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 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 November 12, 2024, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and nine months ended September 30, 2024 ("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, 2024, 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 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: November 12, 2024

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer

Exhibit 99.1

Heron Therapeutics Announces Third Quarter 2024 Financial Results and Narrows Financial Guidance

- *Reported positive YTD 2024 Adjusted EBITDA of $1.4 million*
- *Company expects Q4 2024 Net Revenue in the range of $37 million - $43 million*
- *ZYNRELEF® (bupivacaine and meloxicam) extended-release solution Vial Access Needle ("VAN") approved in September and on track for Q4 2024 launch*
- *CMS Final Rule Non-Opioid Policy for Pain Relief includes ZYNRELEF as a qualifying product for separate payment in both the hospital outpatient department and ambulatory surgical center settings of care*

SAN DIEGO, November 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 nine months ended September 30, 2024, and highlighted recent corporate updates.

"We are pleased to report that with our prudent financial management and continued revenue growth we were able to achieve positive Adjusted EBITDA for the quarter," said Craig Collard, Chief Executive Officer. "The future looks bright as we continue to grow all product revenue. The CrossLink partnership roll out, FDA approval of the VAN in September, and inclusion in the CMS Final Rule Non-Opioid Policy for Pain Relief, positions ZYNRELEF for significant growth within the surgical setting."

"We continue to deliver on our commitment to financial efficiency while growing revenue. The team has made great strides in the transformation of Heron over the past year. We are looking forward to a strong fourth quarter which is off to a great start. As such, we are narrowing guidance for full-year 2024."

Financial Guidance for 2024

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

	Original	Q2 Updated Guidance	Q3 Updated Guidance
Product Revenues, Net	$138.0 to $158.0 million		$140.0 to $146.0 million
Adjusted Operating Expenses	$108.0 to $116.0 million	$107.0 to $111.0 million	$101.0 to $105.0 million
Adjusted EBITDA	$(22.0) to $3.0 million	$(10.0) to $3.0 million	$2.0 to $5.0 million

Business Highlights

- **The ZYNRELEF VAN will be available for initial use in the fourth quarter** following approval by the U.S. Food and Drug Administration ("FDA") on September 24, 2024. The VAN will replace the current vented vial spike and has the potential to simplify aseptic preparation, while also significantly reducing ZYNRELEF's withdrawal time down to between twenty and forty-five seconds.
- **ZYNRELEF will continue to receive separate payment from April 1, 2025, until at least the end of 2027** as the result of inclusion in the "CMS OPPS and ASC Final Rule CY 2025 Non-Opioid Policy for Pain Relief" by the Centers for Medicare & Medicaid Services ("CMS"). The payment limitation for ZYNRELEF is set at $2,267.26, in line with similar products, and it will be granted the status indicator of "K1" – for Non-Opioid Drugs and Biologicals For Post-Surgical Pain Relief. The goal of the policy is to ensure there are no financial incentives to use opioids

instead of non-opioid alternatives like ZYNRELEF. To qualify under the new policy, ZYNRELEF needed to meet strict criteria establishing that it does not act upon the body's opioid receptors and that it successfully demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid requirements in clinical trials or peer reviewed literature. These criteria set a strong precedent from CMS that we expect other payors to follow.

- **Cash and Cash Equivalents were $70.9 million** as of September 30, 2024**,** compared with $80.4 million on December 31, 2023.

Acute Care Franchise

- **Acute Care Franchise Net Product Sales:** For the three and nine months ended September 30, 2024, acute care franchise Net Product Sales were $7.4 million and $19.7 million, respectively, compared to $4.7 million and $12.9 million, respectively, for the same period in 2023.

- **ZYNRELEF Net Product Sales:** Net Product Sales of ZYNRELEF for the three and nine months ended September 30, 2024 were $6.3 million and $17.1 million, respectively, compared to $4.4 million and $12.0 million, respectively, for the same period in 2023.

