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 23, 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 March 23, 2023, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and twelve months ended December 31, 2022 ("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, 2022, 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 23, 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: March 23, 2023

/s/ Lisa Peraza

Lisa Peraza

Vice President, Chief Accounting Officer

EXHIBIT 99.1

Heron Therapeutics Announces Financial Results for the Three and Twelve Months Ended December 31, 2022 and Highlights Recent Corporate Updates

- Annual Net Product Sales Across the Company Grew 25% to $107.7 million in 2022, Compared to Annual Net Product Sales in 2021 -

- APONVIE™ Commercially Launched on March 6, 2023 -

- ZYNRELEF® Net Product Sales for Fourth Quarter of 2022 Increased 44% Over Prior Quarter to $3.9 Million -

- Oncology Care Franchise Net Product Sales for 2022 Grew 17% Over Prior Year to $97.5 Million –

SAN DIEGO, March 23, 2023 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), 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 twelve months ended December 31, 2022 and highlighted recent corporate updates.

Recent Corporate Updates

Acute Care Franchise

- **ZYNRELEF:**
  - Net product sales of ZYNRELEF (bupivacaine and meloxicam) extended-release solution for the three and twelve months ended December 31, 2022 were $3.9 million and $10.2 million, respectively. Net product sales of ZYNRELEF for the three and twelve months ended December 31, 2021 were $0.8 million and $2.9 million, respectively (ZYNRELEF was launched July 1, 2021). ZYNRELEF end-user (ambulatory surgical centers and hospitals) demand unit sales were 20,765 in the fourth quarter of 2022, representing an increase of 38% over the prior quarter. We currently expect first quarter 2023 ZYNRELEF demand unit sales to increase approximately 10% over the prior quarter.
  - Since launch on July 1, 2021 through December 31, 2022, 793 unique accounts purchased ZYNRELEF with 90% of those accounts reordering the product.
  - The supplemental New Drug Application (sNDA) for ZYNRELEF, to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures, was submitted in December 2022 to the U.S. Food and Drug Administration (FDA). The FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of October 23, 2023.
- **APONVIE:**
  - The APONVIE (aprepitant) injectable emulsion, the only intravenous (IV) substance P/neurokinin-1 (NK_1) receptor antagonist (RA) indicated for the prevention of postoperative nausea and vomiting (PONV) in adults, became commercially available in the U.S. in March 2023.

- The Centers for Medicare and Medicaid Services granted pass-through payment status for APONVIE, effective April 1, 2023, under C-code **C9145**.

- PONV represents a significant opportunity that leverages our existing sales organization in the acute care setting. There are approximately 36 million surgical procedures annually in patients at moderate to high risk for PONV, where guidelines recommend using multiple agents from different classes of drugs for prophylaxis.

Oncology Care Franchise

- **2022 Oncology Care Franchise Net Product Sales:** For the three and twelve months ended December 31, 2022, oncology care franchise net product sales were $26.1 million and $97.5 million, respectively, compared to $19.9 million and $83.4 million, respectively, for the same periods in 2021.

- **CINVANTI® Net Product Sales:**Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and twelve months ended December 31, 2022 were $23.1 million and $87.3 million, respectively, compared to $17.4 million and $73.5 million, respectively, for the same periods in 2021.

- Validation of large-scale manufacturing of CINVANTI was completed, resulting in a significant reduction in cost of product sales beginning in the fourth quarter of 2022.

- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and twelve months ended December 31, 2022 were $3.0 million and $10.2 million, respectively, compared to $2.5 million and $9.9 million, respectively, for the same periods in 2021.

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

“2022 was an important year for Heron, highlighted by the expansion of our acute care franchise to cover the two most common concerns for patients and clinicians after surgery, pain and nausea and vomiting. We were thrilled with the approval and recent launch of our fourth commercial product, APONVIE, for PONV, and remain encouraged with the continued growth of ZYNRELEF sales even in a quarter where seasonal declines are anticipated,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “In our oncology care franchise, we saw strong growth, exceeding our full-year 2022 guidance with $97.5 million in net product sales. In addition, the significant reduction in cost of goods for CINVANTI achieved in the fourth quarter will have an important impact on reducing cash burn in 2023 and beyond.”

