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 5, 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 August 5, 2020, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and six months ended June 30, 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 and six months ended June 30, 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 August 5, 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: August 5, 2020

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

EXHIBIT 99.1

Heron Therapeutics Announces Financial Results for the Three and Six Months Ended June 30, 2020 and Highlights Recent Corporate Updates

SAN DIEGO, Aug. 5, 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 and six months ended June 30, 2020 and highlighted recent corporate updates.

Recent Corporate Updates

Pain Management Franchise

- **Positive CHMP Opinion Received for ZYNRELEF™ for the Management of Postoperative Pain:** In July 2020, the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for ZYNRELEF (formerly known as HTX-011), intended for the treatment of postoperative pain. The CHMP's positive opinion will now be reviewed by the European Commission (EC), with a final decision on the Marketing Authorisation Application expected in the coming months. An EC marketing authorisation through the centralized procedure is valid in all 27 European Union (EU) member countries as well as the European Economic Area countries. The CHMP recommended that ZYNRELEF be indicated for treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults.

- **Complete Response Letter Received from the FDA Regarding the NDA for HTX-011 for the Management of Postoperative Pain:** In June 2020, Heron received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the New Drug Application (NDA) for HTX-011. The CRL stated that the FDA is unable to approve the NDA in its present form based on the need for additional non-clinical information. Based on the complete review of the NDA, the FDA did not identify any clinical safety or efficacy issues or chemistry, manufacturing and controls (CMC) issues. There are four non-clinical issues in the CRL, none of which relate to any observed toxicity. Three relate to confirming exposure of excipients in preclinical reproductive toxicology studies, and the fourth relates to changing the manufacturing release specification of the allowable level of an impurity based on animal toxicology coverage. We do not believe that any of the issues are significant barriers to ultimate approval, as all of the excipients have extensive histories of use in pharmaceuticals and the specification can be revised.

- **Initiation of Phase 1b/2 Clinical Study of HTX-034 for the Treatment of Postoperative Pain:** In May 2020, Heron initiated a Phase 1b/2 clinical study in patients undergoing bunionectomy of HTX-034, Heron's next-generation product for the treatment of postoperative pain. The study initiation followed clearance from the FDA of Heron's Investigational New Drug (IND) application for HTX-034 for the treatment of postoperative pain.

CINV Franchise

- **Initiation of Phase 2 Clinical Study of CINVANTI® for the Treatment of COVID-19:** In July 2020, Heron initiated the GUARDS-1 Study, a Phase 2 clinical study evaluating CINVANTI (aprepitant) injectable emulsion in early hospitalized patients with Coronavirus Disease 2019 (COVID-19). The study initiation followed clearance from the FDA of Heron's IND application for CINVANTI for the treatment of COVID-19.

- **CINV Net Product Sales:** For the three and six months ended June 30, 2020, chemotherapy-induced nausea and vomiting (CINV) franchise net product sales were $22.7 million and $48.1 million, respectively, compared to $36.7 million and $68.3 million, respectively, for the same periods in 2019.
    - **CINVANTI Net Product Sales:** Net product sales of CINVANTI for the three and six months ended June 30, 2020 were $22.6 million and $47.8 million, respectively, compared to $33.2 million and $61.2 million, respectively, for the same periods 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 and six months ended June 30, 2020 were $0.1 million and $0.3 million, respectively, compared to $3.5 million and $7.1 million, respectively, for the same periods 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:** Although Heron anticipates a decrease in new diagnoses and chemotherapy patient starts because of the onging COVID-19 pandemic, the Company is maintaining its 2020 guidance for net product sales for the CINV franchise of $70 million to $80 million.

“We are pleased with the CHMP’s recent positive opinion for ZYNRELEF in the EU, and we remain committed to bringing this important non-opioid analgesic to patients in the U.S. as soon as possible. We have submitted a request for a Type A meeting with the FDA and look forward to working with the FDA to achieve this goal,” said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron. “In our CINV franchise, we are encouraged by the continued performance of CINVANTI during both a generic arbitrage period and the COVID-19 pandemic and are maintaining our 2020 net product sales guidance of $70 million to $80 million.”

Financial Results

Net product sales for the three and six months ended June 30, 2020 were $22.7 million and $48.1 million, respectively, compared to $36.7 million and $68.3 million, respectively, for the same periods in 2019.

Heron’s net loss for the three and six months ended June 30, 2020 was $55.2 million and $106.8 million, or $0.61 per share and $1.18 per share, respectively, compared to $50.2 million and $113.2 million, or $0.63 per share and $1.43 per share, respectively, for the same periods in 2019. Net loss for the three and six months ended June 30, 2020 included non-cash, stock-based compensation expense of $11.1 million and $23.1 million, respectively, compared to $12.7 million and $30.6 million, respectively, for the same periods in 2019.

As of June 30, 2020, Heron had cash, cash equivalents and short-term investments of $300.8 million, compared to $391.0 million as of December 31, 2019. Net cash used for operating activities for the six months ended June 30, 2020 was $90.2 million, compared to $72.1 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 (ZYNRELEF in the European Union) for Postoperative Pain

HTX-011 (ZYNRELEF in the European Union), an investigational non-opioid analgesic, 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 2018 and received Priority Review designation in December 2018. A complete response letter (CRL) was received from the FDA regarding the NDA for HTX-011 on June 26, 2020 relating to non-clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls (CMC) issues were identified. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion for ZYNRELEF in July 2020. 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. Heron is working to respond to a list of questions received from Health Canada in July 2020.

