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): December 29, 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 8.01 Other Events.

On December 29, 2022, Heron Therapeutics, Inc. (the "Company") issued a press release announcing the submission of a supplemental New Drug Application for ZYNRELEF® (bupivacaine and meloxicam) extended-release solution to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures and a newly passed congressional bill that is anticipated to provide separate reimbursement outside of the packaged surgical payment for ZYNRELEF for almost 3 years, as described in the press release furnished herewith as Exhibit 99.1 (the "Press Release").

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 29, 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: December 29, 2022

/s/ David Szekeres

David Szekeres
Executive Vice President, Chief Operating Officer

Heron Therapeutics Announces Filing of an Efficacy Supplement for ZYNRELEF® and Provision in Newly Passed Congressional Bill Anticipated to Provide Separate Reimbursement Outside of the Packaged Surgical Payment for ZYNRELEF

- Supplemental New Drug Application Submitted Requesting Expansion of Indication to Broadly Cover Soft Tissue and Orthopedic Surgical Procedures -

- Omnibus Spending Bill (H.R. 2617) Includes Provision to Provide Separate Payments for Non-Opioid Treatment for Pain Relief in the Outpatient Setting Beginning January 1, 2025 -

SAN DIEGO, Dec. 29, 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 the submission of a supplemental New Drug Application (sNDA) for ZYNRELEF (bupivacaine and meloxicam) extended-release solution to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures and a newly passed congressional bill that is anticipated to provide separate reimbursement outside of the packaged surgical payment for ZYNRELEF for almost 3 years.

ZYNRELEF is currently indicated 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. The current sNDA is based on safety and pharmacokinetic data from recently completed clinical trials in total shoulder arthroplasty, spinal surgery, abdominoplasty, and C-section showing comparable results to the previously completed pivotal safety and efficacy trials of ZYNRELEF.

H.R. 2617, the omnibus spending bill approved by Congress last week includes a provision (SEC. 4135. ACCESS TO NON-OPIOID TREATMENTS FOR PAIN RELIEF) requiring the Centers for Medicare and Medicaid Services (CMS) to pay for certain non-opioids outside the existing bundled payment for surgeries for the period of January 1, 2025 through December 31, 2027. In two Phase 3 trials, ZYNRELEF demonstrated the ability to significantly increase the proportion of patients taking no opioids after surgery and we believe it qualifies for this separate payment. ZYNRELEF currently has pass-through status in the outpatient setting of care through March 31, 2025 and this provision should extend separate reimbursement outside of the packaged surgical payment through December 31, 2027.

“Submission of this sNDA is designed to further expand ZYNRELEF’s indication for use in soft tissue and orthopedic procedures, which would double the current target surgical procedures to 14 million. The combination of the existing CMS pass-through payments with the new legislation providing separate payments for ZYNRELEF in the outpatient setting of care through December 31, 2027 will provide for more than 4 years of separate reimbursement payments after the 10-month anticipated action date for this sNDA,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “Expanding the indicated surgical procedures and gaining almost three additional years of separate payments from CMS is anticipated to significantly accelerate uptake of ZYNRELEF in large hospital systems, and allow many more patients to benefit from superior pain management over 72 hours with a reduced need for opioids.”

Important Safety Information for Patients

ZYNRELEF contains an NSAID (non-steroidal anti-inflammatory drug), a type of medicine which:

- **can increase the risk of a heart attack or stroke that can lead to death. This risk increases with higher doses and longer use of an NSAID.**
- **cannot be used during heart bypass surgery.**
- **can increase the risk of gastrointestinal bleeding, ulcers, and tears.**

ZYNRELEF should also not be used if you are allergic to any components of ZYNRELEF, similar local anesthetics, aspirin or other NSAIDs (such as ibuprofen or naproxen), or have had an asthma attack, hives, or other allergic reaction after taking any of these medicines; or as a paracervical block, during childbirth.

The most common side effects of ZYNRELEF are constipation, vomiting, and headache.

The medicines in ZYNRELEF (a local anesthetic and an NSAID) may affect the nervous and cardiovascular system; may cause liver or kidney problems; may reduce the effects of some blood pressure medicines; should be avoided if you have severe heart failure; may have adverse effects on cartilage; may cause a rare blood disorder, or life-threatening skin or allergic reactions; may harm your unborn baby if received at 20 weeks of pregnancy or later; and may cause low red blood cells (anemia).

Please see full Prescribing Information, including Boxed Warning.

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 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 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, the timing of the FDA's review process and whether the FDA approves the sNDA for ZYNRELEF to expand the U.S. label; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF; 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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