Heron Therapeutics Announces Second Quarter 2024 Financial Results and Narrows Financial Guidance

August 6, 2024

- *Second quarter Net Product Sales of $36.0 million, which increased from $31.8 million for the same period in 2023*
- *ZYNRELEF® Vial Access Needle ("VAN") PDUFA goal date set for September 23, 2024*
- *ZYNRELEF included in the proposed 2025 Non-Opioid Policy for Pain Relief ("NOPAIN Act")*

SAN DIEGO, Aug. 6, 2024 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX) ("Heron" or the "Company"), a commercial-stage biotechnology company, today announced financial results for the three and six months ended June 30, 2024, and highlighted recent corporate updates.

"We have had an exciting start to 2024 with many encouraging milestones that provide the foundation for ongoing commercial success. We are improving the financial efficiency of the business by growing revenues, improving margins, and reducing expenses. Regarding ZYNRELEF, we continue to expand our partnership with CrossLink and progress our regulatory activities in anticipation of a fourth quarter launch of the VAN," said Craig Collard, Chief Executive Officer of Heron.

Business Highlights

- The range for adjusted operating expenses guidance for 2024 is being narrowed from $108.0 million to $116.0 million to a revised $107.0 million to $111.0 million. Additionally, the range for adjusted EBITDA guidance is being narrowed from $(22.0) million to $3.0 million to a revised $(10) million to $3.0 million.
- The ZYNRELEF VAN PDUFA goal date is set for September 23, 2024. The VAN is designed to allow for easier and more efficient preparation and administration of ZYNRELEF in the operating room, with anticipated launch before year-end.
- Our development program for the ZYNRELEF Prefilled Syringe ("PFS"), which will allow for immediate use of ZYNRELEF, continues to progress with an expected U.S. Food and Drug Administration ("FDA") submission for approval in 2026.
- ZYNRELEF is included in the proposed 2025 NOPAIN Act under the Medicare hospital Outpatient Prospective Payment System ("OPPS") and the Medicare Ambulatory Surgical Center ("ASC") payment system (the "Proposed Rule") as a qualifying product effective April 1, 2025. The Proposed Rule's April 1, 2025 effective date for ZYNRELEF is expected to allow ZYNRELEF to maintain separate reimbursement in the HOPD and ASC settings without disruption.
- The training and integration of CrossLink sales representatives to promote ZYNRELEF to orthopedic surgeons continues its rapid progress. To date, 561 CrossLink sales representatives have completed training and are building the foundation for increased adoption.

Financial Guidance for 2024

The Company narrows its full-year 2024 guidance for Adjusted Operating Expenses and Adjusted EBITDA:

Product Revenues, Net	$138.0 to $158.0 million	
Adjusted Operating Expenses	Original	Revised
	$108.0 to $116.0 million	$107.0 to $111.0 million
Adjusted EBITDA	Original	Revised
	$(22.0) to $3.0 million	$(10.0) to $3.0 million

Acute Care Franchise

- **Acute Care Franchise Net Product Sales:** For the three and six months ended June 30, 2024, acute care franchise Net Product Sales were $6.8 million and $12.3 million, respectively, which increased from $4.5 million and $8.3 million, respectively, for the same period in 2023.

- **ZYNRELEF Net Product Sales:** Net Product Sales of ZYNRELEF (bupivacaine and meloxicam) extended-release solution for the three and six months ended June 30, 2024 were $5.8 million and $10.8 million, respectively, which increased from $4.2 million and $7.7 million, respectively, for the same period in 2023.

- **APONVIE® Net Product Sales:** Net Product Sales of APONVIE for the three and six months ended June 30, 2024 were $1.0 million and $1.5 million, respectively, which increased from $0.3 million and $0.6 million, respectively, for the same period in 2023.

Oncology Care Franchise

- **Oncology Care Franchise Net Product Sales:** For the three and six months ended June 30, 2024, oncology care franchise Net Product Sales were $29.2 million and $58.4 million, respectively, which increased from $27.3 million and $53.1 million for the same period in 2023.

- **CINVANTI® Net Product Sales:** Net Product Sales of CINVANTI (aprepitant) injectable emulsion for the three and six months ended June 30, 2024 were $24.9 million and $50.5 million, which increased from $24.5 million and $47.3 million for the same period in 2023.

- **SUSTOL® Net Product Sales:** Net Product Sales of SUSTOL (granisetron) extended-release injection for the three and six months ended June 30, 2024 were $4.3 million and $7.9 million, respectively, which increased from $2.8 million and $5.8 million, respectively, for the same period in 2023.

Conference Call and Webcast

Heron will host a conference call and webcast on August 6, 2024 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 1737564 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 sixty 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 to include foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures. On January 23, 2024, the FDA approved ZYNRELEF for soft tissue and orthopedic surgical procedures including foot and ankle, and other procedures in which direct exposure to articular cartilage is avoided. 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 Postoperative Nausea and Vomiting (PONV)

APONVIE is a substance NK_1 Receptor Antagonist (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 and became commercially available in the U.S. on March 6, 2023.

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 a 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.

Non-GAAP Financial Measures

To supplement our financial results presented on a GAAP basis, we have included information about certain non-GAAP financial measures. We believe the presentation of these non-GAAP financial measures, when viewed with our results under GAAP, provide analysts, investors, lenders, and other third parties with insights into how we evaluate normal operational activities, including our ability to generate cash from operations, on a comparable year-over-year basis and manage our budgeting and forecasting.

In our quarterly and annual reports, earnings press releases and conference calls, we may discuss the following financial measures that are not calculated in accordance with GAAP, to supplement our consolidated financial statements presented on a GAAP basis.

