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 8, 2022

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 8, 2022, Heron Therapeutics, Inc. ("Company") issued a press release announcing its financial results for the three and nine months ended September 30, 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 nine months ended September 30, 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 November 8, 2022
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 8, 2022

/s/ Lisa Peraza
Lisa Peraza
Vice President, Chief Accounting Officer

EXHIBIT 99.1

Heron Therapeutics Announces Financial Results for the Three and Nine Months Ended September 30, 2022 and Highlights Recent Corporate Updates

- APONVIE™ approval by FDA, U.S. launch planned for Q1 2023 –

- ZYNRELEF® unit demand grew 18% over prior quarter in Q3 2022 –

- Oncology Care Franchise net product sales grew 13% over prior year in Q3 2022 –

SAN DIEGO, Nov. 8, 2022 /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 nine months ended September 30, 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 nine months ended September 30, 2022 were $2.7 million and $6.3 million, respectively. Net product sales of ZYNRELEF for both the three and nine months ended September 30, 2021 were $2.1 million (ZYNRELEF was launched July 1, 2021). ZYNRELEF end-user (ambulatory surgical centers (ASCs) and hospitals) demand unit sales were 15,077 in the third quarter of 2022, representing an increase of 18% over the prior quarter. Growth has substantially increased in October with weekly average ZYNRELEF demand unit sales increasing 27% over the weekly average in the third quarter. We currently expect fourth quarter 2022 ZYNRELEF net product sales to increase in the range of 30% to 40% over the prior quarter.
  - Since launch on July 1, 2021 through September 30, 2022, 704 unique accounts purchased ZYNRELEF with 84% of those accounts reordering the product.
  - All clinical studies planned for inclusion in the supplemental New Drug Application (NDA) to further expand the ZYNRELEF indication to soft tissue and orthopedic procedures are complete, with submission planned for late 2022.
- **APONVIE:**
  - The APONVIE (aprepitant) injectable emulsion NDA was approved by the U.S. Food and Drug Administration (FDA) on September 16, 2022. We expect to make APONVIE commercially available in the U.S. in the first quarter of 2023.
  - APONVIE is 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.

- 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 for prophylaxis.

Oncology Care Franchise

- **2022 Oncology Care Franchise Net Product Sales:** For the three and nine months ended September 30, 2022, oncology care franchise net product sales were $23.9 million and $71.3 million, respectively, compared to $21.1 million and $63.6 million, respectively, for the same periods in 2021.

- **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and nine months ended September 30, 2022 were $21.2 million and $64.2 million, respectively, compared to $18.0 million and $56.2 million, respectively, for the same periods in 2021.

    - Validation of large-scale manufacturing of CINVANTI was completed, which will result in a significant reduction in cost of product sales in the fourth quarter of 2022 and beyond.

- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and nine months ended September 30, 2022 were $2.7 million and $7.1 million, respectively, compared to $3.1 million and $7.4 million, respectively, for the same periods in 2021.

- **2022 Oncology Care Franchise Net Product Sales Guidance:** Heron currently expects full-year 2022 net product sales for the oncology care franchise of $93 million to $95 million.

“Approval of APONVIE expands our acute care franchise to cover the two most common concerns of patients and clinicians after surgery, pain and PONV. We are gratified to see improved growth of ZYNRELEF in October following the slower than anticipated growth in the third quarter, which coincided with a greater than 10% decline in indicated surgical procedures,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “Our oncology care franchise reported solid net product sales of $23.9 million for the third quarter of 2022 and we remain on track to achieve our full-year 2022 guidance of $93 million to $95 million. In addition, we strengthened our balance sheet with a $75 million private placement to advance our commercial franchises and extend our runway against a challenging external backdrop.”

Financial Results

Net product sales for the three and nine months ended September 30, 2022 were $26.6 million and $77.6 million, respectively, compared to $23.2 million and $65.7 million, respectively, for the same periods in 2021.

