# 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 9, 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 December 9, 2021, Heron Therapeutics, Inc. issued a press release announcing that the U.S. Food and Drug Administration has approved its supplemental New Drug Application for ZYNRELEF® (bupivacaine and meloxicam) extended-release solution for use in foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures, as described in the press release furnished herewith as Exhibit 99.1.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated December 9, 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: December 9, 2021

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

# Heron Therapeutics Announces FDA Approval of a Significant Indication Expansion for ZYNRELEF®

*- Approval provides a significantly broader indication for ZYNRELEF, now covering approximately 7 million procedures a year -*

*- Conference call and webcast today, December 9, 2021 at 8:30 a.m. ET -*

SAN DIEGO, Dec. 9, 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 that the U.S. Food and Drug Administration (FDA) has approved its supplemental New Drug Application (sNDA) for ZYNRELEF (bupivacaine and meloxicam) extended-release solution to significantly expand the indication. ZYNRELEF is now 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.

ZYNRELEF is the first and only therapy for postoperative pain management to be rigorously tested in Phase 3 studies and demonstrate superiority to bupivacaine solution, the current standard-of-care. ZYNRELEF demonstrated superior, sustained postoperative pain relief for up to 72 hours and decreased the need for opioids, with more patients opioid-free compared to bupivacaine solution. With this approval, the FDA has confirmed that the superior efficacy demonstrated for ZYNRELEF in the pivotal trials supports its use in a broader group of related surgical procedures.

This expanded indication for ZYNRELEF will now cover approximately 7 million procedures annually. The use of ZYNRELEF in the additional procedures offers surgeons the opportunity to further reduce their patients need for opioids following surgery, which can positively impact the patients and limit the postoperative discharge opioids that can lead to misuse. Postoperative opioids have been shown to be a doorway to addiction with over 2 million Americans becoming persistent opioid users after receiving opioids following surgery. According to the Centers for Disease Control and Prevention, the highest number of overdose deaths on record occurred during the 12-month period ending April 2021, with over 100,000 American lives lost.

“The FDA approved the label expansion based on the strength of the ZYNRELEF clinical data in less than 6 months after our successful initial launch and only a little over 2 months from the sNDA submission,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “With this label expansion, ZYNRELEF is now indicated in significantly more surgeries per year, enabling more institutions to consider therapeutic substitution for a broad range of surgical procedures. To make it easier for healthcare providers to use ZYNRELEF in patients having surgeries included in our newly expanded indications, reimbursement for ZYNRELEF outside the surgical bundle payment is now up to 120 million commercial and Medicaid covered lives in the ASC setting of care, which we believe will continue to grow over the next several quarters.”

“As a surgeon, I have successfully used ZYNRELEF in over 200 total knee arthroplasty procedures and I have been very pleased with the results,” said Alexander Sah, M.D., orthopedic surgeon at Sah Orthopaedic Associates. “With ZYNRELEF used as the foundation of a multimodal analgesic regimen, most of my patients experienced mild, very manageable pain following surgery and only a few have needed a small amount of opioids for the pain. I have been eagerly awaiting the FDA label expansion to begin using this medication in total hip arthroplasty and additional procedures to provide effective pain management for my patients.”

Heron is continuing to study ZYNRELEF in additional procedures with plans to submit a second sNDA to the FDA in the second half of 2022 to support a broad indication for soft tissue and orthopedic surgical procedures, which is intended to cover the full 14 million target procedures.

**Conference Call and Webcast**

Heron will host a conference call and webcast on December 9, 2021 at 8:30 a.m. ET. The conference call can be accessed by dialing 877-311-5906 for domestic callers and 281-241-6150 for international callers. Please provide the operator with the passcode 5463776 to join the conference call. The conference call will also be available via webcast under the Investor Relations section of Heron's website at www.herontx.com. An archive of the teleconference and webcast will also be made available on Heron’s website for 60 days following the call.

**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 (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 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 now 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. 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 potential additional market opportunity for the ZYNRELEF 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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