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): October 4, 2021

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 October 4, 2021, Heron Therapeutics, Inc. (the "Company") issued a press release announcing submission of a supplemental New Drug Application ("NDA") for ZYNRELEF® (bupivacaine and meloxicam) extended-release solution ("ZYNRELEF") for an expanded indication statement to include foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures without the need for additional clinical studies, as described in the press release furnished herewith as Exhibit 99.1 (the "Press Release"). The Company also announced that it has reached alignment with the U.S. Food and Drug Administration on the data needed to support a future supplemental NDA to further expand the ZYNRELEF indication statement to broadly include soft tissue and orthopedic surgical procedures with pharmacodynamic, pharmacokinetic and safety data from a limited number of additional procedures, as described in the Press Release.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 4, 2021
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: October 4, 2021

/s/ David Szekeres
David Szekeres
Executive Vice President, Chief Operating Officer

Exhibit 99.1

Heron Therapeutics Announces Filing of a Supplemental New Drug Application for Significant Expansion of ZYNRELEF® Indication Statement Based on Successful Outcome of FDA Type C Meeting

- FDA agreed to the immediate filing of supplemental NDA to significantly expand the ZYNRELEF indication statement based on previously submitted data with no new clinical studies -

- FDA also agreed on the required studies to support a broad soft tissue and orthopedic indication statement with a second supplemental NDA, planned for 2022 -

SAN DIEGO, Oct. 4, 2021 /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 submission of a supplemental New Drug Application (NDA) for ZYNRELEF (bupivacaine and meloxicam) extended-release solution for an expanded indication. ZYNRELEF is currently indicated 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. At a recent Type C meeting with the U.S. Food and Drug Administration (FDA), Heron gained agreement on the content of the supplement for expansion of the ZYNRELEF indication statement to include foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures without the need for additional clinical studies. This submission is based on the consistent safety, efficacy and pharmacokinetic data from previously completed clinical trials.

Alignment was also reached with the FDA on the data needed to support a future supplemental NDA to further expand the ZYNRELEF indication statement to broadly include soft tissue and orthopedic surgical procedures with pharmacodynamic, pharmacokinetic and safety data from a limited number of additional procedures. The studies in these additional surgeries are already in progress with the plan to submit the next supplement in the second half of 2022.

“Our Type C meeting with the FDA was very positive, with alignment on next steps for the submission of two sequential supplemental NDAs designed to expand the ZYNRELEF indication statement in a stepwise fashion. The first label expansion is designed to significantly increase the annual number of indicated surgical procedures and the second label expansion is anticipated to broadly cover 14 million targeted surgical procedures. Based on the strength of the clinical data already generated with ZYNRELEF, the FDA agreed Heron could immediately submit the first supplement, which we have done,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “Submission of the first supplement within three months of launching ZYNRELEF is a major accomplishment, with the second supplement planned for next year.”

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, 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) can 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 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 (DALA) 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 modified-release local anesthetic to be classified by FDA as an "extended-release" product because ZYNRELEF is also 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 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. 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. For more information visit 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 timing of the FDA's review process and whether the FDA approves the supplemental NDA for ZYNRELEF to expand the U.S. label to related procedures; the potential additional market opportunity for the expanded U.S. label; the timing and results of studies for the further expansion of the U.S. label for ZYNRELEF; the timing of the commercial launch of ZYNRELEF in Europe; the potential market opportunity for ZYNRELEF in the U.S. and Europe; the extent of the impact of the ongoing Coronavirus Disease 2019 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.

Investor Relations and Media Contact:

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