileus occur.

Hypersensitivity reactions have been reported and may occur up to 7 days or longer following SUSTOL administration and may have an extended course. If a reaction occurs, administer appropriate treatment and monitor until signs and symptoms resolve.

Serotonin syndrome has been reported with 5-HT₃ receptor antagonists alone but particularly with concomitant use of serotonergic drugs.

Avoid SUSTOL in patients with severe renal impairment. In patients with moderate renal impairment, administer SUSTOL not more frequently than once every 14 days.

Most common adverse reactions (33%) are injection site reactions, constipation, fatigue, headache, diarrhea, abdominal pain, insomnia, dyspepsia, dizziness, asthenia, and gastroesophageal reflux.

Please see accompanying Full Prescribing Information at www.SUSTOL.com

About Chemotherapy-Induced Nausea and Vomiting (CINV)

While chemotherapy is one of the most effective and common used therapies to help patients fight cancer, it is accompanied by debilitating side effects, including varying degrees of nausea and vomiting, often attributed as a leading cause of premature discontinuation of cancer treatment. Delayed nausea and vomiting, which occurs 2-5 days following chemotherapy treatment, is considered particularly debilitating for patients. The National Comprehensive Cancer Network (NCCN) and the American Society of Clinical Oncology (ASCO) have categorized chemotherapy regimens based on the degree to which they cause nausea and vomiting: low emetogenic chemotherapy (LEC), moderately emetogenic chemotherapy (MEC) and highly emetogenic chemotherapy (HEC).

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents for patients suffering from cancer or pain. For more information, visit www.heronrx.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 potential market opportunity for SUSTOL and expected timing of the SUSTOL commercial launch, safety information for SUSTOL, the progress in the research and development of HTX-019, HTX-011 and our other programs, including the timing of preclinical, clinical, and manufacturing activities, safety and efficacy results from our studies, the commercial acceptance of our products, our financial position, business plans and our ability to raise additional capital, and other risks and uncertainties identified in the Company’s filings with the 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.

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Associate Director, Investor Relations 858-703-6063

jcapuzelo@herontx.com

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SUSTOL[®] Approval

August 10, 2016



Forward-Looking Statements

This presentation contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. We caution investors that forward-looking statements are based on management's expectations and assumptions as of the date of this presentation, and involve substantial risks and uncertainties that could cause our clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, those associated with: the potential market opportunity for SUSTOL[®], the expected timing of the SUSTOL[®] commercial launch, safety information for SUSTOL[®], the SUSTOL[®] indication, and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. Forward-looking statements reflect our analysis only on their stated date, and we take no obligation to update or revise these statements except as may be required by law.

SUSTOL[®]

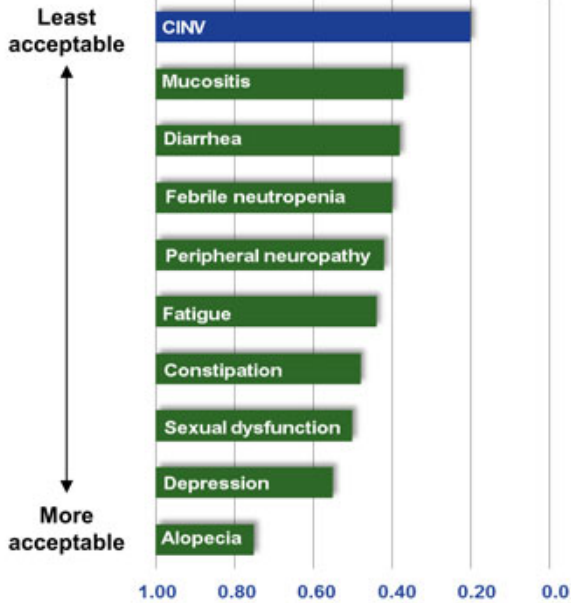
Now approved by U.S. FDA



U.S. Commercial Launch Planned For Q4 2016

Preventing CINV throughout both acute and delayed phases remains a significant unmet need

Patients identified CINV as the side effect of chemotherapy they most wanted to avoid

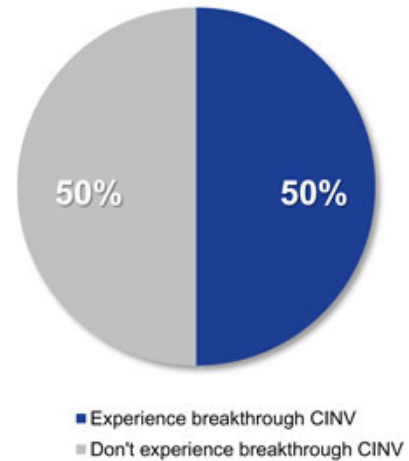


Median visual analog scale (VAS) where 0 is the least favorable and 1 is the most acceptable/favorable

Sun CC et al. *Support Care Cancer*. 2005;13:219-227.
 Van Laar ES et al. *Support Care Cancer*. 2015;23:151-7

% of emetogenic chemotherapy patients with breakthrough CINV despite prophylaxis

Physician perception



Source: Instar Market Research, Dec 2015, N=75 oncologists

SUSTOL Indication



SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens.

