# Heron Therapeutics Announces Financial Results for the Three Months Ended March 31, 2023 and Highlights Recent Corporate Updates

May 11, 2023

· *Net Product Sales for First Quarter of 2023 Grew 26% to $29.6 million, Compared to First Quarter Net Product Sales in 2022*

· *Appointment of Craig Collard as Chief Executive Officer (CEO) and Jason Grillot as Vice President (VP), Sales and Marketing, of the Acute Care Franchise.*

SAN DIEGO, May 11, 2023 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX) (the "Company"), a commercial-stage biotechnology company focused on improving the lives of patients by developing and commercializing therapeutic innovations that improve medical care, today announced financial results for the three months ended March 31, 2023 and highlighted recent corporate updates.

First quarter 2023 net product sales grew 26% to $29.6 million, compared to the first quarter of 2022. The sales growth was mainly driven by our oncology care franchise, which increased 15%, compared to the same period in 2022. First quarter also reflected continued advancement of our acute care franchise, with $3.5 million in net product sales from ZYNRELEF® and initial orders from the launch of APONVIE® in March.

With the appointment of Craig Collard as CEO in April and the recent hiring of Jason Grillot as VP of sales and marketing of the acute care franchise, the team is conducting a thorough review of the Company's business practices and strategies to develop a long-term plan that maximizes the potential of the Company. We have identified two areas of immediate priority for our commercial team: first, is to enhance the value of ZYNRELEF through a broader and deeper penetration of accounts; second, to address application issues through training and expanded indications. Further, we are looking at ways to reduce cash burn through improved operational efficiency. We look forward to updating investors on these fronts in the coming months.

***Acute Care Franchise***

- **ZYNRELEF:**
  - Net product sales of ZYNRELEF (bupivacaine and meloxicam) extended-release solution for the three months ended March 31, 2023 was $3.5 million.
  - Since launch on July 1, 2021 through March 31, 2023, 907 unique accounts purchased ZYNRELEF with 80% of those accounts reordering the product.
  - The supplemental New Drug Application (sNDA) for ZYNRELEF, to support expanded use in soft tissue and orthopedic surgical procedures remains on track for the Prescription Drug User Fee Act (PDUFA) approval goal date of October 23, 2023.
- **APONVIE:**
  - The APONVIE (aprepitant) injectable emulsion, the only intravenous (IV) substance P/neurokinin-1 ($NK_1$) receptor antagonist (RA) indicated for the prevention of postoperative nausea and vomiting (PONV) in adults, launched commercially in the U.S. on March 6, 2023.
  - Net product sales of APONVIE for the three months ended March 31, 2023 were $0.3 million.
  - The Centers for Medicare and Medicaid Services granted pass-through payment status for APONVIE, effective April 1, 2023, under C-code C9145.

***Oncology Care Franchise***

- **Oncology Care Franchise Net Product Sales:** For the three months ended March 31, 2023, oncology care franchise net product sales were $25.8 million, which increased 15% from $22.4 million for the same period in 2022.
- **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three months ended March 31, 2023 were $22.8 million, compared to $20.3 million for the same period in 2022.
- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three months ended March 31, 2023 were $3.0 million, compared to $2.1 million for the same period in 2022.

"We continued to make steady progress in the first quarter of 2023 at Heron, highlighted by the approval and launch of our fourth commercial product, APONVIE. We are pleased with the steady growth in the oncology care franchise and remain encouraged by the market potential for ZYNRELEF and APONVIE," said Craig Collard, new Chief Executive Officer of Heron. "Looking ahead, we are focused on reducing our cash burn and advancing a streamlined organization that we believe will begin to show significant growth while also continuing to improve patient's lives."

**Financial Results**

Net product sales for the three months ended March 31, 2023 were $29.6 million, compared to $23.5 million for the same period in 2022.

For the three months ended March 31, 2023, total operating expenses were $62.7 million, compared to $86.4 million for the same period in 2022, representing a decrease of $23.7 million, or a 27% reduction year-over-year. This decrease was driven by cost management efforts and a reduction in development projects, offset by higher cost of goods sold and increased litigation expenses. Cost of product sales were $16.9 million in the first quarter of 2023, compared to $11.4 million for the same period in the prior year. The product gross margin rate decreased year-over-year primarily as a result of a one time inventory write-off due to short-dated product. Sales and marketing expenses decreased by $2.3 million, primarily due to a reduction in personnel expenses and external costs to support the ongoing commercialization of ZYNRELEF. Research and development expenses decreased by $28.3 million, primarily driven by lower personnel and project-related expenses, including manufacturing projects to increase operational efficiencies. General and administrative expenses increased by $1.3 million, primarily driven by increased litigation and activist shareholder issues.

Heron's net loss for the three months ended March 31, 2023 was $32.8 million, or $0.27 per share, compared to $63.9 million, or $0.63 per share, for the same period in 2022. Net loss for the three months ended March 31, 2023 included non-cash, stock-based compensation expense of $7.9 million, compared to $10.9 million for the same period in 2022.

