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 14, 2023

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 14, 2023, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and six months ended June 30, 2023 ("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, 2023, 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 14, 2023
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 14, 2023

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer

Heron Therapeutics Announces Second Quarter 2023 Financial Results and Provides Corporate Updates

- *Company is well capitalized after signing $50 million working capital credit facility and recent $30 million equity raise*
- *Favorable outcome at Markman hearing in pending CINVANTI® ANDA patent litigation*
- *New management team in place*
- *Reiterating full-year net product sales guidance for the oncology care franchise of $99-$103 million*

SAN DIEGO, August 14, 2023 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX) ("Heron" or the "Company"), a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care, today announced financial results for the three and six months ended June 30, 2023 and highlighted recent corporate updates.

"During the second quarter of 2023, the new executive management team has been focused on resizing the business and recently announced a cost reduction program that is anticipated to save the Company approximately $75 million in cash spend through 2025," said Craig Collard, Chief Executive Officer of Heron. "We are in the early stages of revamping Heron into a commercially focused company with efficient operations. As we move through the remainder of 2023, our team is focused on commercial execution and we look forward to updating you on those efforts in the near-term. In addition to the cost-cutting, we were able to bolster the balance sheet by completing a $30 million equity financing with some of our largest shareholders, as well as closing on a $50 million working capital facility. Based on our current operational plan, we expect that this will provide the Company with enough capital to achieve profitability."

Recent Corporate Updates

- **Financings:**
  - In July 2023, Heron completed a private placement equity financing with estimated net proceeds from the sale of Company common stock and pre-funded warrants of $29.7 million.
  - In August 2023, Heron entered into a working capital facility, providing for an aggregate gross principal amount of up to $50.0 million in working capital for the Company, subject to certain terms and conditions, with approximately $24.5 million in net proceeds drawn at closing.

Acute Care Franchise

- **Acute Care Franchise Net Product Sales:** For the three and six months ended June 30, 2023, acute care franchise net product sales were $4.5 million and $8.3 million, respectively, which increased from $2.5 million and $3.5 million, respectively, for the same periods in 2022.

- **ZYNRELEF® Net Product Sales and PDUFA Update:**

  - Net product sales of ZYNRELEF (bupivacaine and meloxicam) extended-release solution for the three and six months ended June 30, 2023 were $4.2 million and $7.7 million, respectively, which increased from $2.5 million and $3.5 million, respectively, for the same periods in 2022.

  - On July 31, 2023, Heron was notified by the U.S. Food and Drug Administration (FDA) that the Prescription Drug User Fee Act (PDUFA) approval goal date for the supplemental New Drug Application (sNDA) for ZYNRELEF was extended by three months to provide for a full review of the submission. The FDA has set a new extended PDUFA approval goal date of January 23, 2024.

- **APONVIE® Net Product Sales:**

  - Net product sales of APONVIE for the three and six months ended June 30, 2023 were $0.3 million and $0.6 million, respectively, with no sales in the comparable prior year periods. APONVIE became commercially available in the U.S. on March 6, 2023.

Oncology Care Franchise

- **Oncology Care Franchise Net Product Sales:** For the three and six months ended June 30, 2023, oncology care franchise net product sales were $27.3 million and $53.1 million, respectively, which increased from $25.1 million and $47.5 million, respectively, for the same periods in 2022.

- **CINVANTI Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and six months ended June 30, 2023 were $24.5 million and $47.3 million, respectively, which increased from $22.7 million and $43.0 million, respectively, for the same periods in 2022.

- **CINVANTI ANDA Litigation:** Heron recently had a favorable outcome at the *Markman* hearing in the pending Hatch-Waxman Abbreviated New Drug Application litigation against Fresenius Kabi to enforce our CINVANTI patents. We are pleased with the outcome and will continue to vigorously enforce and defend our patent portfolio.

- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and six months ended June 30, 2023 were $2.8 million and $5.8 million, respectively, which increased from $2.4 million and $4.5 million, respectively, for the same periods in 2022.

- **2023 Oncology Care Franchise Net Product Sales Guidance:** Heron is reiterating full-year 2023 net product sales guidance for the oncology care franchise of $99 million to $103 million.

The Company also recently granted equity awards to four new employees, with grant dates ranging from July 31 through August 14, 2023, as equity inducement awards outside of the Company's Amended and Restated 2007 Equity Incentive Plan. The employees received, in the aggregate, options to purchase up to 710,000 shares of the Company's common stock. The options subject to each respective award have an exercise price equal to the closing price per share of the Company's common stock as reported on the Nasdaq Capital Market on each employee's respective employment start date. The options subject to these awards each have a 10-year term with a four-year vesting schedule, with 25% of the shares subject to the option vesting on the first anniversary of the grant date and the remaining 75% vesting on a monthly basis over the next three years, subject to each respective employee's continuous service through each vesting date. In accordance with Nasdaq Listing Rule 5635(c)(4), the inducement award grants were approved by Heron's Compensation Committee of the Board of Directors and made as a material inducement to each employee entering into employment with the Company.

