Heron Therapeutics Announces Financial Results for the Three and Six Months Ended June 30, 2022 and Highlights Recent Corporate Updates

August 9, 2022

- ZYNRELEF® launch trend continues at a strong pace with sequential quarterly product sales increase of 140% and unit demand increase of 47% -

- Oncology Care Franchise net product sales grew 12% over the prior quarter to $25.1 million in Q2 2022, leading to *an increase in full-year 2022 net product sales guidance to $93 million to $95 million -*

- Improving operating margins, the implementation of a restructuring announced in June, and other cost cutting activities are projected to achieve over $50 million in reductions in annual operating expense in 2023 -

- With the proceeds from the recent private placement, pro-forma cash at the end of second quarter was $158.7 million, which is projected to provide a cash runway through 2024 -

SAN DIEGO, Aug. 9, 2022 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), 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 and six months ended June 30, 2022 and highlighted recent corporate updates.

Recent Corporate Updates

Acute Care Franchise

- **ZYNRELEF:**
  - Net product sales of ZYNRELEF (bupivacaine and meloxicam) extended-release solution for the three and six months ended June 30, 2022 were $2.5 million and $3.6 million, respectively. During the second quarter, ZYNRELEF net product sales grew by 140% over the prior quarter. Heron currently expects third quarter 2022 ZYNRELEF net product sales to increase in the range of 40% to 50% over the prior quarter.
  - ZYNRELEF end-user (ambulatory surgical centers (ASC) and hospitals) demand unit sales were 12,773 in the second quarter of 2022, representing an increase of 47% over the prior quarter.
  - During the first year of commercial launch and as of June 30, 2022, 602 unique accounts purchased ZYNRELEF with 84% of those accounts reordering the product.
  - As of July 31, 2022, ZYNRELEF has received 384 formulary approvals, reflecting a greater than 90% approval rate of formulary evaluations, with an estimated 68% of approvals supporting unrestricted use. Approximately 80 additional formulary review meetings are scheduled for the remainder of 2022.
  - Effective April 1, 2022, ZYNRELEF became the only local anesthetic separately reimbursed for Medicare patients in the Hospital Outpatient Department (HOPD) setting of care under a 3-year transitional pass-through status. Multiple commercial and Medicaid payers covering over 123 million lives have agreed to reimburse ZYNRELEF outside of the surgical bundle payment for surgeries performed in ASCs, with many of these covered lives also having their hospital outpatient procedures reimbursed outside the surgical bundle payment. Commercial and Medicaid payers represent greater than 80% of our targeted patients in the outpatient setting. Additionally, a specific C-code (C9088) for separate reimbursement in the ASC setting of care has been received.
  - All clinical studies planned for inclusion in the supplemental NDA to further expand the ZYNRELEF indication to soft tissue and orthopedic procedures are fully enrolled, with submission planned for late 2022.
- **HTX-019 for Prevention of PONV**
  - Postoperative nausea and vomiting (PONV) represents a significant market opportunity in the acute care setting that leverages our existing sales organization. There are approximately 39 million surgical procedures annually where patients are at risk for PONV.
  - **NDA Submission for HTX-019 for Prevention of PONV in Adults Under Review:** A 505(b)(2) New Drug Application (NDA) for HTX-019 for the prevention of postoperative nausea and vomiting (PONV) in adults was submitted to the U.S. Food and Drug Administration (FDA) in November 2021. The FDA accepted the NDA for filing and set a Prescription Drug User Fee Act (PDUFA) goal date of September 17, 2022.

