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 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 November 5, 2020, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and nine months ended September 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 nine months ended September 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 November 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: November 5, 2020

/s/ Lisa Peraza
Lisa Peraza
Vice President, Chief Accounting Officer

EXHIBIT 99.1

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

SAN DIEGO, Nov. 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 nine months ended September 30, 2020 and highlighted recent corporate updates.

Recent Corporate Updates

Pain Management Franchise

- **European Commission Authorization for ZYNRELEF™ for the Treatment of Postoperative Pain:** In September 2020, the European Commission (EC) granted a marketing authorization for ZYNRELEF (formerly known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. The marketing authorization follows the European Medicines Agency's positive opinion from the Committee for Medicinal Products for Human Use in July 2020. The EC's centralized marketing authorization is valid for the 27 countries that are members of the European Union (EU), and the other countries in the European Economic Area (EEA). We are currently assessing the evolving global environment for pharmaceuticals and developing a coordinated global marketing strategy, and at this time we anticipate making ZYNRELEF available to patients in Europe during the second half of 2021.

- **Successful Outcome of FDA Type A Meeting to Discuss HTX-011 for the Management of Postoperative Pain:** In September 2020, we announced a successful Type A meeting with the U.S. Food and Drug Administration (FDA) in which alignment was reached on the plans for Heron to resubmit the New Drug Application (NDA) for HTX-011 for the management of postoperative pain in the fourth quarter of 2020.

CINV Franchise

- **CINV Net Product Sales:** For the three and nine months ended September 30, 2020, chemotherapy-induced nausea and vomiting (CINV) franchise net product sales were $20.0 million and $68.0 million, respectively, compared to $42.6 million and $110.9 million, respectively, for the same periods in 2019.

    - **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and nine months ended September 30, 2020 were $19.8 million and $67.6 million, respectively, compared to $36.4 million and $97.6 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 nine months ended September 30, 2020 were $0.2 million and $0.4 million, respectively, compared to $6.2 million and $13.3 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 ongoing COVID-19 pandemic (COVID-19), the Company has increased its 2020 guidance for net product sales for the CINV franchise from a range of $70 million to $80 million to net product sales of $85 million.

“The third quarter was highlighted by the authorization of ZYNRELEF in the EU and we remain focused on resubmitting the New Drug Application for HTX-011 in the U.S. as quickly as possible in order to bring this innovative non-opioid medicine to patients suffering from postoperative pain,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “In addition, our CINV franchise is advancing well, with continued strong performance of CINVANTI against a backdrop of arbitrage and the ongoing global pandemic. Based on the strong commercial execution, we are very pleased to increase our guidance for 2020 to $85 million in net product sales.”

Financial Results

Net product sales for the three and nine months ended September 30, 2020 were $20.0 million and $68.0 million, respectively, compared to $42.6 million and $110.9 million, respectively, for the same periods in 2019.

Heron’s net loss for the three and nine months ended September 30, 2020 was $58.2 million and $165.0 million, or $0.64 per share and $1.82 per share, respectively, compared to $33.6 million and $146.8 million, or $0.42 per share and $1.85 per share, respectively, for the same periods in 2019. Net loss for the three and nine months ended September 30, 2020 included non-cash, stock-based compensation expense of $11.1 million and $34.2 million, respectively, compared to $9.7 million and $40.3 million, respectively, for the same periods in 2019.

As of September 30, 2020, Heron had cash, cash equivalents and short-term investments of $258.1 million, compared to $391.0 million as of December 31, 2019. Net cash used for operating activities for the nine months ended September 30, 2020 was $132.3 million, compared to $97.6 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 (ZYNRELEF in the EU and EEA)

HTX-011, 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. The FDA granted Breakthrough Therapy designation to HTX-011 and the NDA received Priority Review designation. A complete response letter (CRL) was received from the FDA regarding the NDA for HTX-011 in June 2020 relating to non-clinical information. No clinical safety or efficacy issues and no chemistry, manufacturing and controls issues were identified. Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was accepted by Health Canada. Heron is working to respond to a list of questions received from Health Canada in July 2020. In September 2020, the EC granted a marketing authorization for ZYNRELEF (also known as HTX-011) for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. The EC's centralized marketing authorization is valid for the 27 countries that are members of the EU, and the other countries in the EEA.

