### 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 28, 2015

### Heron Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

> 123 Saginaw Drive Redwood City CA (Address of principal executive offices)

001-33221 (Commission File Number) 94-2875566 (I.R.S. Employer Identification No.)

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)

Dere-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))

#### ITEM 8.01 Other Events.

On May 28, 2015, Heron Therapeutics, Inc. (the "Company") issued a press release announcing topline results from the Company's Phase 3 MAGIC study, evaluating the efficacy and safety of its product candidate SUSTOL<sup>®</sup> (granisetron injection, extended release) for the prevention of delayed-onset chemotherapy induced nausea and vomiting following the administration of highly emetogenic chemotherapy agents, as described in the press release furnished herewith as Exhibit 99.1.

A copy of presentation materials describing the results of the Phase 3 MAGIC study, 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 <u>www.herontx.com</u>. The Company does not undertake any obligation to update this presentation.

#### ITEM 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 28, 2015
99.2	Company Presentation, dated May 2015

#### 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: May 28, 2015

Heron Therapeutics, Inc.

/s/ Esme C. Smith

Esme C. Smith Vice President, General Counsel & Secretary



#### Heron Therapeutics Announces Positive Results from Phase 3 MAGIC Study of SUSTOL®

-Primary endpoint achieved

-SUSTOL, as part of a three-drug regimen, is the first 5-HT<sub>3</sub> antagonist to demonstrate superiority to standard-of-care for delayed nausea and vomiting after HEC

-SUSTOL-based regimen was associated with significantly reduced nausea and improved patient satisfaction

-Conference call and webcast Friday, May 29 at 8:30 A.M. ET

REDWOOD CITY, Calif. – May 28, 2015 – Heron Therapeutics, Inc. (NASDAQ: HRTX) today announced positive, top-line results from its recently completed Phase 3 MAGIC study. MAGIC evaluated the efficacy and safety of the Company's 5-HT<sub>3</sub> receptor antagonist product candidate SUSTOL<sup>®</sup> (granisetron injection, extended release) as part of a three-drug regimen with the intravenous (IV) neurokinin-1 (NK<sub>1</sub>) receptor antagonist fosaprepitant and the IV corticosteroid dexamethasone for the prevention of delayed-onset chemotherapy-induced nausea and vomiting (CINV) following administration of highly emetogenic chemotherapy (HEC) agents.

The MAGIC study is the only Phase 3 CINV prophylaxis study in a HEC population performed to-date to use as a comparator the currently recommended, standard-of-care, three-drug regimen: a 5-HT<sub>3</sub> receptor antagonist (in this case ondansetron), fosaprepitant and dexamethasone. The study was conducted entirely in the U.S. and enrolled over 900 patients undergoing HEC treatment for various tumor types.

The primary endpoint in this study was the proportion of patients who achieved a Complete Response, defined as no emesis and no rescue medications during the delayed-onset phase of CINV, occurring 24-120 hours following administration of HEC agents. The study's major efficacy findings include:

• The study's primary endpoint was achieved. The percentage of patients who achieved a Complete Response was significantly higher in the SUSTOL group than the comparator group (64.7% vs. 56.6%, p=0.014).

- The percentage of patients who achieved Complete Control, defined as Complete Response plus no more than mild nausea during the delayed-onset phase, also reached statistical significance in favor of SUSTOL (p = 0.022).
- The percentage of patients who experienced no nausea or infrequent nausea during the delayed-onset phase was significantly higher in the SUSTOL arm compared with the comparator arm (p = 0.032).
- Significantly more patients in the SUSTOL arm were satisfied with their therapy based on a quality-of-life questionnaire (p = 0.040).

SUSTOL was well tolerated, with no clinically significant differences in the rate or severity of adverse events between the SUSTOL arm and the comparator arm. Injection site reactions observed were consistent with previous trials and generally considered mild, as were the majority of adverse events observed in the study.

"The MAGIC study demonstrated that use of SUSTOL with an NK<sub>1</sub> receptor antagonist and dexamethasone for patients receiving HEC significantly reduced symptoms of CINV. It is significant that both arms of the study had a three-drug prophylactic regimen, which has not been previously evaluated in prior Phase 3 trials in this high-risk patient group. Symptom management in patients receiving cancer treatment represents a significant unmet medical need, and the results of this study represent another step forward in this important clinical space," stated Ian Schnadig, M.D., Principal Investigator, US Oncology Research, Compass Oncology, Tualatin, Oregon.