	Acute	Delayed
MEC	Yes	Yes
HEC	AC-based regimens	AC-based regimens

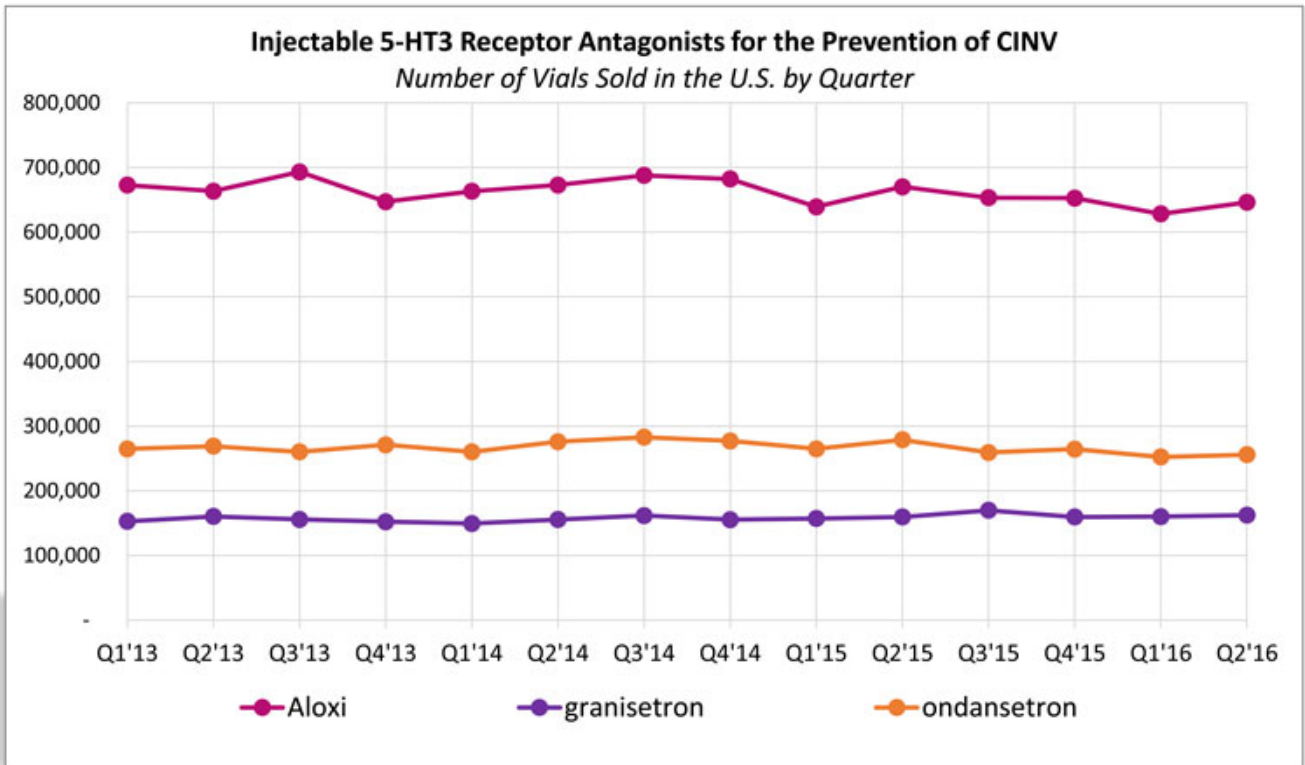
SUSTOL is the first and only extended-release 5-HT₃ receptor antagonist indicated to provide 5-day CINV prevention in MEC and AC-based regimens¹

¹ SUSTOL is indicated for prevention of CINV due to MEC and AC combination chemotherapy. National clinical practice guidelines for antiemesis classify AC-based regimens as highly emetogenic.

AC-based regimens are classified as highly emetogenic by national clinical practice guidelines