Adjusted EBITDA

Adjusted EBITDA is a non-GAAP financial measure that represents GAAP net income or loss adjusted to exclude interest expense, interest income, the benefit from or provision for income taxes, depreciation, amortization, stock-based compensation, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations. Adjusted EBITDA, as used by us, may be calculated differently from, and therefore may not be comparable to, similarly titled measures used by other companies.

There are several limitations related to the use of adjusted EBITDA rather than net income or loss, which is the nearest GAAP equivalent, such as:

- adjusted EBITDA excludes depreciation and amortization and, although these are non-cash expenses, the assets being depreciated or amortized may have to be replaced in the future, the cash requirements for which are not reflected in adjusted EBITDA;
- we exclude stock-based compensation expense from adjusted EBITDA although: (i) it has been, and will continue to be for the foreseeable future, a significant recurring expense for our business and an important part of our compensation strategy; and (ii) if we did not pay out a portion of our compensation in the form of stock-based compensation, the cash salary expense included in operating expenses would be higher, which would affect our cash position;
- we exclude impairment of long-lived assets, the amount and/or frequency of which are not part of our underlying business.
- we exclude inventory write-downs (and write-ups should they occur), the amount and/or frequency of which are not part of our underlying business.
- adjusted EBITDA does not reflect changes in, or cash requirements for, working capital needs;
- adjusted EBITDA does not reflect the benefit from or provision for income taxes or the cash requirements to pay taxes;
- adjusted EBITDA does not reflect historical cash expenditures or future requirements for capital expenditures or contractual commitments; and
- we exclude restructuring expenses from adjusted EBITDA. Restructuring expenses primarily include employee severance and contract termination costs that are not related to acquisitions. The amount and/or frequency of these restructuring expenses are not part of our underlying business.

Adjusted Operating Expenses

Adjusted operating expenses is a non-GAAP financial measure that represents GAAP operating expenses adjusted to exclude stock-based compensation expense, depreciation and amortization, and other adjustments to reflect changes that occur in our business but do not represent ongoing operations.

The Company has not provided a reconciliation of its full-year 2024 guidance for adjusted EBITDA or adjusted operating expenses to the most directly comparable forward-looking GAAP measures, in reliance on the unreasonable efforts exception provided under Item 10(e)(1)(i)(B) of Regulation S-K, because the Company is unable to predict, without unreasonable efforts, the timing and amount of items that would be included in such a reconciliation, including, but not limited to, stock-based compensation expense, acquisition related expense and litigation settlements. These items are uncertain and depend on various factors that are outside of the Company's control or cannot be reasonably predicted. While the Company is unable to address the probable significance of these items, they could have a material impact on GAAP net income and operating expenses for the guidance period.

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. Therefore, you should not place undue reliance on forward-looking

statements. Examples of forward-looking statements include, among others, statements we make regarding the potential market opportunities for ZYNRELEF, APONVIE, CINVANTI and SUSTOL; revenue, adjusted EBITDA and other financial guidance provided by the Company; the results of the commercial launch of APONVIE; the potential additional market opportunity for the expanded U.S. label for ZYNRELEF or inclusion of ZYNRELEF under the OPPS and the ASC payment system; the timing of the Company's development of the VAN program and receipt of required regulatory approvals; our ability to establish and maintain successful commercial arrangements like our co-promotion agreement with CrossLink Life Sciences; the outcome of the Company's pending ANDA litigation; 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. Important factors that could cause actual results to differ materially from those in the forward-looking statements are set forth in our most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q, and in our other reports filed with the Securities and Exchange Commission, including under the caption "Risk Factors." 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,	
	2024	**2023**	**2024**	**2023**
Revenues:	(unaudited)			
Net product sales	$ 36,024	$ 31,762	$ 70,694	$ 61,377
Cost of product sales	10,518	20,158	18,962	37,012
Gross Profit	25,506	11,604	51,732	24,365
Operating expenses:				
Research and development	4,432	13,210	9,040	22,046
General and administrative	13,905	19,592	28,879	35,426
Sales and marketing	13,614	21,205	25,056	42,359
Total operating expenses	31,951	54,007	62,975	99,831
Loss from operations	(6,445)	(42,403)	(11,243)	(75,466)
Other (expense) income, net	(2,790)	344	(1,152)	639
Net loss	$ (9,235)	$ (42,059)	$ (12,395)	$ (74,827)
Basic and diluted net loss per share	$ (0.06)	$ (0.35)	$ (0.08)	$ (0.63)
Weighted average common shares outstanding, basic and diluted	152,305	119,719	151,900	119,484

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

	June 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,386	$ 28,677
Short-term investments	48,961	51,732
Accounts receivable, net	73,708	60,137
Inventory	42,864	42,110
Prepaid expenses and other current assets	7,249	6,118
Total current assets	191,168	188,774
Property and equipment, net	15,900	20,166
Right-of-use lease assets	4,138	5,438
Other assets	6,930	8,128
Total assets	$ 218,136	$ 222,506
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 10,226	$ 3,240
Accrued clinical and manufacturing liabilities	17,554	22,291
Accrued payroll and employee liabilities	7,085	9,224
Other accrued liabilities	42,258	41,855
Current lease liabilities	3,194	3,075
Total current liabilities	80,317	79,685

Non-current lease liabilities	1,289	2,800
Non-current notes payable, net	24,634	24,263
Non-current convertible notes payable, net	149,595	149,490
Other non-current liabilities	241	241
Total liabilities	256,076	256,479
Stockholders' deficit:		
Common stock	1,516	1,503
Additional paid-in capital	1,878,961	1,870,525
Accumulated other comprehensive (loss) income	(8)	13
Accumulated deficit	(1,918,409)	(1,906,014)
Total stockholders' deficit	(37,940)	(33,973)
Total liabilities and stockholders' deficit	$ 218,136	$ 222,506

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