Conference Call and Webcast

Heron will host a conference call and webcast on August 14, 2023 at 4:30 p.m. ET. The conference call can be accessed by dialing (646) 307-1963 for domestic callers and (800) 715-9871 for international callers. Please provide the operator with the passcode 5410567 to join the conference call. The conference call will also be available via webcast under the Investor Relations section of Heron's website at www.herontx.com. An archive of the teleconference and webcast will also be made available on Heron's website for 60 days following the call.

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 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 initially 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. In December 2021, the FDA approved an expansion of ZYNRELEF's indication. In December 2022, we submitted an sNDA to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures. On July 31, 2023, the FDA notified Heron of an extension of the PDUFA approval goal date by three months to provide for a full review of the submission. The FDA has set a new extended PDUFA approval goal date of January 23, 2024. ZYNRELEF is now indicated in the U.S. in adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures. Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures. ZYNRELEF was granted a marketing authorization by the European Commission in September 2020 and by the United Kingdom Regulatory Authority in January 2021. In August 2023, we cancelled the U.K. marketing authorization for ZYNRELEF, as we do not plan to commercially launch ZYNRELEF in the U.K. As of August 2, 2023, ZYNRELEF is approved in 30 European countries including the countries of the European Union and the European Economic Area. ZYNRELEF is indicated in Europe for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults.

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

About APONVIE for Postoperative Nausea and Vomiting (PONV)

APONVIE is a substance NK_1 Receptor Antagonist (RA), indicated for the prevention of PONV in adults. Delivered via a 30-second IV push, APONVIE 32 mg was demonstrated to be bioequivalent to oral aprepitant 40 mg with rapid achievement of therapeutic drug levels. APONVIE is the same formulation as Heron's approved drug product CINVANTI. APONVIE is supplied in a single-dose vial that delivers the full 32 mg dose for PONV. APONVIE was approved by the FDA in September 2022 and became commercially available in the U.S. on March 6, 2023.

Please see full prescribing information at www.APONVIE.com.

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 include 100 mg or 130 mg administered as 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 and commercializing therapeutic innovations that improve medical care. 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, uncertainties related to market conditions; the potential market opportunities for ZYNRELEF, APONVIE, CINVANTI and SUSTOL; the net product sales guidance for the oncology care franchise and the acute care franchise; the results of the commercial launch of APONVIE; the timing of the FDA’s review process and whether the FDA approves the sNDA for ZYNRELEF to further expand the U.S. label; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF, if approved; 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 the risk that future equity financings may be needed; failure to realize the expected benefits from the cost reduction plan and restructuring; any inability or delay in achieving profitability; 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,	
	2023	2022	2023	2022
Revenues:				
Net product sales	$ 31,762	$ 27,630	$ 61,377	$ 51,087
Operating expenses:				
Cost of product sales	20,158	16,175	37,012	27,530
Research and development	17,572	28,834	31,389	70,904
General and administrative	15,230	9,181	26,083	18,714
Sales and marketing	21,205	22,938	42,359	46,360
Total operating expenses	74,165	77,128	136,843	163,508
Loss from operations	(42,403)	(49,498)	(75,466)	(112,421)
Other income (expense), net	344	(6,861)	639	(7,826)
Net loss	$ (42,059)	$ (56,359)	$ (74,827)	$ (120,247)
Basic and diluted net loss per share	$ (0.35)	$ (0.55)	$ (0.63)	$ (1.18)
Weighted average common shares outstanding, basic and diluted	119,719	102,405	119,484	102,265

Heron Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands)

	June 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 13,462	$ 15,364
Short-term investments	19,782	69,488
Accounts receivable, net	76,693	52,049
Inventory	44,623	54,573
Prepaid expenses and other current assets	10,720	13,961
Total current assets	165,280	205,435
Property and equipment, net	20,873	22,160
Right-of-use lease assets	6,488	7,645
Other assets	8,583	15,711
Total assets	$ 201,224	$ 250,951
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,957	$ 3,225
Accrued clinical and manufacturing liabilities	19,881	24,468
Accrued payroll and employee liabilities	9,856	13,416
Other accrued liabilities	52,448	38,552
Current lease liabilities	2,580	2,694
Total current liabilities	86,722	82,355
Non-current lease liabilities	4,158	5,499
Non-current convertible notes payable, net	149,387	149,284
Other non-current liabilities	241	241
Total liabilities	240,508	237,379
Stockholders' equity (deficit):		
Common stock	1,199	1,191
Additional paid-in capital	1,829,805	1,807,855
Accumulated other comprehensive loss	(6)	(19)
Accumulated deficit	(1,870,282)	(1,795,455)
Total stockholders' equity (deficit)	(39,284)	13,572
Total liabilities and stockholders' equity	$ 201,224	$ 250,951

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