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 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 November 14, 2023, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and nine months ended September 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 nine months ended September 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 November 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: November 14, 2023

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer

Heron Therapeutics Announces Third Quarter 2023 Financial Results and Updates Financial Guidance

- *Heron is increasing full-year 2023 Net Product Sales guidance for the oncology care franchise to a range of $104 million to $106 million from a prior range of $99 million to $103 million*
- *We anticipate full-year 2023 Net Product Sales to be in the range of $123 million to $125 million and full-year 2024 Net Product Sales to be in the range of $138 million to $158 million*
- *Full-year 2024 EBITDA (excluding stock compensation) expected to be in the range of ($22 million) to $3 million*
- *Cost reduction plan implemented decreasing operating expenses (excluding stock compensation and depreciation and amortization) by 26% in 2023 compared to 2022 and full-year 2024 operating expenses (excluding stock compensation and depreciation and amortization) are expected to be in the range of $108 million to $116 million*

SAN DIEGO, November 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 nine months ended September 30, 2023 and highlighted recent corporate updates.

Craig Collard, Chief Executive Officer, commented, "In just six months of initiating our corporate restructuring plan, I am pleased to announce its near completion. The enhanced clarity in our sales projections and operational visibility brings optimism for our path to profitability. I am delighted to offer this quarterly update on our expectations for the fourth quarter and to unveil our 2024 guidance. Heron is now strategically positioned to deliver substantial value in the coming years, boasting a robust balance sheet, a dedicated management team, and a steadfast commitment to operational excellence."

Corporate Updates

- **Guidance for 2023 and 2024:**
  - The Company is updating guidance for the remainder of 2023 and establishing guidance for the full year 2024 that reflects the growth potential of the product portfolio and the output of our continual operational improvements. Based on our current operational plan, we expect the Company to have sufficient capital to achieve profitability:
    - Full-year 2023 net product sales are expected to be in the range of $123 million to $125 million.
    - Full-year 2023 net product sales guidance for the oncology care franchise is being increased to a range of $104 million to $106 million from a prior range of $99 million to $103 million.
    - EBITDA (excluding stock compensation) expected in the range of ($10 million) to ($6 million) in the fourth quarter of 2023.
    - Full-year 2024 net product sales are expected to be in the range of $138 million to $158 million, with our oncology care franchise growing 3% to 5% in 2024 over 2023. and the acute care franchise growing in excess of 48% year-over-year.

- Full-year 2024 operating expenses (excluding stock compensation, depreciation and amortization) are expected to be in the range of $108 million to $116 million
- Full-year 2024 EBITDA (excluding stock compensation) expected to be in the range of ($22 million) to $3 million.
- Positive EBITDA (excluding stock compensation) is expected during the fourth quarter of 2024.
- Expected year-end 2023 cash, cash equivalents, and short-term investments to exceed $65 million with additional access to $25 million from our working capital facility.
- Gross margin is expected to improve from 41% in 2023 to 69% in 2024, and to over 75% in 2025 and beyond.

- **Adjustments during Third Quarter 2023:**

  - Inventory write-offs during the quarter totaled $7.5 million as a reflection of our reforecast of the ZYNRELEF® product launch. Had we not incurred the write-offs, gross profit for the quarter would have been $20.7 million, or a gross margin of approximately 66%. We do not currently anticipate additional inventory write-offs in the future.

  - One-time expenses during the quarter were $4.1 million, consisting of reorganization costs and severance charges.

  - Loss from operations was $24.9 million for the quarter. Excluding inventory write-offs and one-time expenses, loss from operations would have been $13.3 million.

- **Financings:**

  - In July 2023, Heron completed a private placement equity financing with net proceeds from the sale of Company's common stock and pre-funded warrants of $29.8 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 $24.4 million in net proceeds drawn at closing.

- **Product Development:** The Vial Access Needle ("VAN") program remains on track for a Prior Approval Supplement ("PAS") submission in early 2024 and an anticipated launch in the third quarter of 2024.

Acute Care Franchise

- **Acute Care Franchise Net Product Sales:** For the three and nine months ended September 30, 2023, acute care franchise net product sales were $4.7 million and $12.9 million, respectively, which increased from $2.7 million and $6.3 million, respectively, for the same periods in 2022.