"The substantial benefit observed with SUSTOL in Complete Response, nausea and overall satisfaction with therapy is all the more impressive given the comparator was a three-drug, standard-of-care regimen. Also, unlike previous CINV studies, all patients in the MAGIC trial came from U.S.-based community oncology centers, so the results are highly representative of what we would expect to see in our patients," stated Jeffrey Vacirca, M.D., Principal Investigator, North Shore Hematology/Oncology Associates.

"We are extremely gratified to report that SUSTOL is the first 5-HT<sub>3</sub> receptor antagonist to demonstrate a statistically significant improvement in delayed nausea and vomiting in patients receiving HEC. As the first large clinical study to compare two three-drug regimens using the definition for HEC in the 2011 ASCO guidelines, the results reported today further demonstrate the potential for SUSTOL to be the foundation of the new standard-of-care injectable anti-emetic regimen," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "We look forward to presenting additional data from the MAGIC study at an appropriate upcoming scientific conference, but our

immediate focus is now the resubmission of our New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA), which we expect in mid-2015. In addition, we are planning for the commercial launch of SUSTOL, pending FDA approval."

#### **Conference Call and Webcast**

Heron Therapeutics will host a conference call and webcast on Friday, May 29 at 8:30 a.m. ET (5:30 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 "Heron" to join the conference call. The conference call will also be available via webcast under the investor relations section of Heron's website at <u>www.herontx.com</u> and will be archived there for 90 days following the call. 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.

#### About the MAGIC Study

The MAGIC (Modified Absorption Granisetron In the Prevention of Chemotherapy-Induced Nausea and Vomiting) study is a prospective, randomized, placebocontrolled, two-arm, Phase 3 study that randomized 942 patients undergoing highly emetogenic chemotherapy (HEC) treatment for various tumor types. HEC regimens were defined by the 2011 American Society of Clinical Oncology (ASCO) guidelines and included cisplatin regimens of  $\geq$  50 mg/m<sup>2</sup> among other agents. MAGIC, which was conducted entirely in the U.S. at 83 community oncology centers, is the first and only Phase 3 CINV study in which patients in the comparator arm received the standard-of-care, three-drug regimen used for prophylaxis in a HEC population. On day 1 of the first treatment cycle, patients were randomized 1:1 to receive either: (i) SUSTOL administered subcutaneously plus IV fosaprepitant 150 mg and IV dexamethasone 12 mg; or (ii) IV ondansetron 0.15 mg/kg (up to 16 mg) plus IV fosaprepitant 150 mg and IV dexamethasone 12 mg. On day 2 following administration of chemotherapy, all study patients received oral dexamethasone 8 mg once (QD), and, on days 3 and 4 following administration of chemotherapy, all study patients received oral dexamethasone 8 mg twice daily (BID). The primary endpoint of the study was the proportion of patients who achieved a Complete Response, defined as no emesis and no rescue medications, during the delayed-onset phase of CINV, occurring 24-120 hours following administration of HEC agents.

#### About SUSTOL<sup>®</sup> for Chemotherapy-Induced Nausea and Vomiting

Heron's lead investigational product candidate, SUSTOL<sup>®</sup> (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. SUSTOL is not approved by the FDA or any other regulatory authority. 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-HT<sub>3</sub>) 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 occurs on days 2-5 following administration of chemotherapy agents. For delayed-onset CINV, only one injectable 5-HT<sub>3</sub> receptor antagonist is approved for use following the administration of MEC agents, and no 5-HT<sub>3</sub> receptor antagonists are approved for use following administration of MEC agents. SUSTOL contains the 5-HT<sub>3</sub> 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<sup>®</sup> 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.

SUSTOL was the subject of a recently completed, multi-center, placebo-controlled, Phase 3 study in patients receiving HEC agents known as MAGIC. MAGIC evaluated the efficacy and safety of SUSTOL as part of a three-drug regimen with the intravenous (IV) neurokinin-1 (NK<sub>1</sub>) receptor antagonist fosaprepitant and the IV corticosteroid dexamethasone for the prevention of delayed nausea and vomiting in patients receiving HEC. MAGIC, which was conducted entirely in the U.S., is the only Phase 3 CINV study to-date to use as a comparator the currently recommended, standard-of-care, three-drug regimen for CINV prophylaxis in a HEC population: a 5-HT<sub>3</sub> receptor antagonist (in this case ondansetron), fosaprepitant and dexamethasone. The study's primary endpoint was achieved. Specifically, the percentage of patients who achieved a Complete Response was significantly higher in the SUSTOL arm compared with the comparator arm (p=0.014). Heron intends to resubmit its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA) in mid-2015. SUSTOL is not approved by the FDA or any other regulatory authority.

