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): March 12, 2024

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 March 12, 2024, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and twelve months ended December 31, 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 twelve months ended December 31, 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 March 12, 2024
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: March 12, 2024

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer

EXHIBIT 99.1

Heron Therapeutics Announces Fourth Quarter and Full-Year 2023 Financial Results and Highlights Recent Corporate Updates

- *2023 oncology care franchise revenue was $107.9 million, exceeding full-year 2023 guidance*
- *ZYNRELEF® achieved quarterly record of $5.6 million in Q4 Net Product Sales*
- *Ended 2023 with cash and cash equivalents of $80.4 million*
- *Announced partnership with CrossLink Life Sciences, LLC to expand ZYNRELEF promotional efforts on January 7, 2024*
- *Received FDA approval for expanded indication of ZYNRELEF on January 23, 2024*

SAN DIEGO, March 12, 2024 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX) ("Heron" or the "Company"), a commercial-stage biotechnology company, today announced financial results for the three and twelve months ended December 31, 2023 and highlighted recent corporate updates.

"In the fourth quarter of 2023, Heron saw continued positive momentum and an increased sales trajectory in both our acute care and oncology care franchises, illustrating how the strategic decisions made over the past year have positioned the Company for long-term success and profitability," said Craig Collard, Chief Executive Officer of Heron. "I am pleased to share this quarterly update and look forward to building upon what we achieved in the fourth quarter of 2023, providing substantial value and meaningful solutions in the acute care and oncology care settings."

Business Highlights

- The ZYNRELEF Vial Access Needle ("VAN") program, to allow for the rapid preparation and administration of ZYNRELEF in the operating room, remains on track for a Prior Approval Supplement ("PAS") submission in Q2 2024 and an anticipated launch in the second half of 2024.
- The ZYNRELEF Prefilled Syringe ("PFS"), to allow for immediate use of ZYNRELEF, continues to progress with an expected submission for approval in 2026.
- Gross Margin improved to 71% for the quarter, up from 58% in the same period last year.
- ZYNRELEF generated record quarterly revenues of approximately $5.6 million.
- The CrossLink Life Sciences, LLC partnership finalized on January 7, 2024, will ultimately provide up to 650 additional sales representatives promoting ZYNRELEF to orthopedic surgeons.
- Received FDA approval of our supplemental New Drug Application ("sNDA") for ZYNRELEF which expands the ZYNRELEF label to approximately 13 million procedures annually.

Financial Guidance for 2024

The Company reaffirms its full-year 2024 guidance for Product Revenues, Net, Adjusted Operating Expenses and Adjusted EBITDA:

Product Revenues, Net	$138.0 to $158.0 million
Adjusted Operating Expenses (Excluding Stock-Based Compensation and Depreciation and Amortization)	$108.0 to $116.0 million
Adjusted EBITDA (Excluding Stock-Based Compensation and Depreciation and Amortization)	$(22.0) to $3.0 million

Acute Care Franchise

- **Acute Care Franchise Net Product Sales:** For the three and twelve months ended December 31, 2023, acute care franchise Net Product Sales were $6.1 million and $19.1 million, respectively, which increased from $3.9 million and $10.2 million, respectively, for the same periods in 2022.

- **ZYNRELEF Net Product Sales:** Net Product Sales of ZYNRELEF (bupivacaine and meloxicam) extended-release solution for the three and twelve months ended December 31, 2023 were $5.6 million and $17.7 million, respectively, which increased from $3.9 million and $10.2 million, respectively, for the same periods in 2022.

- **APONVIE® Net Product Sales:** Net Product Sales of APONVIE for the three and twelve months ended December 31, 2023 were $0.5 million and $1.4 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 twelve months ended December 31, 2023, oncology care franchise Net Product Sales were $28.1 million and $107.9 million, respectively, which increased from $26.1 million and $97.5 million, respectively, for the same periods in 2022.

- **CINVANTI® Net Product Sales:**Net Product Sales of CINVANTI (aprepitant) injectable emulsion for the three and twelve months ended December 31, 2023 were $24.3 million and $94.9 million, respectively, which increased from $23.1 million and $87.3 million, respectively, for the same periods in 2022.

- **SUSTOL® Net Product Sales:** Net Product Sales of SUSTOL (granisetron) extended-release injection for the three and twelve months ended December 31, 2023 were $3.8 million and $13.0 million, respectively, which increased from $3.0 million and $10.2 million, respectively, for the same periods in 2022.