As of March 31, 2023, Heron had cash, cash equivalents and short-term investments of $60.0 million, compared to $84.9 million as of December 31, 2022. Net cash used for operating activities for the three months ended March 31, 2023 was $24.9 million, compared to $43.9 million for the same period in 2022. The decrease in our net cash used for operating activities was primarily due to a decrease in net loss, the reduction in headcount implemented in June 2022 and changes in working capital.

**Conference Call and Webcast**

Heron will host a conference call and webcast on May 11, 2023 at 4:30 p.m. ET. The conference call can be accessed by dialing (646) 307-1963 for domestic callers and (800) 715-9871 for international callers. Please provide the operator with the passcode 1933547 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.

**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. 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, and the FDA assigned a PDUFA goal date of October 23, 2023. 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.

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

**About APONVIE for PONV**

APONVIE is a substance $NK_1$ RA, indicated for the prevention of PONV in adults. Delivered via a 30-second IV push, APONVIE 32 mg was demonstrated to be bioequivalent to oral aprepitant 40 mg with rapid achievement of therapeutic drug levels. APONVIE is the same formulation as Heron's approved drug product CINVANTI. APONVIE is supplied in a single-dose vial that delivers the full 32 mg dose for PONV. APONVIE was approved by the FDA in September 2022.

Please see full prescribing information at www.APONVIE.com.

**About CINVANTI for Chemotherapy Induced Nausea and Vomiting (CINV) Prevention**

CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen. CINVANTI is an IV formulation of aprepitant, an $NK_1$ RA. CINVANTI is the first IV formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent $NK_1$ RA to significantly reduce nausea and vomiting in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy). The FDA-approved dosing administration included in the U.S. prescribing information for CINVANTI include 100 mg or 130 mg administered as a 30-minute IV infusion or a 2-minute IV injection.

Please see full prescribing information at www.CINVANTI.com.

**About SUSTOL for CINV Prevention**

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-hydroxytryptamine type 3 RA that utilizes Heron's Biochronomer® drug delivery technology to maintain therapeutic levels of granisetron for ≥5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical studies that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (0–24 hours after chemotherapy) and delayed phase (24–120 hours after chemotherapy).

Please see full prescribing information at www.SUSTOL.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, 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 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, if approved; 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; the ability for the Company to reach 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.

**Heron Therapeutics, Inc.**
Consolidated Statements of Operations
(In thousands, except per share amounts)

| | Three Months Ended March 31, | |
|---|---|---|
| | **2023** | **2022** |
| Revenues: | (unaudited) | |
| Net product sales | $ 29,615 | $ 23,457 |
| Operating expenses: | | |
| Cost of product sales | 16,854 | 11,355 |
| Research and development | 13,817 | 42,070 |
| General and administrative | 10,853 | 9,533 |
| Sales and marketing | 21,154 | 23,422 |
| Total operating expenses | 62,678 | 86,380 |
| Loss from operations | (33,063) | (62,923) |
| Other income (expense) | 295 | (965) |
| Net loss | $ (32,768) | $ (63,888) |

**Heron Therapeutics, Inc.**
Consolidated Balance Sheets
(in thousands)

| | **March 31, 2023** | **December 31, 2022** |
|---|---|---|
| | **(Unaudited)** | |
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 27,090 | $ 15,364 |
| Short-term investments | 32,932 | 69,488 |
| Accounts receivable, net | 51,448 | 52,049 |
| Inventory | 52,059 | 54,573 |
| Prepaid expenses and other current assets | 14,630 | 13,961 |
| Total current assets | 178,159 | 205,435 |
| Property and equipment, net | 21,512 | 22,160 |
| Right-of-use lease assets | 7,071 | 7,645 |
| Other assets | 14,136 | 15,711 |
| Total assets | $ 220,878 | $ 250,951 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |

| | | |
|---|---|---|
| Current liabilities: | | |
| Accounts payable | $ 4,065 | $ 3,225 |
| Accrued clinical and manufacturing liabilities | 21,273 | 24,468 |
| Accrued payroll and employee liabilities | 9,510 | 13,416 |
| Other accrued liabilities | 40,290 | 38,552 |
| Current lease liabilities | 2,762 | 2,694 |
| Total current liabilities | 77,900 | 82,355 |
| Non-current lease liabilities | 4,831 | 5,499 |
| Non-current convertible notes payable, net | 149,335 | 149,284 |
| Other non-current liabilities | 241 | 241 |
| Total liabilities | 232,307 | 237,379 |
| Stockholders' equity (deficit): | | |
| Common stock | 1,193 | 1,191 |
| Additional paid-in capital | 1,815,592 | 1,807,855 |
| Accumulated other comprehensive income (loss) | 9 | (19) |
| Accumulated deficit | (1,828,223) | (1,795,455) |
| Total stockholders' equity (deficit) | (11,429) | 13,572 |
| Total liabilities and stockholders' equity (deficit) | $ 220,878 | $ 250,951 |

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