#### About HTX-019 for Chemotherapy Induced Nausea and Vomiting

HTX-019 is a proprietary intravenous formulation of aprepitant, a neurokinin-1 (NK<sub>1</sub>) receptor antagonist for the prevention of CINV. NK<sub>1</sub> receptor antagonists are typically used in combination with 5-HT<sub>3</sub> receptor antagonists. At present, the only injectable NK<sub>1</sub> 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 commercially available injectable NK<sub>1</sub> receptor antagonist. Heron intends to file an NDA for HTX-019 using the 505(b)(2) pathway in the second half of 2016.

#### 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: results of the HEC study, the New Drug Application (NDA) resubmission for SUSTOL, potential regulatory approval of SUSTOL and the timing for such approval, if approved at all; the progress in research and development of HTX-019, HTX-011, HTX-003 and our other product candidate programs, including the timing of planned toxicology and clinical studies; safety and efficacy data from our clinical studies that may not warrant further development of our product candidates; the launch and acceptance of SUSTOL and 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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###

Exhibit 99.2



### MAGIC: A Phase 3 Study of SUSTOL<sup>®</sup> in Patients Receiving Highly Emetogenic Chemotherapy

### **Positive Top-Line Results**

May 28, 2015

## Legal Disclaimer



This presentation contains "forward-looking statements" as defined by the Private Securities Litigation Reform Act of 1995. These forward-looking statements involve risks and uncertainties, including uncertainties associated with the development, regulatory approval, manufacture, launch and acceptance of new products, completion of clinical studies and the results thereof, the ability to establish strategic alliances and/or acquire desirable assets, progress in research and development programs and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. The Company's lead product candidate, SUSTOL, which is discussed in this presentation, has not been approved by the FDA or any other regulatory authority. Actual results may differ materially from the results anticipated in our forward-looking statements. 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.



# **SUSTOL Background**

- SUSTOL® (granisetron injection, extended release) is an injectable, extended-release formulation of granisetron that utilizes Heron's proprietary Biochronomer<sup>®</sup> drug delivery technology
- Granisetron is a widely used 5-HT<sub>3</sub> antagonist approved for the prevention of chemotherapy induced nausea and vomiting (CINV)
  - Long track record of safe and effective use
  - Lacks cardiac toxicity (QT prolongation) observed with many other 5-HT<sub>3</sub> antagonists
  - Short half-life, so limited benefit in the delayed phase of CINV
- SUSTOL is designed to deliver granisetron over 5 days to address the problem of delayed-onset CINV
- Prior randomized, controlled, Phase 3 study in 1,341 patients demonstrated efficacy in acute and delayed CINV after moderately emetogenic chemotherapy (MEC), and acute-onset CINV after highly emetogenic chemotherapy (HEC)



### SUSTOL 5-Day Profile: Granisetron Pharmacokinetics

Granisetron is released rapidly following injection of SUSTOL and continues to be released for 5 days, providing long-acting coverage for CINV



# **Rationale for Pursuing HEC Study**

- <u>No</u> 5-HT<sub>3</sub> antagonist has demonstrated efficacy in delayed nausea and vomiting in patients receiving HEC
- There is a significant unmet medical need for better prophylaxis against delayed nausea and vomiting in patients receiving HEC
- Reanalysis of prior Phase 3 study of SUSTOL using the 2011 ASCO definition for HEC suggested that SUSTOL may represent the best-in-class 5-HT<sub>3</sub> antagonist



# Reanalysis of Prior Phase 3 Study Using ASCO 2011 Guidelines

### Protocol-Specified HEC Population ASCO 2011 Guidelines HEC Population



### MAGIC (<u>Modified Absorption Granisetron In the</u> Prevention of <u>Chemotherapy Induced Nausea and</u> Vomiting) Trial Background