Heron’s net loss for the three and nine months ended September 30, 2022 was $41.9 million, or $0.38 per share, and $162.2 million, or $1.54 per share, respectively, compared to $52.4 million, or $0.51 per share, and $166.0 million, or $1.71 per share, respectively, for the same periods in 2021. Net loss for the three and nine months ended September 30, 2022 included non-cash, stock-based compensation expense of $11.2 million and $32.5 million, respectively, compared to $11.2 million and $34.0 million, respectively, for the same periods in 2021.

As of September 30, 2022, Heron had cash, cash equivalents and short-term investments of $121.7 million, compared to $157.6 million as of December 31, 2021. Net cash used for operating activities for the three and nine months ended September 30, 2022 was $37.1 million and $109.4 million, respectively, compared to $53.2 million and $158.1 million, respectively, for the same periods in 2021. The decrease in our net cash used for operating activities was primarily due to changes in working capital related to the launch of ZYNRELEF, including manufacturing of commercial inventory, as well as a decrease in net loss.

Conference Call and Webcast

Heron will host a conference call and webcast on November 8, 2022 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 4433557 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. 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. In September 2020, the European Commission granted a marketing authorization for ZYNRELEF for the treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults. As of January 1, 2021, ZYNRELEF is approved in 31 European countries including the countries of the European Union and European Economic Area and the United Kingdom. In March 2022, Health Canada issued a Notice of Compliance for ZYNRELEF for instillation into the surgical wound for postoperative analgesia after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty surgical procedures.

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

About APONVIE for PONV

APONVIE (aprepitant) injectable emulsion is a substance NK_1 RA, indicated for the prevention of postoperative nausea and vomiting in adults. Delivered via a 30-second intravenous (IV) injection, 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 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 NK1 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 NK1 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 timing and results of the commercial launch of APONVIE; 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; the extent of the impact of the ongoing COVID-19 pandemic on our business; 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,	
	2022	2021	2022	2021
Revenues:				
Net product sales	$ 26,557	$ 23,230	$ 77,644	$ 65,691
Operating expenses:				
Cost of product sales	14,717	11,351	42,247	35,080
Research and development	25,545	28,595	96,449	101,944
General and administrative	9,799	9,786	28,513	30,266
Sales and marketing	18,378	25,206	64,738	62,692
Total operating expenses	68,439	74,938	231,947	229,982
Loss from operations	(41,882)	(51,708)	(154,303)	(164,291)
Other expense, net	(26)	(700)	(7,852)	(1,746)
Net loss	$ (41,908)	$ (52,408)	$ (162,155)	$ (166,037)
Basic and diluted net loss per share	$ (0.38)	$ (0.51)	$ (1.54)	$ (1.71)

Heron Therapeutics, Inc.

Consolidated Balance Sheets

(in thousands)

	September 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 50,438	$ 90,541
Short-term investments	71,308	67,039
Accounts receivable, net	42,188	35,499
Inventory	52,239	48,382
Prepaid expenses and other current assets	7,631	12,962
Total current assets	223,804	254,423
Property and equipment, net	22,619	23,734
Right-of-use lease assets	8,204	9,829
Other assets	17,325	17,720
Total assets	$ 271,952	$ 305,706
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 6,547	$ 3,803
Accrued clinical and manufacturing liabilities	37,298	23,716
Accrued payroll and employee liabilities	14,708	15,263
Other accrued liabilities	32,703	25,859
Current lease liabilities	2,620	2,417
Total current liabilities	93,876	71,058
Non-current lease liabilities	6,151	7,996
Non-current convertible notes payable, net	149,234	149,082
Other non-current liabilities	241	—
Total liabilities	249,502	228,136
Stockholders' equity:		
Common stock	1,188	1,020
Additional paid-in capital	1,796,905	1,689,987
Accumulated other comprehensive loss	(57)	(6)
Accumulated deficit	(1,775,586)	(1,613,431)
Total stockholders' equity	22,450	77,570
Total liabilities and stockholders' equity	$ 271,952	$ 305,706

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