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): July 2, 2024

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 7.01 Regulation FD Disclosure.

On July 2, 2024, Heron Therapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration (the "FDA") has acknowledged the receipt of the Company's Prior Approval Supplement application for ZYNRELEF® (bupivacaine and meloxicam) extended-release solution Vial Access Needle, as further described in the press release. The FDA has assigned a Prescription Drug User Fee Act goal date of September 23, 2024. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated by reference in this Item 7.01.

As provided in General Instruction B.2 of Form 8-K, the information in this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, nor shall such information or Exhibit 99.1 be deemed to be incorporated by reference in any filing under the Securities Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated July 2, 2024
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: July 2, 2024

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer

Exhibit 99.1

Heron Therapeutics Announces Acceptance of the Prior Approval Supplement Application for ZYNRELEF® Vial Access Needle ("VAN")

-The U.S. Food and Drug Administration ("FDA") assigned a Prescription Drug User Fee Act ("PDUFA") goal date of September 23, 2024

SAN DIEGO, July 2, 2024 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX) ("Heron" or the "Company"), a commercial-stage biotechnology company, today announced that the FDA acknowledged the receipt of the Company's Prior Approval Supplement ("PAS") application for ZYNRELEF® (bupivacaine and meloxicam) extended-release solution VAN. The FDA has assigned a PDUFA goal date of September 23, 2024.

If approved, the introduction of the VAN will replace the current vented vial spike and has the potential to simplify aseptic preparation, while also significantly reducing ZYNRELEF's withdrawal time from up to three minutes down to between twenty and forty-five seconds. The user-friendly "container-like" design of the VAN may enhance the safe use of ZYNRELEF, increase adoption, and improve the preparation process. If approved, the VAN is expected to be available for use in the fourth quarter of this year.

In addition to the anticipated launch of the VAN, the national rollout of the CrossLink Life Sciences, LLC ("CrossLink") partnership continues to make progress and is expected to add ~650 representatives to the promotion of ZYNRELEF by year-end. The Company anticipates that this partnership will be instrumental in successfully launching the VAN to a large base of orthopedic surgeons across the country.

"The acknowledgement of the VAN submission and corresponding designation of a four-month review for ZYNRELEF is exciting and we look forward to working with the FDA during the application review process," said Craig Collard, Chief Executive Officer at Heron. "With the continued integration of CrossLink and the launch of the VAN, we are optimistic about the potential for more accounts to adopt ZYNRELEF as an essential part of their surgical procedures."

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 to include foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures. On January 23, 2024, the FDA approved ZYNRELEF for soft tissue and orthopedic surgical procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided. Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures.

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 component 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.
- as a paracervical block, during childbirth.

The most common side effects of ZYNRELEF are soft tissue procedures; vomiting and orthopedic procedures; constipation 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 cause 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).

Tell your healthcare provider about all your medical conditions and about all the medicines you take including prescription or over-the-counter medicines, vitamins, or herbal supplements to discuss if ZYNRELEF is right for you.

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

The information provided here is not comprehensive. 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. Therefore, you should not place undue reliance on forward-looking statements. Examples of forward-looking statements include, among others, statements we make regarding the potential market opportunities for ZYNRELEF®, APONVIE®, CINVANTI® and SUSTOL®; revenue, adjusted EBITDA and other financial guidance provided by the Company; the results of the commercial launch of APONVIE; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF; the timing of the Company’s development of the VAN program and receipt of required regulatory approvals, including any potential delays in the anticipated PDUFA goal date; our ability to establish and maintain successful commercial arrangements like our co-promotion agreement with CrossLink; the realization of anticipated benefits from our co-promotion agreement with CrossLink; the outcome of the Company’s pending abbreviated new drug application litigation; whether the Company is required to write-off any additional inventory in the future; 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 and the risk that future equity financings may be needed; and any inability or delay in achieving profitability. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, and in our other reports filed with the Securities and Exchange Commission, including under the caption “Risk Factors.” 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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