

**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): January 5, 2024

Heron Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-33221
(Commission
File Number)

94-2875566
(I.R.S. Employer
Identification No.)

4242 Campus Point Court, Suite 200, San Diego, CA
(Address of principal executive offices)

92121
(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 1.01 Entry into a Material Definitive Agreement.

On January 5, 2024, Heron Therapeutics, Inc. (the “Company”) and Crosslink Network, LLC (“Crosslink”) entered into a Co-Promotion Agreement (the “Co-Promotion Agreement”). Pursuant to the Co-Promotion Agreement, the Company appointed Crosslink to co-promote the sale of ZYNRELEF® (bupivacaine and meloxicam) extended-release solution (the “Product”) in the United States on a co-exclusive basis for all of the Product’s current and future U.S. Food and Drug Administration (“FDA”) approved indications involving surgical procedures performed within the United States during the term of the Co-Promotion Agreement. Under the Co-Promotion Agreement, Crosslink commits to having: (i) at least 325 sales representatives promoting the Product within the United States by July 1, 2024 and (ii) at least 650 sales representatives promoting the Product within the United States by January 1, 2025 and continuing thereafter throughout the term of the Co-Promotion Agreement.

Pursuant to the Co-Promotion Agreement, the Company commits to paying Crosslink certain cash base compensation on a fixed-fee per vial basis, based on growth over a pre-determined baseline period. The Company also commits to paying Crosslink certain cash compensation in an amount up to \$5,000,000 throughout the term of the Co-Promotion Agreement if certain year-over-year sales-growth milestones are met. In addition, the Company commits to awarding to a limited liability company (“Crosslink Newco”) to be formed by Crosslink up to 1,666,670 shares of common stock, par value \$0.01 per share (the “Common Stock”), of the Company, subject to certain performance criteria pursuant to the Co-Promotion Agreement. In the event the Co-Promotion Agreement expires or is terminated, any shares subject to this award that have not been awarded at the time of such expiration or termination are automatically forfeited by Crosslink Newco. In the event the Company undergoes a Change of Control (as defined in the Company’s Amended and Restated 2007 Equity Incentive Plan), during the Initial Period (as defined below), this award of Common Stock will be subject to acceleration pursuant to the terms of the Co-Promotion Agreement.

The term of the Co-Promotion Agreement expires on December 31, 2028 (the “Initial Period”), and will automatically renew for successive periods of one year each, unless terminated by either party pursuant to the Co-Promotion Agreement (each additional one year renewal term, a “Renewal Period”). Either party may terminate the Co-Promotion Agreement at the expiration of the Initial Period or any Renewal Period, without cause, by giving 90 days prior written notice of such termination to the other party. Subject to specified notice periods and limitations, the Company may terminate the Co-Promotion Agreement early if certain identified events or activities occur. In addition, subject to specified notice periods and limitations, either the Company or Crosslink may terminate the Co-Promotion Agreement early if upon mutual written agreement of the parties and other specified events.

The foregoing summary description of certain terms of the Co-Promotion Agreement is not complete and is qualified in its entirety by reference to the text of the Co-Promotion Agreement, which the Company expects to file as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ending December 31, 2023. A copy of the press release announcing entry into the Co-Promotion Agreement is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished as part of this report:

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release, dated January 7, 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.

Date: January 11, 2024

Heron Therapeutics, Inc.

/s/ Ira Duarte

Ira Duarte

Executive Vice President, Chief Financial Officer

Heron Therapeutics Announces Partnership with CrossLink Life Sciences to Expand Promotional Effort for ZYNRELEF®, the First and Only Non-Opioid Dual Acting Local Anesthetic for Post-Operative Pain

SAN DIEGO, January 7, 2024 /PRNewswire/ — Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company, today announced that it has entered into a five-year distributor partnership with CrossLink Life Sciences, LLC to expand the sales network supporting ZYNRELEF® (bupivacaine and meloxicam) extended-release solution.

The partnership will launch in several phases, initially at a regional level, followed by an expanded national rollout. In total, approximately 650 representatives will be added to Heron’s sales network over the next year. CrossLink will be the lead partner in the United States to expand ZYNRELEF promotion for orthopedic indications. Under the terms of the agreement, CrossLink is compensated on a fixed-fee per vial basis, based on growth over a pre-determined baseline period.

“This partnership will allow Heron to expand access to this pain-reducing product for orthopedic surgery patients, allowing more accounts to adopt ZYNRELEF as an essential part of their surgical procedures,” said Craig Collard, Chief Executive Officer of Heron. “CrossLink has a proven track record of success in building relationships, providing superior service to healthcare providers and improving patient outcomes. We look forward to kicking off a successful collaboration and further positioning Heron to deliver substantial value and impact patient lives in the coming years.”

“We are excited about the partnership with Heron and its upcoming potential expansion of the ZYNRELEF label and the vial-access needle (VAN) which will streamline the product preparation. We have seen first-hand the impact that ZYNRELEF can have on post-operative pain, and our team is excited to deliver ZYNRELEF to more patients across the country,” said Thomas Fleetwood, Chief Executive Officer of CrossLink.

CrossLink is the largest private orthopedic, spine and sports medicine device distributorship in the United States, consisting of experienced sales, operations and logistics teams driven by the foundational goal of improving patient outcomes. Over the past 45 years, its world class specialty sales organization and national network of distributors have become the market leaders in each of the regional markets they serve.

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 U.S. Food and Drug Administration (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. In December 2022, we submitted an sNDA to support the proposed indication for greatly expanded use of ZYNRELEF in soft tissue and orthopedic surgical procedures. On July 31, 2023, the FDA notified Heron of an extension of the PDUFA approval goal date by three months to provide for a full review of the submission. The FDA has set a new extended PDUFA approval goal date of January 23, 2024. 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. ZYNRELEF was granted a marketing authorization by the European Commission in September 2020 and by the United Kingdom Regulatory Authority in January 2021. In August 2023, we cancelled the ZYNRELEF U.K. marketing authorization and, in October 2023, we cancelled the ZYNRELEF European Union (EU) marketing authorization, as we do not plan to commercially launch ZYNRELEF in the U.K. or the EU.

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.heronrx.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, uncertainties related to market conditions; the potential market opportunities for ZYNRELEF, APONVIE, CINVANTI and SUSTOL; the net product sales guidance for the oncology care franchise and the acute care franchise; the EBITDA guidance provided by the Company; the results of the commercial launch of APONVIE; the timing of the FDA’s review process and whether the FDA approves the sNDA for ZYNRELEF to further expand the U.S. label; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF, if approved; the timing of the Company’s development of the VAN program; the timing of the Company’s submission of the PAS to the FDA for the VAN; the timing of the FDA’s review process and whether the FDA approves the PAS for the VAN; the outcome of the Company’s pending ANDA litigation related to CINVANTI; 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; any inability or delay in achieving profitability; 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.

Please see full prescribing information, including Boxed Warning, at www.ZYNRELEF.com.

Investor Relations and Media Contact:

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