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 9, 2021

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 9, 2021, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and six months ended June 30, 2021 ("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, 2021, 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 9, 2021
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 9, 2021

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

EXHIBIT 99.1

Heron Therapeutics Announces Financial Results for the Three and Six Months Ended June 30, 2021 and Highlights Recent Corporate Updates

- ZYNRELEF® Commercially Launched on July 1, 2021 with 61 Unique Accounts Already Purchasing the Product and Multiple Commercial and Medicaid Payers Covering 86 Million Lives Agreeing to Reimburse ZYNRELEF -

- The Oncology Care Franchise Continued to Show Growth with an Overall 12% Increase in Net Product Sales -

SAN DIEGO, Aug. 9, 2021 /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, 2021 and highlighted recent corporate updates.

Recent Corporate Updates

Acute Care Franchise

- **ZYNRELEF Now Available:** In May 2021, the U.S. Food and Drug Administration (FDA) approved the Company's New Drug Application (NDA) for ZYNRELEF (bupivacaine and meloxicam) extended-release solution. ZYNRELEF is indicated for use in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty. ZYNRELEF became commercially available in the U.S. on July 1, 2021. During the initial weeks of commercial launch, the reception to ZYNRELEF has been positive with 61 unique accounts already purchasing the product. The Company has applied for a unique C-code for ZYNRELEF, which would provide 3-year Medicare reimbursement outside the surgical bundle payment for outpatient procedures. In the interim, Medicare will reimburse ZYNRELEF under a miscellaneous C-code. In addition, multiple payers covering over 86 million commercial and Medicaid lives have already agreed to reimburse ZYNRELEF outside the surgical bundle payment for surgeries performed in ambulatory surgical centers, with many of these covered lives also having their hospital outpatient procedures reimbursed outside the surgical bundle payment.

- **NDA for HTX-019 for Prevention of PONV in Adults Planned in Late 2021:** A 505(b)(2) NDA for HTX-019 for prevention of postoperative nausea and vomiting (PONV) in adults is on track for filing in late 2021.

Oncology Care Franchise

- **2021 Net Product Sales:** For the three and six months ended June 30, 2021, oncology care franchise net product sales were $22.4 million and $42.5 million, respectively, compared to $22.7 million and $48.1 million, respectively, for the same periods in 2020. During the second quarter of 2021, the net product sales increased by 12% compared to the prior quarter and this increase was in-line with the 10% to 20% growth anticipated for the quarter. Heron continues to expect growth of the oncology care franchise net product sales, but at a slower rate than originally projected. Key factors influencing our growth rate projections are the lower rate of new cancer patient treatment starts due to the COVID-19 pandemic, fewer clinic anti-emetic administrations during the first half of 2021 compared to the prior year, stronger than expected competition, and the impact of value-based payer reimbursement.

- **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and six months ended June 30, 2021 were $19.7 million and $38.2 million, respectively, compared to $22.6 million and $47.8 million, respectively, for the same periods in 2020. During the second quarter of 2021, CINVANTI demand units increased by 22% over the prior quarter, which was partially offset by a lower net selling price.

- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and six months ended June 30, 2021 were $2.7 million and $4.3 million, respectively, compared to $0.1 million and $0.3 million, respectively, for the same periods in 2020. During the second quarter of 2021, SUSTOL demand units increased by 108% over the prior quarter, which was partially offset by a lower net selling price.

- **2021 Oncology Care Franchise Net Product Sales Guidance:** Heron currently expects third quarter of 2021 net product sales for the oncology care franchise to increase approximately 5% to 10% compared to the prior quarter. The Company is withdrawing its full-year 2021 net product sales guidance for the oncology care franchise based on the uncertainty associated with the rate of new cancer patient treatment starts and the impact of value-based contracting reimbursement.

“The reception in the marketplace for ZYNRELEF has been outstanding, with a large number of ordering accounts for the first weeks of a launch. Another important accomplishment in these first weeks of launch has been securing an unprecedented number of commercial and Medicaid payers agreeing to reimburse ZYNRELEF outside the surgical bundled payment. We are currently working with the FDA to determine the requirements to expand the drug's label for use in additional indications,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “For the oncology care franchise, our net product sales for the first half of 2021 were $42.5 million, and we expect sales for CINVANTI and SUSTOL to continue to grow in the second half of the year. In addition, we continue to advance HTX-019 and remain on track to submit an NDA to the FDA for PONV prevention in Q4 2021.”

Financial Results

Net product sales for the three and six months ended June 30, 2021 were $22.4 million and $42.5 million, respectively, compared to $22.7 million and $48.1 million, respectively, for the same periods in 2020.

Heron’s net loss for the three and six months ended June 30, 2021 was $61.0 million and $113.6 million, or $0.62 per share and $1.20 per share, respectively, compared to $55.2 million and $106.8 million, or $0.61 per share and $1.18 per share, respectively, for the same periods in 2020. Net loss for the three and six months ended June 30, 2021 included non-cash, stock-based compensation expense of $11.2 million and $22.7 million, respectively, compared to $11.1 million and $23.1 million, respectively, for the same periods in 2020.