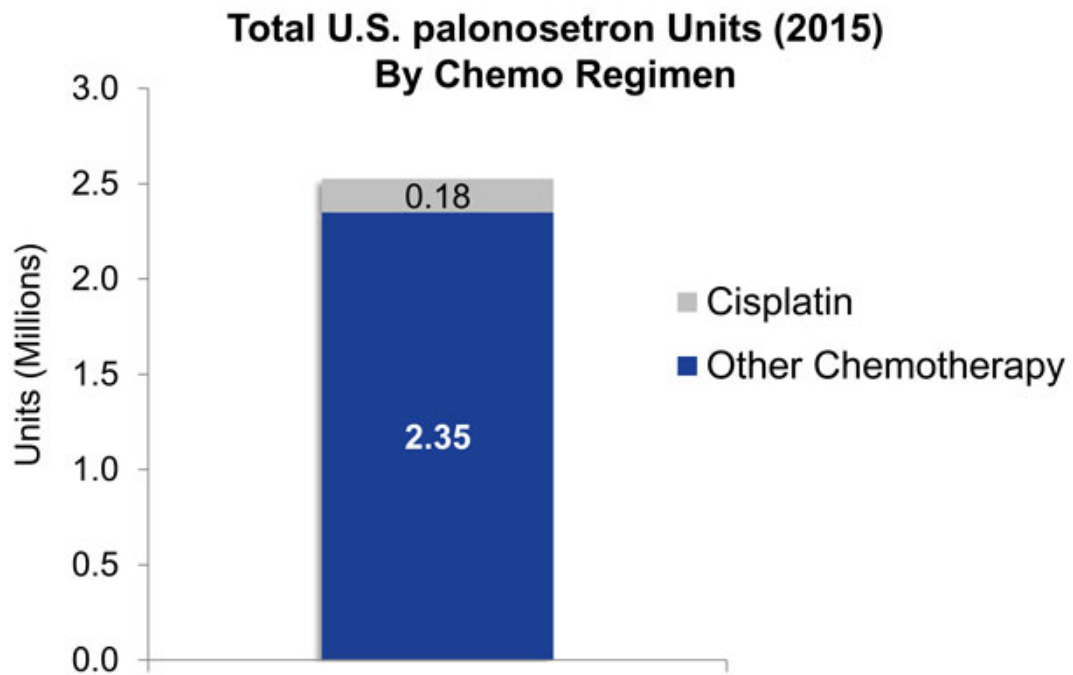
Highly Emetogenic Chemotherapy	
NCCN	<ul style="list-style-type: none"> • AC combination chemotherapy* • Carmustine >250 mg/m² • Cisplatin • Cyclophosphamide ≥1,500 mg/m² <p>*Defined as either doxorubicin or epirubicin with cyclophosphamide</p> <ul style="list-style-type: none"> • Dacarbazine • Doxorubicin ≥60 mg/m² • Epirubicin >90 mg/m² • Ifosfamide ≥2 g/m² • Mechlorethamine • Streptozotocin
ASCO	<ul style="list-style-type: none"> • AC combination chemotherapy* • Carmustine • Cisplatin • Cyclophosphamide ≥1,500 mg/m² <p>*Defined as doxorubicin, epirubicin, idarubicin, or daunorubicin with cyclophosphamide</p> <ul style="list-style-type: none"> • Dacarbazine • Dactinomycin • Mechlorethamine • Streptozotocin

The branded 5-HT3 market (Aloxi) consists of ~2.5 million units



Source: Symphony Health Solutions data, 2016

93% of palonosetron units are used outside of cisplatin



Source: Intrinsiq 2013 (for Aloxi units); Symphony 2015 (for proportion of chemo that is cisplatin)

Our target market can be reached by a small but focused commercial team

Commercial launch to be highly-targeted with two key phases



Phase 1 Targets

- ✓ Highly-concentrated
 - 700K branded units (50%) in 70 practices (533 sites)
- ✓ Value clinical advances over 1st generation 5-HT3s
- ✓ Prioritize branded agents
- ✓ Have shorter time-to-adoption
- ✓ Include 100% of MAGIC sites

Heron's commercial plans will address potential launch barriers for providers, patients, and payers



	Objectives	Action Plan
Providers	Establish SUSTOL clinical value & address objections	<ul style="list-style-type: none"> • First and only 5-HT3 with advanced, extended-release technology and 5-day CINV prevention in MEC and AC-based HEC regimens¹ • Robust in-office and peer-to-peer education • Comprehensive RN in-services with administration demonstration kits
	Build differentiated value proposition	<ul style="list-style-type: none"> • Performance-based contract that delivers sustained value
	Establish "coverage confidence"	<ul style="list-style-type: none"> • Best-in-class reimbursement support services • Extended payment terms • Innovative "stand by your drug" program (qualified payer denials)
Patients	Optimize access	<ul style="list-style-type: none"> • \$0 co-pay for commercially insured patients • Strong uninsured patient program
Payers	Optimize access	<ul style="list-style-type: none"> • Proactive payer engagement with traditionally restrictive plans • Engagement between community practices and regional payers

¹ SUSTOL is indicated for prevention of CINV due to MEC and AC combination chemotherapy. National clinical practice guidelines for antiemesis classify AC-based regimens as highly emetogenic.

U.S. commercial organization is poised for launch



U.S. Commercial Organization

- ✓ Marketing
- ✓ Sales
- ✓ Market Access
- ✓ GPO Account Team
- ✓ Payer Account Team
- ✓ MSLS / Nurse Educators



Phase 1 Targets
(First 12-18 months)
~1.4MM Units

SUSTOL Now Approved



“Despite advances in the management of CINV, up to half of patients receiving chemotherapy can still experience CINV, with delayed CINV being particularly challenging to control,” commented Ralph V. Boccia, MD, FACP, Medical Director, Center for Cancer and Blood Disorders. “In our experience, other 5-HT₃ receptor antagonists, including palonosetron, are generally effective for 48 hours or less. SUSTOL, due to its extended-release profile, represents a novel option that can protect patients from CINV for a full 5 days.”

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