- **ZYNRELEF Net Product Sales and PDUFA Date:**

    - Net product sales of ZYNRELEF (bupivacaine and meloxicam) extended-release solution for the three and nine months ended September 30, 2023 were $4.4 million and $12.0 million, respectively, which increased from $2.7 million and $6.3 million, respectively, for the same periods in 2022.

    - The Prescription Drug User Fee Act ("PDUFA") action date for the supplemental New Drug Application ("sNDA") for the ZYNRELEF expanded label is on track for January 23, 2024.

- **APONVIE® Net Product Sales:** Net product sales of APONVIE for the three and nine months ended September 30, 2023 were $0.3 million and $0.9 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 nine months ended September 30, 2023, oncology care franchise net product sales were $26.7 million and $79.9 million, respectively, which increased from $23.9 million and $71.3 million, respectively, for the same periods in 2022.

- **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and nine months ended September 30, 2023 were $23.3 million and $70.6 million, respectively, which increased from $21.2 million and $64.2 million, respectively, for the same periods in 2022.

- **CINVANTI ANDA Litigation:** Heron 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 nine months ended September 30, 2023 were $3.4 million and $9.3 million, respectively, which increased from $2.7 million and $7.1 million, respectively, for the same periods in 2022.

Conference Call and Webcast

Heron will host a conference call and webcast on November 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 5940799 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 U.S. Food and Drug Administration (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 ZYNRELEF U.K. marketing authorization and, in October 2023, we cancelled the ZYNRELEF European Union (EU) marketing authorization, as we do not plan to commercially launch ZYNRELEF in the U.K. or the EU.

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 EBITDA guidance provided by the Company; 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 timing of the Company's development of the VAN program; the timing of the Company's submission of the PAS to the FDA for the VAN; the timing of the FDA's review process and whether the FDA approves the PAS for the VAN; the outcome of the Company's pending ANDA litigation related to CINVANTI; whether the Company is required to write-off any additional inventory in the future; 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; 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	(unaudited)			
Revenues:				
Net product sales	$ 31,434	$ 26,557	$ 92,811	$ 77,644
Cost of product sales	18,208	14,717	55,220	42,247
Gross profit	13,226	11,840	37,591	35,397
Operating expenses:				
Research and development	13,558	25,545	44,947	96,449
General and administrative	11,641	9,799	37,724	28,513
Sales and marketing	12,956	18,378	55,315	64,738
Total operating expenses	38,155	53,722	137,986	189,700
Loss from operations	(24,929)	(41,882)	(100,395)	(154,303)
Other income (expense), net	(79)	(26)	560	(7,852)
Net loss	$ (25,008)	$ (41,908)	$ (99,835)	$ (162,155)
Basic and diluted net loss per share	$ (0.17)	$ (0.38)	$ (0.75)	$ (1.54)

Heron Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands)

	September 30, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,859	$ 15,364
Short-term investments	42,553	69,488
Accounts receivable, net	63,795	52,049
Inventory	42,007	54,573
Prepaid expenses and other current assets	10,765	13,961
Total current assets	193,979	205,435
Property and equipment, net	20,785	22,160
Right-of-use lease assets	6,069	7,645
Other assets	8,366	15,711
Total assets	$ 229,199	$ 250,951
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,860	$ 3,225
Accrued clinical and manufacturing liabilities	24,740	24,468
Accrued payroll and employee liabilities	10,376	13,416
Other accrued liabilities	39,770	38,552
Current lease liabilities	2,999	2,694
Total current liabilities	79,745	82,355
Non-current lease liabilities	3,537	5,499
Non-current notes payable, net	24,023	—
Non-current convertible notes payable, net	149,439	149,284
Other non-current liabilities	241	241
Total liabilities	256,985	237,379
Stockholders' equity (deficit):		
Common stock	1,411	1,191
Additional paid-in capital	1,866,094	1,807,855
Accumulated other comprehensive loss	(1)	(19)
Accumulated deficit	(1,895,290)	(1,795,455)
Total stockholders' equity (deficit)	(27,786)	13,572
Total liabilities and stockholders' equity	$ 229,199	$ 250,951

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