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 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: the timing of the NDA resubmission to the FDA; whether the FDA approves the NDA for HTX-011; the timing of the commercial launch of HTX-011 in the U.S.; 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 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.
Condensed Consolidated Balance Sheets
(In thousands)

	September 30, 2020	December 31, 2019
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 95,141	$ 71,898
Short-term investments	163,005	319,074
Accounts receivable, net	33,654	39,879
Inventory	42,749	24,968
Prepaid expenses and other current assets	16,446	23,245
Total current assets	350,995	479,064
Property and equipment, net	21,741	19,618
Right-of-use lease assets	16,941	13,754
Other assets	346	346
Total assets	$ 390,023	$ 512,782
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 12,067	$ 2,758
Accrued clinical and manufacturing liabilities	40,718	34,614
Accrued payroll and employee liabilities	13,235	15,248
Other accrued liabilities	22,009	36,535
Current lease liabilities	2,912	1,926
Convertible notes payable to related parties, net of discount	6,637	5,624
Total current liabilities	97,578	96,705
Non-current lease liabilities	15,298	12,242
Total liabilities	112,876	108,947
Stockholders' equity:		
Common stock	909	903
Additional paid-in capital	1,606,165	1,568,317
Accumulated other comprehensive income	540	85
Accumulated deficit	(1,330,467)	(1,165,470)
Total stockholders' equity	277,147	403,835
Total liabilities and stockholders' equity	$ 390,023	$ 512,782

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(Unaudited)			
Revenues:				
Net product sales	$ 19,965	$ 42,624	$ 68,033	$ 110,885
Operating expenses:				
Cost of product sales	7,170	17,195	26,797	45,745
Research and development	49,182	34,708	130,080	119,105
General and administrative	9,482	8,597	29,723	28,023
Sales and marketing	12,515	16,977	48,300	69,344
Total operating expenses	78,349	77,477	234,900	262,217
Loss from operations	(58,384)	(34,853)	(166,867)	(151,332)
Other income, net	156	1,258	1,870	4,503
Net loss	$ (58,228)	$ (33,595)	$ (164,997)	$ (146,829)
Basic and diluted net loss per share	$ (0.64)	$ (0.42)	$ (1.82)	$ (1.85)
Shares used in computing basic and diluted net loss per share	90,849	79,940	90,671	79,308

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

	Nine Months Ended September 30,	
	2020	2019
	(Unaudited)	
Operating activities:		
Net loss	$ (164,997)	$ (146,829)
Adjustments to reconcile net loss to net cash used for operating activities:		
Stock-based compensation expense	34,183	40,312
Depreciation and amortization	2,135	1,480
Amortization of debt discount	1,013	780
Realized gain on available-for-sale securities	—	(8)
Amortization of premium (accretion of discount) on short-term investments	39	(3,264)
Impairment of property and equipment	61	80
Loss on disposal of property and equipment	—	53
Change in operating assets and liabilities:		
Accounts receivable	6,225	(2,303)
Inventory	(17,781)	14,860
Prepaid expenses and other assets	6,799	(5,549)
Accounts payable	9,309	(15,236)
Accrued clinical and manufacturing liabilities	6,104	1,603
Accrued payroll and employee liabilities	(2,013)	(3,263)
Other accrued liabilities	(13,343)	19,681
Net cash used for operating activities	(132,266)	(97,603)
Investing activities:		
Purchases of short-term investments	(92,040)	(287,579)
Maturities and sales of short-term investments	248,525	395,406
Purchases of property and equipment	(4,319)	(3,251)
Net cash provided by investing activities	152,166	104,576
Financing activities:		
Net proceeds from sale of common stock	—	(110)
Proceeds from stock option exercises	1,833	20,239
Proceeds from purchases under the Employee Stock Purchase Plan	1,507	1,170
Proceeds from warrant exercises	3	—
Net cash provided by financing activities	3,343	21,299
Net increase in cash and cash equivalents	23,243	28,272
Cash and cash equivalents at beginning of year	71,898	31,836
Cash and cash equivalents at end of period	$ 95,141	$ 60,108

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