- The <u>only</u> Phase 3 study where the comparator arm contains the currently recommended, standard-of-care, three-drug regimen for prophylaxis in a HEC population (5-HT<sub>3</sub> antagonist + NK<sub>1</sub> antagonist + dexamethasone)
- Ondansetron was selected for the comparator arm because it has been commonly used as a comparator in CINV trials and is viewed by the FDA as an appropriate comparator to evaluate delayed nausea and vomiting in patients receiving HEC
  - The three-drug combination of ondansetron, aprepitant and dexamethasone was the first combination approved for delayed nausea and vomiting after HEC
  - Palonosetron is <u>not</u> approved for delayed CINV after HEC because it failed to show a significant difference versus ondansetron



# MAGIC Conducted Entirely in U.S. Community Oncology Centers

83 U.S. Study Sites



### **MAGIC Study Design**





942 patients scheduled to receive HEC\* randomized 1:1 Standard-of-Care

Ondansetron 0.15 mg/kg IV (up to 16 mg IV) d1 + fosaprepitant 150 mg IV d1 + dexamethasone 12 mg IV d1 & 8 mg PO QD d2 + 8 mg PO BID d3-4 + placebo SC d1

SUSTOL (granisetron injection, extended release) SC d1 + fosaprepitant 150 mg IV d1 + dexamethasone 12 mg IV d1 & 8 mg PO QD d2 + 8 mg PO BID d3-4 + placebo IV d1

### Prospectively Defined Primary Endpoint: Complete Response in the Delayed-Onset Phase

\*HEC agents as defined in the 2011 ASCO CINV guidelines



### MAGIC Patient Disposition: Arms Well Balanced



	SUSTOL Regimen	Ondansetron Regimen
Randomized (ITT Population)	471	471
Treated (Safety Population)	456 (96.8%)	459 (97.5%)
Modified ITT Population	450 (95.5%)	452 (96.0%)
Cisplatin Regimen ≥50 mg/m²		
Yes	124 (27.6%)	128 (28.3%)
No	326 (72.4%)	324 (71.7%)



### MAGIC Primary Analysis: SUSTOL Regimen Statistically Superior to Standard-of-Care



# SUSTOL Provides an Important Benefit in Nausea Reduction and Patient QoL

Results for Delayed Phase (24 to 120 Hours)	p-value <sup>1</sup>
Complete Response	0.014
Complete Control (CR plus no more than mild nausea)	0.022
No or Infrequent Nausea <sup>2</sup>	0.032
Global Satisfaction with Therapy <sup>3</sup>	0.040

 P-values are based on the Cochran-Mantel-Haenszel chi-square test controlled by use of cisplatin, not adjusted for multiplicity

2. Patients with zero, one or two episodes of nausea

3. Patient quality of life (QoL) question: How satisfied are you with the study medication's ability to control your nausea and vomiting?



# **MAGIC Safety Summary**

- No clinically significant differences between arms on safety
  - No significant differences in SAEs
  - No significant differences in discontinuations, or discontinuations due to adverse events
- Consistent with previous trials, injection site reactions were relatively common, but generally mild and usually resolved prior to the next cycle of chemotherapy
  - Not an impediment to treatment as evidenced by the significant improvement in patient satisfaction with SUSTOL therapy, with over 80% of patients either very satisfied or satisfied with SUSTOL treatment



# **MAGIC Trial Summary**

- MAGIC is the first Phase 3 CINV study:
  - Using a control group that receives a standard-of-care, three-drug regimen for HEC
  - Conducted entirely at U.S. community oncology centers
- Complete Response in delayed nausea and vomiting was significantly greater with the SUSTOL-based, three-drug regimen compared to standard-of-care
  - Complete Control (which includes a measure of nausea) was significantly greater with SUSTOL
  - Significantly more patients had no nausea or infrequent nausea with SUSTOL
  - SUSTOL patients reported significantly greater satisfaction with therapy
- Adverse events were as expected with no clinically significant differences between arms for any safety measure

### Conclusion



SUSTOL, as part of a three-drug regimen, is the <u>first</u> 5-HT<sub>3</sub> antagonist to demonstrate <u>superiority</u> to a standard-of-care, three-drug regimen in delayed nausea and vomiting in patients receiving HEC

- Detailed results to be presented at future medical meeting
- NDA resubmission on schedule for mid-2015

