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 13, 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 13, 2023, Heron Therapeutics, Inc. (the "Company") issued a press release announcing that Centers for Medicare & Medicaid Services has approved transitional pass-through status for APONVIE™ (aprepitant) injectable emulsion, which will be established for three years beginning April 1, 2023 under C-code C9145, 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 13, 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 13, 2023

/s/ David Szekeres

David Szekeres
Executive Vice President, Chief Operating Officer

Heron Therapeutics Announces Centers for Medicare & Medicaid Services (CMS) Granted Pass-through Payment Status for APONVIE™, Effective April 1, 2023

SAN DIEGO, March 13, 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 that CMS has approved transitional pass-through status for APONVIE (aprepitant) injectable emulsion, which will be established for three years beginning April 1, 2023 under C-code C9145. APONVIE was approved by the U.S. Food and Drug Administration (FDA) for intravenous use in adults for the prevention of postoperative nausea and vomiting (PONV) and became commercially available on March 6, 2023.

CMS grants pass-through status to certain new and innovative medical devices, drugs, and biological products. Drugs that are administered in the hospital-based outpatient department (HOPD) and Ambulatory Surgical Center (ASC) settings can have pass-through status and be reimbursed accordingly by Medicare. APONVIE will be reimbursed separately outside of the surgical bundle payment by Medicare at an Average Sales Price +6% in both the HOPD and ASC settings of care.

“The granting of pass-through status for APONVIE further facilitates patient access and streamlines billing and reimbursement for all HOPD and ASC settings, which is important with over 70% of the surgery opportunity being conducted in these outpatient settings of care,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “Receiving pass-through only days after the U.S. launch is encouraging and will provide patients undergoing surgery that are at risk for developing PONV an easy to use, convenient, and highly effective treatment option.”

“APONVIE is the only drug for the prevention of PONV with Medicare reimbursement in both the HOPD and ASC settings of care,” said Kevin Warner, Pharm.D., Clinical Pharmacist in Saginaw, Michigan. “Pass-through status for APONVIE will facilitate patient access to a highly effective PONV prophylactic medication while minimizing costs to the institution. Incorporation of APONVIE into enhanced recovery after surgery protocols as part of PONV prophylaxis for moderate to high-risk patients could improve postoperative outcomes and satisfaction for patients.”

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 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 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:

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