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.

CINVANTI is under investigation for the treatment of COVID-19 as a daily 2-minute IV injection when added to the current standard of care.

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 HTX-034 for Postoperative Pain

HTX-034, an investigational non-opioid, is a fixed-dose combination, extended-release solution of the local anesthetic bupivacaine, the nonsteroidal anti-inflammatory drug meloxicam and an additional agent that further potentiates the activity of bupivacaine. HTX-034 is formulated in the same proprietary polymer as HTX-011. By combining two different mechanisms that each enhance the activity of the local anesthetic bupivacaine, HTX-034 is designed to provide superior and prolonged analgesia. Local administration of HTX-034 in a validated preclinical postoperative pain model resulted in sustained analgesia for 7 days.

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 in the U.S.; the timing of the European Commission’s (EC) review process for ZYNRELEF; whether the EC authorizes the Marketing Authorisation Application for ZYNRELEF; the timing of the commercial launch of ZYNRELEF in Europe; the timing of Health Canada’s 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; the extent of the impact of the ongoing Coronavirus Disease 2019 (COVID-19) pandemic on our business; 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)

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 80,728	$ 71,898
Short-term investments	220,114	319,074
Accounts receivable, net	37,502	39,879
Inventory	41,442	24,968
Prepaid expenses and other current assets	13,109	23,245
Total current assets	392,895	479,064
Property and equipment, net	21,886	19,618
Right-of-use lease assets	17,594	13,754
Other assets	346	346
Total assets	$ 432,721	$ 512,782
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 18,458	$ 2,758
Accrued clinical and manufacturing liabilities	30,173	34,614
Accrued payroll and employee liabilities	11,193	15,248
Other accrued liabilities	23,728	36,535
Current lease liabilities	2,830	1,926
Convertible notes payable to related parties, net of discount	6,269	5,624
Total current liabilities	92,651	96,705
Non-current lease liabilities	16,012	12,242
Total liabilities	108,663	108,947
Stockholders' equity:		
Common stock	908	903
Additional paid-in capital	1,594,436	1,568,317
Accumulated other comprehensive income	953	85
Accumulated deficit	(1,272,239)	(1,165,470)
Total stockholders' equity	324,058	403,835
Total liabilities and stockholders' equity	$ 432,721	$ 512,782

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(Unaudited)			
Revenues:				
Net product sales	$ 22,668	$ 36,659	$ 48,068	$ 68,261
Operating expenses:				
Cost of product sales	9,005	13,588	19,627	28,550
Research and development	44,004	41,425	80,898	84,397
General and administrative	9,819	9,778	20,241	19,426
Sales and marketing	15,589	23,647	35,785	52,367
Total operating expenses	78,417	88,438	156,551	184,740
Loss from operations	(55,749)	(51,779)	(108,483)	(116,479)
Other income, net	559	1,557	1,714	3,245
Net loss	$ (55,190)	$ (50,222)	$ (106,769)	$ (113,234)
Basic and diluted net loss per share	$ (0.61)	$ (0.63)	$ (1.18)	$ (1.43)
Shares used in computing basic and diluted net loss per share	90,753	79,548	90,581	78,987

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

	Six Months Ended June 30,	
	2020	**2019**
	(Unaudited)	
Operating activities:		
Net loss	$ (106,769)	$ (113,234)
Adjustments to reconcile net loss to net cash used for operating activities:		
Stock-based compensation expense	23,088	30,608
Depreciation and amortization	1,366	959
Amortization of debt discount	645	507
Realized gain on available-for-sale securities	—	(8)
Accretion of discount on short-term investments	(82)	(2,437)
Impairment of property and equipment	53	54
Loss on disposal of property and equipment	—	53
Change in operating assets and liabilities:		
Accounts receivable	2,377	(2,169)
Inventory	(16,474)	9,762
Prepaid expenses and other assets	10,136	2,454
Accounts payable	15,700	(8,866)
Accrued clinical and manufacturing liabilities	(4,441)	913
Accrued payroll and employee liabilities	(4,055)	(4,415)
Other accrued liabilities	(11,756)	13,687
Net cash used for operating activities	(90,212)	(72,132)
Investing activities:		
Purchases of short-term investments	(66,915)	(204,358)
Maturities and sales of short-term investments	166,825	284,606
Purchases of property and equipment	(3,687)	(4,299)
Net cash provided by investing activities	96,223	75,949
Financing activities:		
Proceeds from stock option exercises	1,309	16,215
Proceeds from purchases under the Employee Stock Purchase Plan	1,507	1,170
Proceeds from warrant exercises	3	—
Net cash provided by financing activities	2,819	17,385
Net increase in cash and cash equivalents	8,830	21,202
Cash and cash equivalents at beginning of year	71,898	31,836
Cash and cash equivalents at end of period	$ 80,728	$ 53,038

Investor Relations and Media Contact:
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