- **APONVIE® Net Product Sales:** Net Product Sales of APONVIE for the three and nine months ended September 30, 2024 were $1.1 million and $2.6 million, respectively, compared to $0.3 million and $0.9 million, respectively, for the same period in 2023.

Oncology Care Franchise

- **Oncology Care Franchise Net Product Sales:** For the three and nine months ended September 30, 2024, oncology care franchise Net Product Sales were $25.4 million and $83.8 million, respectively, compared to $26.7 million and $79.9 million for the same period in 2023.

- **CINVANTI® Net Product Sales:** Net Product Sales of CINVANTI (aprepitant) injectable emulsion for the three and nine months ended September 30, 2024 were $22.6 million and $73.2 million, compared to $23.3 million and $70.6 million for the same period in 2023.

- **SUSTOL® Net Product Sales:** Net Product Sales of SUSTOL (granisetron) extended-release injection for the three and nine months ended September 30, 2024 were $2.8 million and $10.6 million, respectively, compared to $3.4 million and $9.3 million, respectively, for the same period in 2023.

Conference Call and Webcast

Heron will host a conference call and live webcast on Tuesday, November 12, 2024, at 8:00 a.m. ET. The conference call can be accessed by phone by utilizing the following registration link which will provide participants with dial-in details. To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time. 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 sixty 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 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.

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 a 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, 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;
- we exclude impairment of long-lived assets, the amount and/or frequency of which are not part of our underlying business.
- we exclude inventory write-downs (and write-ups should they occur), the amount and/or frequency of which are not part of our underlying business.
- 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; and
- 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.

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 or inclusion of ZYNRELEF under the OPPS and the ASC payment system; 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 with CrossLink Life Sciences, LLC (“CrossLink”); 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 September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues:		(unaudited)		
Net product sales	$ 32,810	$ 31,434	$ 103,504	$ 92,811
Cost of product sales	9,458	18,208	28,420	55,220
Gross Profit	23,352	13,226	75,084	37,591
Operating expenses:				
Research and development	4,465	9,285	13,505	31,331
General and administrative	12,373	15,914	41,252	51,340
Sales and marketing	10,972	12,956	36,028	55,315
Total operating expenses	27,810	38,155	90,785	137,986
Loss from operations	(4,458)	(24,929)	(15,701)	(100,395)
Other (expense) income, net	(390)	(79)	(1,542)	560
Net loss	$ (4,848)	$ (25,008)	$ (17,243)	$ (99,835)
Basic and diluted net loss per share	$ (0.03)	$ (0.17)	$ (0.11)	$ (0.75)
Weighted average common shares outstanding, basic and diluted	152,830	144,990	152,213	133,747

Heron Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands)

	September 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 25,741	$ 28,677
Short-term investments	45,149	51,732
Accounts receivable, net	67,039	60,137
Inventory	45,950	42,110
Prepaid expenses and other current assets	11,308	6,118
Total current assets	195,187	188,774
Property and equipment, net	15,414	20,166
Right-of-use lease assets	3,469	5,438
Other assets	6,707	8,128
Total assets	$ 220,777	$ 222,506
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 10,188	$ 3,240
Accrued clinical and manufacturing liabilities	22,859	22,291
Accrued payroll and employee liabilities	8,531	9,224
Other accrued liabilities	40,717	41,855
Current lease liabilities	3,249	3,075
Total current liabilities	85,544	79,685
Non-current lease liabilities	522	2,800
Non-current notes payable, net	24,828	24,263
Non-current convertible notes payable, net	149,647	149,490
Other non-current liabilities	241	241
Total liabilities	260,782	256,479
Stockholders' deficit:		
Common stock	1,517	1,503
Additional paid-in capital	1,881,695	1,870,525
Accumulated other comprehensive (loss) income	40	13
Accumulated deficit	(1,923,257)	(1,906,014)
Total stockholders' deficit	(40,005)	(33,973)
Total liabilities and stockholders' deficit	$ 220,777	$ 222,506

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