Oncology Care Franchise

- **2022 Oncology Care Franchise Net Product Sales:** For the three and six months ended June 30, 2022, oncology care franchise net product sales were $25.1 million and $47.5 million, respectively, compared to $22.4 million and $42.5 million, respectively, for the same periods in 2021. During the second quarter, Heron's oncology care franchise net product sales grew by 12% over the prior quarter with continued moderate growth compared to the prior year expected for the remainder of 2022.
- **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and six months ended June 30, 2022 were $22.7 million and $43.0 million, respectively, compared to $19.7 million and $38.2 million, respectively, for the same periods in 2021.
- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and six months ended June 30, 2022 were $2.4 million and $4.5 million, respectively, compared to $2.7 million and $4.3 million, respectively, for the same periods in 2021.
- **2022 Oncology Care Franchise Net Product Sales Guidance Increased:** Heron currently expects full-year 2022 net product sales for the oncology care franchise of $93 million to $95 million, up from prior guidance of $89 million to $93 million.

Corporate Restructuring and Cost Reduction Plan

In June 2022, we announced a corporate restructuring and cost reduction plan to address the current market dynamics and prepare the company for long-term sustainability. Annualized cost savings the Company expects from this restructuring, improved operating margins and other cost cutting efforts are expected to achieve over $50 million in reductions in annual operating expense in 2023.

The Company's restructuring and cost reduction plan included the following:

- **Workforce reduction:** The majority of the cost savings will result from a significant workforce reduction across the Company's research and development organization, with approximately 70% of the total employee reductions coming from research and development. The remaining research and development team will support the label expansion for ZYNRELEF and the HTX-019 NDA for PONV. In total, these actions will result in a reduction of the total Company employee base by 34%.
- **Streamlined operational expenditures:** Includes reductions and reallocations in overall sales, general and administrative expenses, as well as savings related to reduced external spend.
- **Improved operating margins:** Heron has invested heavily in large-scale manufacturing capacity for both CINVANTI and ZYNRELEF, which are both expected to come on-line in 4Q2022. Larger scale production from these efforts should significantly improve cost of goods for both products.

"Our recent private placement financing is another important strategic step for Heron. Along with our restructuring and cost reduction plans, we now believe we have sufficient cash to take us through 2024 and to become cash flow positive," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "We are also excited to report today strong growth across both our business units, with a 140% increase in net product sales of ZYNRELEF compared to first quarter. We expect continued momentum in the second half of the year as more hospitals switch to ZYNRELEF due to its favorable clinical profile and strong reimbursement. For the oncology care franchise, we are pleased that our portfolio beat our guidance with net product sales of $25.1 million for the second quarter of 2022 and we are on track to achieve full-year 2022 net product sales of $93 million to $95 million, an increase from prior guidance. We look forward to large-scale manufacturing of CINVANTI coming on-line later this year, which is expected to substantially improve margins and drive greater profitability of the oncology care franchise. With recent changes in CMS reimbursement, CINVANTI has the opportunity for continued growth through 2023. Finally, as we near our September PDUFA date, interactions with the FDA regarding our pending NDA for HTX-019 for PONV remain on track."

Financial Results

Net product sales for the three and six months ended June 30, 2022 were $27.6 million and $51.1 million, respectively, compared to $22.4 million and $42.5 million, respectively, for the same periods in 2021.

Heron's net loss for the three and six months ended June 30, 2022 was $56.4 million, or $0.55 per share, and $120.2 million, or $1.18 per share, respectively, compared to $61.0 million, or $0.62 per share, and $113.6 million, or $1.20 per share, respectively, for the same periods in 2021. Net loss for the three and six months ended June 30, 2022 included non-cash, stock-based compensation expense of $10.4 million and $21.3 million, respectively, compared to $11.2 million and $22.7 million, respectively, for the same periods in 2021.

As of June 30, 2022, Heron had cash, cash equivalents and short-term investments of $83.5 million. Adjusting for net proceeds of $75.2 million from our August 2022 private placement, Heron had pro-forma cash, cash equivalents and short-term investments of $158.7 million. This compares to $157.6 million as of December 31, 2021. Net cash used for operating activities for the three and six months ended June 30, 2022 was $28.4 million and $72.3 million, respectively, compared to $63.0 million and $104.9 million, respectively, for the same periods in 2021. The decrease in our net cash used for operating activities was primarily due to changes in working capital related to the launch of ZYNRELEF, including manufacturing of commercial inventory, partially offset by an increase in net loss.