Conference Call and Webcast

Heron will host a conference call and webcast on March 12th, 2024 at 4:30 pm 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 6135354 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 to include foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures. On January 23, 2024, the FDA approved ZYNRELEF for soft tissue and orthopedic surgical procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided. 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.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we have included information about certain non-GAAP financial measures. We believe the presentation of these non-GAAP financial measures, when viewed with our results under GAAP and the accompanying reconciliations, provide analysts, investors, lenders, and other third parties with insights into how we evaluate normal operational activities, including our ability to generate cash from operations, on a comparable year-over-year basis and manage our budgeting and forecasting.

In our quarterly and annual reports, earnings press releases and conference calls, we may discuss the following financial measures that are not calculated in accordance with GAAP, to supplement our consolidated financial statements presented on a GAAP basis.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income or loss adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations. Adjusted EBITDA, as used by us, may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

There are several limitations related to the use of adjusted EBITDA rather than net income or loss, which is the nearest GAAP equivalent, such as:

- adjusted EBITDA excludes depreciation and amortization, and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude stock-based compensation expense from adjusted EBITDA although: (i) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy; and (ii) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
- adjusted EBITDA does not reflect the benefit from or provision for income taxes or the cash requirements to pay taxes;
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments;
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business;

Adjusted Operating Expenses

Adjusted operating expenses is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense, depreciation and amortization, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations.
Reconciliations of adjusted EBITDA and adjusted operating expenses to the most directly comparable GAAP financial measures are included in this press release.

The Company has not provided a reconciliation of its full-year 2024 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures, in reliance on the unreasonable efforts exception provided under Item 10(e)(1)(i)(B) of Regulation S-K, because the Company is unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation, including, but not limited to, stock-based compensation expense, acquisition related expense and litigation settlements. These items are uncertain and depend on various factors that are outside of the Company's control or cannot be reasonably predicted. While the Company is unable to address the probable significance of these items, they could have a material impact on GAAP net income and operating expenses for the guidance period.

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.Therefore, you should not place undue reliance on forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding the potential market opportunities for ZYNRELEF, APONVIE, CINVANTI and SUSTOL; revenue, adjusted EBITDA and other financial guidance provided by the Company; the results of the commercial launch of APONVIE; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF; the timing of the Company’s development of the VAN program and receipt of required regulatory approvals; our ability to establish and maintain successful commercial arrangements like our co-promotion agreement CrossLink Life Sciences; the outcome of the Company’s pending ANDA litigation; 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. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, and in our other reports filed with the Securities and Exchange Commission, including under the caption "Risk Factors." 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 December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenues:	(unaudited)			
Net product sales	$ 34,233	$ 30,028	$ 127,044	$ 107,672
Cost of product sales	9,885	12,627	65,105	54,874
Gross profit	24,348	17,401	61,939	52,798
Operating expenses:				
Research and development	10,950	11,057	55,897	107,506
General and administrative	11,290	8,924	49,014	37,437
Sales and marketing	12,328	17,775	67,643	82,513
Total operating expenses	34,568	37,756	172,554	227,456
Loss from operations	(10,220)	(20,355)	(110,615)	(174,658)
Other income (expense), net	(504)	486	56	(7,366)
Net loss	$ (10,724)	$ (19,869)	$ (110,559)	$ (182,024)
Basic and diluted net loss per share	$ (0.07)	$ (0.17)	$ (0.80)	$ (1.67)

Heron Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,677	$ 15,364
Short-term investments	51,732	69,488
Accounts receivable, net	60,137	52,049
Inventory	42,110	54,573
Prepaid expenses and other current assets	6,118	13,961
Total current assets	188,774	205,435
Property and equipment, net	20,166	22,160
Right-of-use lease assets	5,438	7,645
Other assets	8,128	15,711
Total assets	$ 222,506	$ 250,951
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,240	$ 3,225
Accrued clinical and manufacturing liabilities	22,291	24,468
Accrued payroll and employee liabilities	9,224	13,416
Other accrued liabilities	41,855	38,552
Current lease liabilities	3,075	2,694
Total current liabilities	79,685	82,355
Non-current lease liabilities	2,800	5,499
Non-current notes payable, net	24,263	—
Non-current convertible notes payable, net	149,490	149,284
Other non-current liabilities	241	241
Total liabilities	256,479	237,379
Stockholders' equity:		
Common stock	1,503	1,191
Additional paid-in capital	1,870,525	1,807,855
Accumulated other comprehensive income (loss)	13	(19)
Accumulated deficit	(1,906,014)	(1,795,455)
Total stockholders' equity	(33,973)	13,572
Total liabilities and stockholders' equity	$ 222,506	$ 250,951

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