

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):

February 27, 2018

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,
California

92121

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code:

(858) 251-4400

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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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 2.02 Results of Operations and Financial Condition.

On February 27, 2018, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and twelve months ended December 31, 2017 ("Earnings Press Release"). A copy of the Earnings Press Release is furnished as Exhibit 99.1.

This Item 2.02 and the Earnings Press Release attached hereto as Exhibit 99.1, insofar as they disclose information regarding the Company's results of operations or financial condition for the three and twelve months ended December 31, 2017, are being furnished to the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No./ Description

99.1 Earnings Press Release, dated February 27, 2018

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Earnings Press Release, dated February 27, 2018

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.

February 27, 2018

By: */s/ Robert E. Hoffman*

Name: Robert E. Hoffman

Title: Chief Financial Officer & Senior Vice President, Finance

Heron Therapeutics Announces Financial Results for the Three and Twelve Months Ended December 31, 2017 and Recent Corporate Progress

SAN DIEGO, Calif.—(BUSINESS WIRE)—February 27, 2018— 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 reported financial results for the three and twelve months ended December 31, 2017 and highlighted recent corporate progress.

Recent Corporate Progress

CINV Franchise

SUSTOL[®] Sales. Net product sales of SUSTOL (granisetron) extended-release injection for the three months ended December 31, 2017 were \$10.1 million, up 17% from the net product sales for the three months ended September 30, 2017 of \$8.6 million. SUSTOL net product sales for the twelve months ended December 31, 2017 were \$30.8 million, versus guidance of \$25 million to \$30 million.

2018 CINV Sales Guidance. Net product sales guidance for full-year 2018 for the CINV franchise is \$60 million to \$70 million.

Permanent J-Code Now Effective. On January 1, 2018, a product-specific billing code, or permanent J-code, for SUSTOL became available. The new J-code was assigned by the Centers for Medicare and Medicaid Services (CMS) and will help simplify the billing and reimbursement process for prescribers of SUSTOL.

CINVANTI[™] Now Available. In November 2017, the U.S. Food and Drug Administration (FDA) approved the Company's New Drug Application (NDA) for CINVANTI (aprepitant) injectable emulsion, the first and only polysorbate 80-free intravenous (IV) formulation of a neurokinin-1 (NK₁) receptor antagonist indicated for the prevention of acute and delayed CINV. CINVANTI became commercially available in the United States on January 4, 2018.

Pain Management Franchise

Enrollment Complete in Phase 3 Pivotal Trials for HTX-011 in Postoperative Pain. Heron completed enrollment in its two pivotal Phase 3 efficacy studies in bunionectomy and hernia repair. Heron anticipates reporting top-line results in the first half of 2018 and expects to file an NDA with the FDA in the second half of 2018.

"2017 was an excellent year for Heron, with significant progress in both our CINV and pain management franchises," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "2018 should be an equally exciting year as we look forward to reporting top-line pivotal Phase 3 data and filing an NDA for HTX-011, while continuing to ramp up net product sales for our CINV franchise."

Financial Results

Net product sales of SUSTOL for the three and twelve months ended December 31, 2017 were \$10.1 million and \$30.8 million, respectively. Heron commenced commercial sales of SUSTOL in October 2016. Net product sales of SUSTOL for both the three and twelve months ended December 31, 2016 were \$1.3 million.

Heron's net loss for the three and twelve months ended December 31, 2017 was \$62.5 million and \$197.5 million, or \$1.09 per share and \$3.65 per share, respectively, compared to a net loss of \$48.0 million and \$173.1 million, or \$1.22 per share and \$4.56 per share, respectively, for the same periods in 2016. Net loss for the three and twelve months ended December 31, 2017 included non-cash, stock-based compensation expense of \$6.9 million and \$30.5 million, respectively, compared to \$7.3 million and \$26.0 million, respectively, for the same periods in 2016.

As of December 31, 2017, Heron had \$172.4 million in cash, cash equivalents and short-term investments, which included net proceeds of \$142.6 million from an underwritten public offering of common stock completed in December 2017. Net cash used for operating activities for the three and twelve months ended December 31, 2017 was \$47.1 million and \$170.3 million, respectively, compared to net cash used for operating activities of \$38.5 million and \$134.1 million, respectively, for the same periods in 2016.

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 prevention 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. The Phase 2 development program for HTX-011 was designed to target the many patients undergoing a wide range of surgeries who experience significant postoperative pain. Heron completed enrollment in its two pivotal Phase 3 efficacy studies in

bunionectomy and hernia repair and anticipates reporting top-line results in the first half of 2018 and expects to file an NDA with the FDA in the second half of 2018.

About CINVANTI (aprepitant) injectable emulsion

CINVANTI is indicated in adults, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). CINVANTI is an intravenous formulation of aprepitant, a substance P/neurokinin-1 (NK₁) receptor antagonist. CINVANTI is the first intravenous (IV) formulation to directly deliver aprepitant, the active ingredient in EMEND[®] capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent NK₁ receptor antagonist to significantly reduce CINV in both the acute phase (0 – 24 hours after chemotherapy) and the delayed phase (24 – 120 hours after chemotherapy). CINVANTI does not contain polysorbate 80 or any other synthetic surfactant. Pharmaceutical formulations containing polysorbate 80 have been linked to hypersensitivity reactions, including anaphylaxis and irritation of blood vessels resulting in infusion-site pain. FDA-approved dosing administration included in the United States prescribing information for CINVANTI is a 30-minute infusion.

Please see Full Prescribing Information at www.CINVANTI.com.

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 studies 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 (0 – 24 hours after chemotherapy) and delayed phase (24 – 120 hours after chemotherapy).

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

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 that 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 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: our capital position and the sufficiency of our capital to fund our operations in future periods; the 2018 net product sales guidance for the CINV franchise; the timing of completion and results of the Phase 3 trials for HTX-011; the timing of the HTX-011 NDA filing and review process; 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.

HERON THERAPEUTICS, INC.

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

	Three Months Ended December 31,		Year Ended December 31,	
	2017	2016	2017	2016
	(unaudited)			
Revenues:				
Net product sales	\$ 10,053	\$ 1,279	\$ 30,767	\$ 1,279
Operating expenses:				
Cost of product sales	1,338	35	4,588	35
Research and development	47,757	29,505	138,582	103,125
General and administrative	6,165	5,892	25,554	21,366
Sales and marketing	16,683	12,650	56,601	47,668
Total operating expenses	71,943	48,082	225,325	172,194
Loss from operations	(61,890)	(46,803)	(194,558)	(170,915)
Interest expense, net	(600)	(1,160)	(2,926)	(2,228)

Net loss	\$ <u>(62,490)</u>	\$ <u>(47,963)</u>	\$ <u>(197,484)</u>	\$ <u>(173,143)</u>
Basic and diluted net loss per share	\$ <u>(1.09)</u>	\$ <u>(1.22)</u>	\$ <u>(3.65)</u>	\$ <u>(4.56)</u>
Shares used in computing basic and diluted net loss per share	<u>57,585</u>	<u>39,280</u>	<u>54,040</u>	<u>37,925</u>

HERON THERAPEUTICS, INC.
Condensed Consolidated Balance Sheet Data
(in thousands)

	<u>December 31, 2017</u>	<u>December 31, 2016</u>
Cash, cash equivalents and short-term investments	\$172,379	\$ 51,138
Accounts receivable, net	41,874	1,960
Total assets	234,307	67,482
Promissory note payable	25,000	50,000
Total stockholders' equity (deficit)	131,136	(21,251)

Investor Relations and Media Contact:

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