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 25, 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 7.01 Regulation FD Disclosure.

Press Release.

On March 25, 2022, Heron Therapeutics, Inc. issued a press release (the "Press Release") announcing that the Centers for Medicare & Medicaid Services has approved transitional pass-through status for ZYNRELEF® (bupivacaine and meloxicam) extended-release solution, which will be established for three years beginning on April 1, 2022, for separate reimbursement outside of the surgical bundle payment in the Hospital Outpatient Department setting of care, as described in the Press Release furnished herewith as Exhibit 99.1.

Corporate Presentation.

A copy of presentation materials describing the business of the Company, all or a part of which may be used by the Company in investor or scientific presentations from time to time, is furnished herewith as Exhibit 99.2 (the "Corporate Presentation"). The Corporate Presentation has also been posted on the Company's website at *www.herontx.com*. The Company does not undertake
any obligation to update the Corporate Presentation.

This Item 7.01, the Press Release and the Corporate Presentation are being furnished to the Securities and Exchange Commission.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 25, 2022
99.2	Corporate Presentation, dated March 25, 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: March 25, 2022

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

Exhibit 99.1

Heron Therapeutics Secures Pass-through Payment Status for ZYNRELEF® from Centers for Medicare & Medicaid Services, Expanding Separate Reimbursement into the Hospital Outpatient Setting of Care

- ZYNRELEF is the only local anesthetic with separate reimbursement in both the Hospital Outpatient and Ambulatory Surgical Center settings of care -

SAN DIEGO, March 25, 2022 /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 Centers for Medicare & Medicaid Services (CMS) has approved transitional pass-through status for ZYNRELEF (bupivacaine and meloxicam) extended-release solution, which will be established for three years beginning on April 1, 2022, for separate reimbursement outside of the surgical bundle payment in the Hospital Outpatient Department (HOPD) setting of care. This CMS approval makes ZYNRELEF the only local anesthetic with separate reimbursement in the hospital outpatient market.

CMS grants pass-through status to certain new and innovative medical devices, drugs, and biological products. Drugs that are administered in the HOPD and Ambulatory Surgical Center (ASC) settings can have pass-through and be reimbursed accordingly by Medicare. By having pass-through status, ZYNRELEF will be separately reimbursed by Medicare at Average Sales Price (ASP) +6% in both the HOPD and ASC settings of care. In the ASC setting, since January 1, 2022, ZYNRELEF, under C-code C9088, has been reimbursed at ASP+6% due to recent changes in Medicare non-opioid pain management drugs and biologicals payment policies. Based on third party claims data, 72% of ZYNRELEF indicated procedures were performed in the outpatient settings in 2021, with 59% in the HOPD market and 13% in the ASC setting of care.

“With almost 60% of our indicated procedures occurring in the HOPD and our primary competitor no longer having reimbursement in this setting, receiving pass-through status from CMS is a hugely important milestone in the successful launch of ZYNRELEF,” said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. “Pass-through status will help accelerate access to ZYNRELEF for the millions of patients looking for superior postoperative pain relief through 72 hours by providing outpatient providers with superior reimbursement when administering ZYNRELEF.”

ZYNRELEF is approved by the U.S. Food and Drug Administration (FDA) for use 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.

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 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 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).

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 now 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. 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. In March 2022, Health Canada issued a Notice of Compliance for ZYNRELEF for instillation into the surgical wound for postoperative analgesia after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty surgical 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 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 market opportunity for ZYNRELEF in the U.S.; 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:

David Szekeres
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Heron Therapeutics, Inc.
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858-251-4447

Exhibit 99.2

ZYNRELEF's Significant Economic Benefit With Pass-Through Status

March 25, 2022

The Outpatient Setting of Care Now Represents >70% of Target Surgeries With Hospital Outpatient Approaching 60%

~14M
High Value Market Procedures[1]

Hospital Inpatient 28% (3.9M procedures)

- Bundled in DRG
- 57% (2.2M) of inpatient procedures are done in 340B hospitals

Hospital Outpatient 59% (8.3M procedures)

