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 6, 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 8.01 Other Events.

On March 6, 2023, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that APONVIE™ (aprepitant) injectable emulsion is now commercially available for intravenous use in adults for the prevention of postoperative nausea and vomiting, as described in the press release filed herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 6, 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 6, 2023

/s/ David Szekeres

David Szekeres
Executive Vice President, Chief Operating Officer

Heron Therapeutics Announces U.S. Commercial Launch of APONVIE™ for the Management of Postoperative Nausea and Vomiting in Adults

- APONVIE, the first and only intravenous (IV) formulation of a substance P/neurokinin-1 (NK_1) receptor antagonist indicated for Postoperative Nausea and Vomiting (PONV) -

- APONVIE is delivered via a single IV push and offers 48 hours of PONV prevention -

- Leveraging existing acute care commercial teams across the U.S. -

SAN DIEGO, March 6, 2023 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced APONVIE (aprepitant) injectable emulsion, is now commercially available for intravenous (IV) use in adults for the prevention of PONV.

Delivered via a single IV injection, APONVIE reaches drug levels associated with ≥97% receptor occupancy in the brain within five minutes and maintains therapeutic plasma concentrations for at least 48 hours. This ready-to-use, easy to administer, innovative IV formulation ensures rapid and consistent exposure in patients undergoing surgery. Treatment with aprepitant resulted in approximately 50% fewer patients vomiting in the first 24 and 48 hours compared to the current standard-of-care, IV ondansetron.

“There are approximately 36 million procedures in the U.S. each year involving patients with high to moderate risk for PONV, the patients who would benefit most from APONVIE. With superior efficacy and convenient dosing, APONVIE has the potential to reach several hundred million dollars in sales,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “This launch supports our ongoing commitment to delivering innovative solutions that improve the postoperative experience by addressing the two most common concerns after surgery, postoperative pain with ZYNRELEF® and postoperative nausea and vomiting with APONVIE.”

“PONV is one of the most common and concerning side effects patients experience after surgery. Inadequately managed PONV can result in poor patient outcomes, decreased patient satisfaction as well as increased healthcare costs,” said Randy Robbins, MD, Managing Partner at Valiant Anesthesia Associates, PLLC. “Aprepitant is proven to be the most effective single agent to prevent PONV based on a comprehensive Cochrane meta-analysis. The launch of APONVIE will now allow providers to prevent PONV without the limitations of the current oral route of administration. We are very excited to see that physicians can now offer patients a more convenient IV push that delivers aprepitant in a rapid, consistent, and reliable way with the same 48-hour duration of effect, providing a better experience for patients postoperatively.”

APONVIE represents a significant opportunity that leverages Heron’s existing commercial organization in the acute care setting, with no additional field force and limited external spend needed for the launch. APONVIE also leverages our recent improvements in manufacturing efficiencies with CINVANTI.

Important Safety Information for Patients

APONVIE should not be used:

- if you are allergic to aprepitant or any of the ingredients in APONVIE
- if you are taking pimozide

APONVIE may cause serious side effects. Tell your doctor or nurse right away if you have any of these signs or symptoms of an allergic reaction:

- trouble breathing or swallowing, shortness of breath or wheezing
- swelling of your eyes, face, tongue, or throat
- flushing or redness of your face or skin
- hives, rash, or itching
- dizziness, a rapid or weak heartbeat, or you feel faint

APONVIE may affect how other medicines work. Other medicines may affect how APONVIE works. Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, or herbal supplements. If you take the blood-thinner medicine warfarin, your doctor may do blood tests after you receive APONVIE to check your blood clotting.

Women who use birth control medicines containing hormones to prevent pregnancy (birth control pills, skin patches, implants, and certain IUDs) should also use back-up methods of birth control (such as condoms and spermicides) for 1 month after receiving APONVIE.

Before you receive APONVIE, tell your doctor if you are pregnant or plan to become pregnant. APONVIE contains alcohol and may harm your unborn baby.

Before you receive APONVIE, tell your doctor if you are breast-feeding or plan to breastfeed because it is likely APONVIE passes into your milk, and it is not known if it can harm your baby. You and your doctor should decide if you will receive APONVIE, if breast-feeding.

The most common side effects of APONVIE are constipation, low blood pressure, tiredness, and headache.

Talk to your healthcare provider for medical advice about side effects. Report side effects to Heron at 1-844-437-6611 or to the Food and Drug Administration (FDA) at 1-800-FDA-1088 or www.fda.gov/medwatch.

The information provided here is not comprehensive. **Please see full Prescribing Information**.

About APONVIE for PONV

APONVIE (aprepitant) injectable emulsion is a substance P/NK_1 receptor antagonist, 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 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 a supplemental new drug application to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures. 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 Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs. 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, the results of the commercial launch of APONVIE; the potential market opportunity for APONVIE; 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.

Investor Relations and Media Contact:

David Szekeres
Executive Vice President, Chief Operating Officer
Heron Therapeutics, Inc.

dszekeres@herontx.com
858-251-4447