

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):

November 6, 2017

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 November 6, 2017, Heron Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the three and nine months ended September 30, 2017 (the "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 nine months ended September 30, 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 November 6, 2017

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated November 6, 2017

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.

November 6, 2017

By: */s/ Robert E. Hoffman*

Name: Robert E. Hoffman

Title: Chief Financial Officer & Senior Vice President, Finance

Heron Therapeutics Reports Financial Results for the Three and Nine Months Ended September 30, 2017 and Recent Corporate Progress

SAN DIEGO, Calif. – (BUSINESS WIRE) – November 6, 2017 – Heron Therapeutics, Inc. (Nasdaq: HRTX) (the Company or Heron), a commercial-stage biotechnology company focused on developing novel, best-in-class treatments to address some of the most important unmet patient needs, today reported financial results for the three and nine months ended September 30, 2017 and highlighted recent corporate progress.

Recent Corporate Progress

Pain Franchise

Initiated Phase 3 Program for HTX-011 in Postoperative Pain. Heron is enrolling patients in two pivotal Phase 3 efficacy studies in bunionectomy and hernia repair. Heron's Phase 3 program is designed to achieve a broad indication for the reduction in postoperative pain and the need for opioid analgesics for 72 hours following surgery. Heron anticipates completing the pivotal Phase 3 efficacy studies in the first half of 2018 and expects to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in 2018.

Fast Track Designation Granted for HTX-011. The FDA has granted Fast Track designation for HTX-011 for local administration into the surgical site to reduce postoperative pain and the need for opioid analgesics for 72 hours. Fast Track designation is intended to facilitate the development and expedite the review of new therapies to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA. HTX-011 is the first opioid alternative for local administration into the surgical site to receive Fast Track designation.

Patent Issued Covering Novel Bupivacaine/Meloxicam Combination. The U.S. Patent and Trademark Office issued to Heron U.S. Patent No. 9,801,945, which covers HTX-011 and all clinically relevant combinations of bupivacaine and meloxicam for the prevention of postoperative pain.

CINV Franchise

SUSTOL[®] Sales. Net product sales of SUSTOL (granisetron) extended-release injection for the three and nine months ended September 30, 2017 were \$8.6 million and \$20.7 million, respectively. Heron commenced commercial sales of SUSTOL in October 2016. Guidance for full-year 2017 net product sales of SUSTOL remains \$25 million to \$30 million.

CINVANTI[™] FDA Action Date in Q4 2017. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of November 12, 2017 for a decision on the Company's NDA for CINVANTI.

"Heron made good progress in the third quarter of 2017, highlighted by the start of Phase 3 studies for HTX-011, which recently has been granted Fast Track designation, and SUSTOL's continued commercial success, outperforming all other CINV new drug launches in the last decade," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "Looking ahead, we are focused on FDA approval of CINVANTI, which, if approved, we expect to launch in January 2018, reporting top-line Phase 3 results for HTX-011 in the first half of next year and filing an NDA for HTX-011 in 2018."

Financial Results

Net product sales of SUSTOL for the three months ended September 30, 2017 were \$8.6 million and totaled \$20.7 million for the nine months ended September 30, 2017. Heron commenced commercial sales of SUSTOL in October 2016.

Heron's net loss for the three and nine months ended September 30, 2017 was \$41.9 million and \$135.0 million, or \$0.77 per share and \$2.55 per share, respectively, compared to a net loss of \$48.5 million and \$125.2 million, or \$1.24 per share and \$3.34 per share, respectively, for the same periods in 2016. Net loss for the three and nine months ended September 30, 2017, included non-cash, stock-based compensation expense of \$7.5 million and \$23.6 million, respectively, compared to \$7.5 million and \$18.7 million, respectively, for the same periods in 2016.

Heron's cash, cash equivalents and short-term investments were \$74.0 million as of September 30, 2017. The Company also had accounts receivable of \$28.9 million, the majority of which the Company expects to collect in the fourth quarter of 2017 and the first quarter of 2018. Net cash used for operating activities for the three months ended September 30, 2017 was \$40.5 million, compared to \$36.1 million for the three months ended September 30, 2016. Net cash used for operating activities for the nine months ended September 30, 2017 was \$123.2 million, compared to \$95.6 million for the nine months ended September 30, 2016.

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 market opportunity for SUSTOL; whether the FDA approves the CINVANTI NDA as submitted; the timing for the commercial launch of CINVANTI, if approved; the timing of completion and results of the Phase 3 studies for HTX-011; the timing of the HTX-011 NDA filing and review; 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 September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2017	2016	2017	2016
Revenues:				
Net product sales	\$ 8,572	\$ —	\$ 20,714	\$ —
Operating expenses:				
Cost of product sales	1,051	—	3,250	—
Research and development	28,844	30,242	90,825	73,620
General and administrative	6,462	5,333	19,389	15,474
Sales and marketing	13,529	12,159	39,918	35,018
Total operating expenses	49,886	47,734	153,382	124,112
Loss from operations	(41,314)	(47,734)	(132,668)	(124,112)
Interest expense, net	(552)	(775)	(2,326)	(1,068)
Net loss	<u>\$(41,866)</u>	<u>\$(48,509)</u>	<u>\$(134,994)</u>	<u>\$(125,180)</u>
Basic and diluted net loss per share	<u>\$ (0.77)</u>	<u>\$ (1.24)</u>	<u>\$ (2.55)</u>	<u>\$ (3.34)</u>
Shares used in computing basic and diluted net loss per share	<u>54,176</u>	<u>39,113</u>	<u>52,846</u>	<u>37,470</u>

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheet Data

(in thousands)

	September 30, 2017 (unaudited)	December 31, 2016
Cash, cash equivalents and short-term investments	\$ 74,016	\$ 51,138
Accounts receivable, net	28,851	1,960
Total assets	118,196	67,482
Promissory note payable	25,000	50,000
Total stockholders’ equity (deficit)	40,053	(21,251)

Investor Relations and Media Contact:

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