With the proceeds from the recent private placement, pro-forma cash at the end of second quarter was $158.7 million, which we believe is projected to provide a cash runway through 2024.

Conference Call and Webcast

Heron will host a conference call and webcast on August 9, 2022 at 8:30 a.m. ET. The conference call can be accessed by dialing 1-646-307-1963 for domestic callers and 1-800-715-9871 for international callers. Please provide the operator with the passcode 4215874 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. 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 HTX-019 for PONV

HTX-019 is an IV injectable emulsion formulation designed to directly deliver aprepitant, the active ingredient in EMEND® (aprepitant) capsules, which is the only substance P/neurokinin-1 (NK_1) receptor antagonist (RA) to be approved in the U.S. for the prevention of PONV in adults.
The FDA-approved dose of oral EMEND is 40 mg for PONV prevention, which is given within 3 hours prior to induction of anesthesia for surgery. In a Phase 1 clinical trial, 32 mg of HTX-019 as a 30-second IV injection was demonstrated to be bioequivalent to oral aprepitant 40 mg. The NDA for HTX-019 for PONV was submitted in November 2021 and the FDA set a PDUFA goal date of September 17, 2022.

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 and the completion of the private placement on the anticipated terms or at all; the potential market opportunities for ZYNRELEF in the U.S., Europe and Canada; the timing of the NDA review process for HTX-019 and whether the FDA approves HTX-019; the net product sales guidance for the oncology care franchise and the acute care franchise; 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 impact of our restructuring plans; the ability for the Company to reach profitability; the extent of the impact of the ongoing COVID-19 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:		(**Unaudited**)		
Net product sales	$ 27,630	$ 22,443	$ 51,087	$ 42,461
Operating expenses:				
Cost of product sales	16,175	14,522	27,530	23,729
Research and development	28,834	35,233	70,904	73,349
General and administrative	9,181	10,907	18,714	20,480
Sales and marketing	22,938	22,250	46,360	37,486
Total operating expenses	77,128	82,912	163,508	155,044
Loss from operations	(49,498)	(60,469)	(112,421)	(112,583)
Other expense, net	(6,861)	(546)	(7,826)	(1,046)
Net loss	$ (56,359)	$ (61,015)	$(120,247)	$ (113,629)
Basic and diluted net loss per share	$ (0.55)	$ (0.62)	$ (1.18)	$ (1.20)
Shares used in computing basic and diluted net loss per share	102,405	98,459	102,265	94,943

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

	June 30, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 48,609	$ 90,541
Short-term investments	34,929	67,039
Accounts receivable, net	40,303	35,499
Inventory	61,318	48,382
Prepaid expenses and other current assets	9,050	12,962
Total current assets	194,209	254,423
Property and equipment, net	23,468	23,734
Right-of-use lease assets	8,754	9,829
Other assets	17,534	17,720
Total assets	$ 243,965	$ 305,706
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	$ 13,804	$ 3,803
Accrued clinical and manufacturing liabilities	43,670	23,716
Accrued payroll and employee liabilities	16,323	15,263
Other accrued liabilities	33,152	25,859
Current lease liabilities	2,549	2,417
Total current liabilities	109,498	71,058
Non-current lease liabilities	6,780	7,996
Non-current convertible notes payable, net	149,182	149,082
Other non-current liabilities	241	—
Total liabilities	265,701	228,136
Stockholders' equity (deficit):		
Common stock	1,025	1,020
Additional paid-in capital	1,710,928	1,689,987
Accumulated other comprehensive loss	(11)	(6)
Accumulated deficit	(1,733,678)	(1,613,431)
Total stockholders' equity (deficit)	(21,736)	77,570
Total liabilities and stockholders' equity (deficit)	$ 243,965	$ 305,706

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