As of June 30, 2021, Heron had cash, cash equivalents and short-term investments of $257.7 million, compared to $208.5 million as of December 31, 2020. Net cash used for operating activities for the six months ended June 30, 2021 was $104.9 million, compared to $90.2 million for the same period in 2020. The increase in our net cash used for operating activities was primarily due to changes in working capital to prepare for the launch of ZYNRELEF in July 2021, including manufacturing of commercial inventory. We expect our net cash used for operating activities to moderate later this year.

About ZYNRELEF for Postoperative Pain

ZYNRELEF is the first and only dual-acting local anesthetic that delivers a fixed-dose combination of the local anesthetic bupivacaine and a low dose of nonsteroidal anti-inflammatory drug meloxicam. ZYNRELEF is the first modified-release local anesthetic to be classified by FDA as an “extended-release” product because ZYNRELEF is also the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and significantly increased proportion of patients requiring no opioids through the first 72 hours following surgery compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. ZYNRELEF was approved by the FDA in May 2021 for use in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy and total knee arthroplasty. Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures. In September 2020, the European Commission granted a marketing authorization for ZYNRELEF for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. As of January 1, 2021, ZYNRELEF is approved in 31 European countries including the countries of the European Union and European Economic Area and the United Kingdom.

Please see full prescribing information, including Boxed Warning, at www.ZYNRELEF.com.

About HTX-019 for PONV

HTX-019 is an IV injectable emulsion formulation designed to directly deliver aprepitant, the active ingredient in EMEND® (aprepitant) capsules, which is the only substance P/neurokinin-1 (NK_1) receptor antagonist (RA) to be approved in the U.S. for the prevention of PONV in adults. The FDA-approved dose of oral EMEND is 40 mg for PONV, which is given within 3 hours prior to induction of anesthesia for surgery. In a Phase 1 clinical trial, 32 mg of HTX-019 as a 30-second IV injection was demonstrated to be bioequivalent to oral aprepitant 40 mg.

About CINVANTI for Chemotherapy Induced Nausea and Vomiting (CINV) Prevention

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, an NK_1 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 U.S. 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 for CINV Prevention

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-hydroxytryptamine type 3 RA 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. Our advanced science, patented technologies, and innovative approach to drug discovery and development have allowed us to create and commercialize a portfolio of products that aim to advance the standard-of-care for acute care and oncology patients. 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, the timing of the commercial launch of ZYNRELEF in Europe; the potential market opportunities for ZYNRELEF in the U.S. and Europe; the timing and results of studies for the potential expansion of the U.S. label for ZYNRELEF and for the HTX-019 development program; whether the FDA approves ZYNRELEF for additional indications; the timing of the NDA filing and review process for HTX-019; the net product sales guidance for the oncology care 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.

Consolidated Statements of Operations

(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
		(Unaudited)		
Revenues:				
Net product sales	$ 22,443	$ 22,668	$ 42,461	$ 48,068
Operating expenses:				
Cost of product sales	14,522	9,005	23,729	19,627
Research and development	35,233	44,004	73,349	80,898
General and administrative	10,907	9,819	20,480	20,241
Sales and marketing	22,250	15,589	37,486	35,785
Total operating expenses	82,912	78,417	155,044	156,551
Loss from operations	(60,469)	(55,749)	(112,583)	(108,483)
Other income (expense)	(546)	559	(1,046)	1,714
Net loss	$ (61,015)	$ (55,190)	$ (113,629)	$ (106,769)
Basic and diluted net loss per share	$ (0.62)	$ (0.61)	$ (1.20)	$ (1.18)
Shares used in computing basic and diluted net loss per share	98,459	90,753	94,943	90,581

Heron Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands)

	June 30, 2021 (unaudited)	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 191,173	$ 105,138
Short-term investments	66,505	103,353
Accounts receivable, net	42,615	41,850
Inventory	42,800	41,905
Prepaid expenses and other current assets	23,733	21,950
Total current assets	366,826	314,196
Property and equipment, net	22,175	22,737
Right-of-use lease assets	14,903	16,277
Other assets	346	346
Total assets	$ 404,250	$ 353,556
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 11,242	$ 525
Accrued clinical and manufacturing liabilities	23,907	49,962
Accrued payroll and employee liabilities	13,681	13,597
Other accrued liabilities	30,151	28,369
Current lease liabilities	3,162	2,997
Convertible notes payable to related parties, net of discount	—	7,053
Total current liabilities	82,143	102,503
Non-current lease liabilities	13,013	14,561
Non-current convertible notes payable, net	148,982	—
Total liabilities	244,138	117,064
Stockholders' equity:		
Common stock	1,019	913
Additional paid-in capital	1,665,429	1,628,070
Accumulated other comprehensive income	41	257
Accumulated deficit	(1,506,377)	(1,392,748)
Total stockholders' equity	160,112	236,492
Total liabilities and stockholders' equity	$ 404,250	$ 353,556

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