Financial Results

Net product sales for the three and twelve months ended December 31, 2022 were $30.0 million and $107.7 million, respectively, compared to $20.7 million and $86.3 million, respectively, for the same periods in 2021.

Heron's net loss for the three and twelve months ended December 31, 2022 was $19.9 million, or $0.17 per share, and $182.0 million, or $1.67 per share, respectively, compared to $54.6 million, or $0.54 per share, and $220.7 million, or $2.24 per share, respectively, for the same periods in 2021. Net loss for the three and twelve months ended December 31, 2022 included non-cash, stock-based compensation expense of $10.5 million and $43.0 million, respectively, compared to $12.9 million and $46.9 million, respectively, for the same periods in 2021.

As of December 31, 2022, Heron had cash, cash equivalents and short-term investments of $84.9 million, compared to $157.6 million as of December 31, 2021. Net cash used for operating activities for the three and twelve months ended December 31, 2022 was $37.5 million and $146.9 million, respectively, compared to $45.3 million and $203.4 million, respectively, for the same periods in 2021. The decrease in our net cash used for operating activities was primarily due to the reduction in headcount implemented in June 2022 and changes in working capital, as well as a decrease in net loss.

Conference Call and Webcast

Heron will host a conference call and webcast on March 23, 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 7469717 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, and the FDA assigned a PDUFA goal date of October 23, 2023. 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.

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

About APONVIE for PONV

APONVIE is a substance NK_1 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.

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, patentedtechnologies, and innovative approachto 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, 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; the ability for the Company to reach 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 December 31,		Twelve Months Ended December 31,	
	2022	2021	2022	2021
Revenues:	(unaudited)			
Net product sales	$ 30,028	$ 20,655	$ 107,672	$ 86,346
Operating expenses:				
Cost of product sales	12,627	10,941	54,874	46,021
Research and development	11,057	28,877	107,506	130,821
General and administrative	8,924	9,887	37,437	40,153
Sales and marketing	17,775	24,487	82,513	87,179
Total operating expenses	50,383	74,192	282,330	304,174
Loss from operations	(20,355)	(53,537)	(174,658)	(217,828)
Other expense, net	486	(1,109)	(7,366)	(2,855)
Net loss	$ (19,869)	$ (54,646)	$ (182,024)	$ (220,683)
Basic and diluted net loss per share	$ (0.17)	$ (0.54)	$ (1.67)	$ (2.24)

Heron Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands)

	December 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,364	$ 90,541
Short-term investments	69,488	67,039
Accounts receivable, net	52,049	35,499
Inventory	54,573	48,382
Prepaid expenses and other current assets	13,961	12,962
Total current assets	205,435	254,423
Property and equipment, net	22,160	23,734
Right-of-use lease assets	7,645	9,829
Other assets	15,711	17,720
Total assets	$ 250,951	$ 305,706
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,225	$ 3,803
Accrued clinical and manufacturing liabilities	24,468	23,716
Accrued payroll and employee liabilities	13,416	15,263
Other accrued liabilities	38,552	25,859
Current lease liabilities	2,694	2,417
Total current liabilities	82,355	71,058
Non-current lease liabilities	5,499	7,996
Non-current convertible notes payable, net	149,284	149,082
Other non-current liabilities	241	—
Total liabilities	237,379	228,136
Stockholders' equity:		
Common stock	1,191	1,020
Additional paid-in capital	1,807,855	1,689,987
Accumulated other comprehensive loss	(19)	(6)
Accumulated deficit	(1,795,455)	(1,613,431)
Total stockholders' equity	13,572	77,570
Total liabilities and stockholders' equity	$ 250,951	$ 305,706

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