- 17% (1.4M) have Medicare reimbursement (3-year pass-through) at ASP +6%
- 58% (4.8M) eligible for 340B discount
- Multiple SKUs – lower average costs

Ambulatory Surgical Centers 13% (1.8M procedures)

- 18% (0.33M) eligible for Medicare reimbursement at ASP + 6%
- 123 million Medicaid and commercial lives covered outside surgical bundle
- Multiple SKUs – lower average costs

72% of the opportunity lends itself to favorable reimbursement and access

OVERALL TOTAL

- **ZYNRELEF has lower acquisition cost benefit versus Exparel**
- **ZYNRELEF will have HOPD reimbursement – 3-year pass-through**
- **ZYNRELEF offers 340B pricing**

SKU: stock keeping unit. **HOPD:** hospital outpatient department. 1. **Breakdown of settings of care based on** 2021 Lexis Nexis claims data

ZYNRELEF is the Only Reimbursed Local Anesthetic in Hospital Outpatient, the Largest Setting of Care

- Effective April 1, 2022 - ZYNRELEF is separately reimbursed for Medicare patients in the HOPD under 3-year transitional pass-through status
  - ZYNRELEF is the only local anesthetic with separate reimbursement in the HOPD
  - With pass-through status, the economic benefits vs Exparel in 340B and HOPD more than double
  - 72% of indicated procedures were performed in outpatient settings in 2021 (59% in HOPD, 13% in ASC)[a]
- Effective January 1, 2022 - ZYNRELEF is separately reimbursed for Medicare patients in the ASC and a product specific C-code (C9088) is assigned
- Multiple commercial payers and state Medicaid agencies covering >123 million lives have agreed to reimburse ZYNRELEF outside of the surgical packaged payment in the ASC
  - Many of these covered lives are also reimbursed separately in the HOPD
- ZYNRELEF's lower price benefits all settings of care, including those in which local anesthetics are reimbursed as part of the surgical packaged payment

HOPD: Hospital Outpatient Department; **ASC**: Ambulatory Surgical Center

[a] Based on third party claims data

HERON THERAPEUTICS

ZYNRELEF's Economic Benefits Significantly Lower Hospital Costs, While Improving the Standard of Care

ZYNRELEF	WAC	340B
400 mg/12 mg	$267.50	$205.36
200 mg/6 mg	$135.50	$104.14

Exparel	WAC	340B
266 mg (20 mL)	$354.53	$354.53
133 mg (10 mL)	$198.84	$198.84

ZYNRELEF Savings vs Exparel

WAC $/unit	WAC %	340B $/unit	340B %
~ $87	25%	~$149	42%
~ $63	32%	~$95	48%

Medicare NCR By Site of Care*

	NCR 340B	NCR HOPD	ASC
ZYNRELEF 400 mg/12 mg	$73.44	$11.30	$11.30
Exparel 266 mg	($354.53)	($354.53)	$1.92
ZYNRELEF 200 mg/6 mg	$35.26	$3.90	$3.90
Exparel 133 mg	($198.84)	($198.84)	($20.62)

Does not include additional cost of bupivacaine to admix with Exparel to achieve efficacy

ZYNRELEF Economic Benefit vs. Exparel*

- 340B accounts: ~ $428 (400 mg to 266 mg) and ~ $234 (200 mg to 133 mg)
- HOPD accounts: ~ $366 (400 mg to 266 mg) and ~ $203 (200 mg to 133 mg)
- Example, 340B facility performing 250 HOPD Medicare TKAs per month save over $1 million in out-of-pocket Exparel costs and make ~ $220,000 in profit by switching to ZYNRELEF
- Lower acquisition cost also seen as significant advantage**

*Estimates Comparing WAC (or 340B) acquisition cost to published ASP reimbursement for Medicare patients to calculate NCR based on ZYNRELEF Q2'22 rate and Exparel Q1'22 rate. Medicare reimbursement is subject to sequestration. .
WAC: wholesale acquisition cost. NCR: net cost recovery. HOPD: hospital outpatient department. ASC: ambulatory surgical center.
**DRG Research Pricing Research 2018 and Mock P&T Research 2019

HERON THERAPEUTICS