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 6, 2020

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, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (858) 251-4400

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**HRTX**	**The Nasdaq Capital Market**

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 May 6, 2020, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three months ended March 31, 2020 ("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 months ended March 31, 2020, 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 May 6, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

Date: May 6, 2020

/s/ Robert Hoffman
Robert Hoffman
Chief Financial Officer & Senior Vice President, Finance

EXHIBIT 99.1

Heron Therapeutics Announces Financial Results for the Three Months Ended March 31, 2020 and Highlights Recent Corporate Updates

SAN DIEGO, May 6, 2020 /PRNewswire/ -- 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 announced financial results for the three months ended March 31, 2020 and highlighted recent corporate updates.

Recent Corporate Updates

Pain Management Franchise

- **New Drug Application for HTX-011:** In September 2019, Heron resubmitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-011, an investigational agent for the management of postoperative pain. The Prescription Drug User Fee Act (PDUFA) goal date is June 26, 2020.

- **Contract Manufacturing Site for HTX-011:** In February 2020, Heron announced that the contract manufacturing site used to manufacture HTX-011 has been reinspected by the FDA with no Form 483 observations issued and with a recommendation by the FDA inspector for approval of the site. Heron has not been informed of any other manufacturing concerns.

- **Marketing Authorisation Application for HTX-011 in the European Union:** In March 2019, Heron's Marketing Authorisation Application (MAA) for HTX-011 for the management of postoperative pain was validated by the European Medicines Agency (EMA) for review under the Centralised Procedure. The medical device certification required for approval in the European Union (EU) for the custom Luer lock applicator developed for application of HTX-011 without a needle was delayed. An opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) is now anticipated in the second half of 2020.

- **New Drug Submission for HTX-011 in Canada:** In December 2019, Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status and accepted by Health Canada. Health Canada's Priority Review status provides an accelerated 6-month review target for the NDS. Heron received the Certificate of Registration for the custom Luer lock applicator issued under the Medical Devices Single Audit Program for the medical device license in Canada. A decision by Health Canada on the NDS is anticipated in the third quarter of 2020.

CINV Franchise

- **CINV Net Product Sales:** For the three months ended March 31, 2020, chemotherapy-induced nausea and vomiting (CINV) franchise net product sales were $25.4 million, compared to $31.6 million for the same period in 2019.

    - **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three months ended March 31, 2020 were $25.2 million, compared to $28.0 million for the same period in 2019. Heron expects the impact of the generic arbitrage to be resolved in 2020, with a return to growth in 2021 and beyond.

- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three months ended March 31, 2020 were $0.2 million, compared to $3.6 million for the same period in 2019. On October 1, 2019, the Company discontinued all discounting of SUSTOL, which resulted in significantly lower SUSTOL net product sales. Heron expects SUSTOL to return to growth in 2021 and beyond.

- **2020 Net Product Sales Guidance:** Heron expects 2020 net product sales for the CINV franchise of $70 million to $80 million and the CINV franchise to return to growth in 2021 and beyond.

“We are encouraged by a recent communication with the FDA where they indicated that they continue on schedule with their review of the NDA for HTX-011, with a PDUFA date of June 26, 2020,” said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. “For the CINV franchise, our customers are benefiting from the administration of CINVANTI by 2-minute IV push, an important product advantage compared to competitive products, which has led to strong first-quarter net product sales of $25.4 million.”

Financial Results

Net product sales for the three months ended March 31, 2020 were $25.4 million, compared to $31.6 million for the same period in 2019.

Heron’s net loss for the three months ended March 31, 2020 was $51.6 million, or $0.57 per share, compared to $63.0 million, or $0.80 per share, for the same period in 2019. Net loss for the three months ended March 31, 2020 included non-cash, stock-based compensation expense of $12.0 million, compared to $17.9 million for the same period in 2019.

As of March 31, 2020, Heron had cash, cash equivalents and short-term investments of $356.3 million, compared to $391.0 million as of December 31, 2019. Net cash used for operating activities for the three months ended March 31, 2020 was $32.9 million, compared to $49.0 million for the same period in 2019. Heron expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2022.

About HTX-011 for Postoperative Pain

HTX-011, an investigational non-opioid, is a dual-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. HTX-011 was granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted a New Drug Application (NDA) to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A Complete Response Letter (CRL) was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to chemistry, manufacturing and controls and non-clinical information. No issues related to clinical efficacy or safety were noted. Heron resubmitted an NDA to the FDA for HTX-011 in September 2019. The Prescription Drug User Fee Act (PDUFA) goal date is June 26, 2020. A Marketing Authorisation Application (MAA) for HTX-011 was validated by the European Medicines Agency (EMA) in March 2019 for review under the Centralised Procedure. Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status by Health Canada in October 2019 and accepted by Health Canada in November 2019.

About CINVANTI (Aprepitant) Injectable Emulsion
CINVANTI, in combination with other antiemetic agents, is indicated in adults 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 as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen. CINVANTI is an IV formulation of aprepitant, a substance P/neurokinin-1 (NK_1) receptor antagonist (RA). CINVANTI is the first IV formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent NK_1 RA to significantly reduce nausea and vomiting in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy). The FDA-approved dosing administration included in the United States prescribing information for CINVANTI is a 30-minute IV infusion or a 2-minute IV injection.

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-HT_3 receptor antagonist that utilizes Heron's Biochronomer® 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 to 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 pain or cancer.

For more information, visit www.herontx.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: whether the U.S. Food and Drug Administration (FDA) approves the New Drug Application (NDA) for HTX-011; the timing of the commercial launch of HTX-011; the timing of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) review process for HTX-011; whether the European Commission (EC) authorizes the Marketing Authorisation Application (MAA) for HTX-011; the timing of Health Canada's New Drug Submission (NDS) review process for HTX-011; whether Health Canada issues a Notice of Compliance for the NDS for HTX-011; the full-year 2020 net product sales guidance for the CINV franchise; the expected future balances of Heron's cash, cash equivalents and short-term investments; the expected duration over which Heron's cash, cash equivalents and short-term investments balances will fund its operations; and other risks and uncertainties identified in the Company's filings with the U.S. 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.
Consolidated Balance Sheets
(In thousands)

	March 31, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 103,285	$ 71,898
Short-term investments	253,061	319,074
Accounts receivable, net	34,811	39,879
Inventory	34,849	24,968
Prepaid expenses and other current assets	12,442	23,245
Total current assets	438,448	479,064
Property and equipment, net	21,908	19,618
Right-of-use lease assets	18,239	13,754
Other assets	346	346
Total assets	$ 478,941	$ 512,782
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,562	$ 2,758
Accrued clinical and manufacturing liabilities	35,321	34,614
Accrued payroll and employee liabilities	8,770	15,248
Other accrued liabilities	32,423	36,535
Current lease liabilities	2,755	1,926
Convertible notes payable to related parties, net of discount	5,934	5,624
Total current liabilities	96,765	96,705
Non-current lease liabilities	16,708	12,242
Total liabilities	113,473	108,947
Stockholders' equity:		
Common stock	906	903
Additional paid-in capital	1,580,903	1,568,317
Accumulated other comprehensive income	708	85
Accumulated deficit	(1,217,049)	(1,165,470)
Total stockholders' equity	365,468	403,835
Total liabilities and stockholders' equity	$ 478,941	$ 512,782

HERON THERAPEUTICS, INC.
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three Months Ended March 31,	
	2020	**2019**
	(Unaudited)	
Revenues:		
Net product sales	$ 25,400	$ 31,602
Operating expenses:		
Cost of product sales	10,622	14,962
Research and development	36,894	42,972
General and administrative	10,422	9,648
Sales and marketing	20,196	28,720
Total operating expenses	78,134	96,302
Loss from operations	(52,734)	(64,700)
Other income, net	1,155	1,688
Net loss	$ (51,579)	$ (63,012)
Basic and diluted net loss per share	$ (0.57)	$ (0.80)
Shares used in computing basic and diluted net loss per share	90,409	78,419

HERON THERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Three Months Ended March 31,	
	2020	**2019**
	(Unaudited)	
Operating activities:		
Net loss	$ (51,579)	$ (63,012)
Adjustments to reconcile net loss to net cash used for operating activities:		
Stock-based compensation expense	11,974	17,902
Depreciation and amortization	621	467
Amortization of debt discount	310	247
Realized gain on available-for-sale securities	—	(8)
Accretion of discount on short-term investments	(117)	(1,357)
Impairment of property and equipment	27	27
Loss on disposal of property and equipment	—	52
Change in operating assets and liabilities:		
Accounts receivable	5,068	(9,355)
Prepaid expenses and other assets	10,803	(346)
Inventory	(9,881)	7,611
Accounts payable	8,804	(6,052)
Accrued clinical and manufacturing liabilities	707	(868)
Accrued payroll and employee liabilities	(6,478)	(6,757)
Other accrued liabilities	(3,194)	12,425
Net cash used for operating activities	(32,935)	(49,024)
Investing activities:		
Purchases of short-term investments	(28,922)	(127,763)
Maturities and sales of short-term investments	95,675	164,009
Purchases of property and equipment	(2,938)	(2,136)
Net cash provided by investing activities	63,815	34,110
Financing activities:		
Proceeds from stock option exercises	504	6,539
Proceeds from warrant exercises	3	—
Net cash provided by financing activities	507	6,539
Net increase (decrease) in cash and cash equivalents	31,387	(8,375)
Cash and cash equivalents at beginning of year	71,898	31,836
Cash and cash equivalents at end of period	$ 103,285	$ 23,461

Investor Relations and Media Contact:
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