Heron Therapeutics Announces Financial Results for the Three Months Ended March 31, 2022 and Highlights Recent Corporate Updates

May 9, 2022

- ZYNRELEF® unit demand increased 68% in the first quarter compared to the prior quarter -

- Centers for Medicare and Medicaid Services approved a 3-year transitional pass-through status for ZYNRELEF beginning April 1, 2022 to support separate reimbursement outside of the surgical bundle payment for the HOPD setting of care -

- Oncology Care Franchise net revenue of $22.4 million in Q1 2022, a 13% increase over the prior quarter -

- Oncology Care Franchise full-year 2022 net revenue expected to be $89 million to $93 million –

SAN DIEGO, May 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 months ended March 31, 2022 and highlighted recent corporate updates.

Recent Corporate Updates

Acute Care Franchise

- **ZYNRELEF:**
  - The ZYNRELEF (bupivacaine and meloxicam) extended-release solution New Drug Application (NDA) was approved by the U.S. Food and Drug Administration (FDA) in May 2021. In December 2021, the FDA approved our supplemental New Drug Application (sNDA) for ZYNRELEF, now covering approximately 7 million procedures annually. ZYNRELEF is currently indicated 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. The FDA also agreed to the contents of a second sNDA, planned for later this year, designed to further expand the indication statement.
  - ZYNRELEF net product sales for the three months ended March 31, 2022 were $1.1 million, which was net of $0.3 million in returns of short-dated ZYNRELEF and a continued reduction of initial distribution channel inventory. Short-dated product returns were due to delays in obtaining initial FDA approval of ZYNRELEF.
  - ZYNRELEF end-user (ambulatory surgical centers (ASC) and hospitals) demand units' sales were 8,673 in the first quarter of 2022, representing an increase of 68% over the prior quarter.
  - During the first three quarters of commercial launch ended March 31, 2022, over 450 unique accounts purchased ZYNRELEF with 80% of those accounts reordering the product.
  - As of April 30, 2022, ZYNRELEF has received 319 formulary approvals, with over a 90% hospital approval rate, and an estimated 68% of formulary approvals have been for unrestricted use. Over 60 additional formulary review meetings are scheduled through June 30, 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 120 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 more than 80% of our target patients in the outpatient setting. On November 2, 2021, we were issued a specific C-code (C9088) for separate reimbursement in the ASC setting of care effective January 1, 2022.
  - In March 2022, Health Canada issued a Notice of Compliance to commercialize ZYNRELEF for instillation into the

surgical wound for postoperative analgesia after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty surgical procedures. Based on prior agreements with the FDA, Heron already has clinical studies underway, which we plan to submit to Health Canada to expand the indication statement. Heron is currently in partnering discussions related to Canada and other countries outside the U.S.

- **NDA Submission for HTX-019 for Prevention of PONV in Adults Under Review:** A 505(b)(2) NDA for HTX-019 for the prevention of postoperative nausea and vomiting (PONV) in adults was submitted to the 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 months ended March 31, 2022, oncology care franchise net product sales were $22.4 million, compared to $20.0 million for the same period in 2021. During the first quarter, Heron's oncology care franchise net product sales grew by 13% over the prior quarter with continued moderate growth expected for the remainder of 2022.

- **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three months ended March 31, 2022 were $20.3 million, compared to $18.5 million for the same period in 2021.

- **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three months ended March 31, 2022 were $2.1 million, compared to $1.5 million for the same period in 2021.

- **2022 Oncology Care Franchise Net Product Sales Guidance:** Heron currently expects the second quarter of 2022 net product sales for the oncology care franchise in the range of $22 million to $23 million, with full-year 2022 net product sales for the oncology care franchise in the range of $89 million to $93 million.

"Although the start of the first quarter was challenging due to the COVID-19 pandemic, in the last few months ZYNRELEF has gained momentum following the FDA approval of the expanded indications. We expect continued strong growth in the current quarter with the receipt of pass-through status from CMS for HOPD, as evidenced by an 85% increase in demand units in the first month of the second quarter versus the first month of the first quarter," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "In oncology care, our CINV portfolio continues to perform well and we look forward to achieving net product sales of $22 million to $23 million in the second quarter of 2022 and full year 2022 net product sales of $89 million to $93 million."

Financial Results

Net product sales for the three months ended March 31, 2022 were $23.5 million, compared to $20.0 million for the same period in 2021.

Heron's net loss for the three months ended March 31, 2022 was $63.9 million, or $0.63 per share, compared to $52.6 million, or $0.58 per share, for the same period in 2021. Net loss for the three months ended March 31, 2022 included non-cash, stock-based compensation expense of $10.9 million, compared to $11.5 million for the same period in 2021.

As of March 31, 2022, Heron had cash, cash equivalents and short-term investments of $111.9 million, compared to $157.6 million as of December 31, 2021. Net cash used for operating activities for the three months ended March 31, 2022 was $43.9 million, compared to $41.9 million for the same period in 2021. The increase 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, and an increase in net loss. We expect net cash used for operating activities of $37 million to $39 million in the second quarter of 2022.

Conference Call and Webcast

Heron will host a conference call and webcast on May 9, 2022 at 4:30 p.m. ET. The conference call can be accessed by dialing 1-844-825-9789 for domestic callers and 1-412-317-5180 for international callers. Please provide the operator with the passcode 10166891 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, the potential additional market opportunity for the ZYNRELEF expanded U.S. label; the timing and results of studies for the further expansion of the U.S. label for ZYNRELEF; the timing of the commercial launch of ZYNRELEF in Europe and Canada; 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; 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 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)

	March 31,	
	2022	**2021**
	(Unaudited)	
Revenues:		
Net product sales	$ 23,457	$ 20,018
Operating expenses:		
Cost of product sales	11,355	9,207
Research and development	42,070	38,116
General and administrative	9,533	9,573
Sales and marketing	23,422	15,236
Total operating expenses	86,380	72,132

Loss from operations	(62,923)	(52,114)
Other expense, net	(965)	(500)
Net loss	$ (63,888)	$ (52,614)
Basic and diluted net loss per share	$ (0.63)	$ (0.58)
Shares used in computing basic and diluted net loss per share	102,123	91,388

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

	March 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 56,911	$ 90,541
Short-term investments	54,999	67,039
Accounts receivable, net	41,103	35,499
Inventory	56,470	48,382
Prepaid expenses and other current assets	13,110	12,962
Total current assets	222,593	254,423
Property and equipment, net	23,858	23,734
Right-of-use lease assets	9,295	9,829
Other assets	17,977	17,720
Total assets	$ 273,723	$ 305,706
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 8,226	$ 3,803
Accrued clinical and manufacturing liabilities	37,277	23,716
Accrued payroll and employee liabilities	12,214	15,263
Other accrued liabilities	32,800	25,859
Current lease liabilities	2,484	2,417
Total current liabilities	93,001	71,058
Non-current lease liabilities	7,391	7,996
Non-current convertible notes payable, net	149,132	149,082
Other non-current liabilities	241	—
Total liabilities	249,765	228,136
Stockholders' equity:		
Common stock	1,021	1,020
Additional paid-in capital	1,700,264	1,689,987
Accumulated other comprehensive loss	(8)	(6)
Accumulated deficit	(1,677,319)	(1,613,431)
Total stockholders' equity	23,958	77,570
Total liabilities and stockholders' equity	$ 273,723	$ 305,706

Investor Relations and Media Contact:
David Szekeres
Executive Vice President, Chief Operating Officer
Heron Therapeutics, Inc.
dszekeres@herontx.com
858-251-4447

View original content:https://www.prnewswire.com/news-releases/heron-therapeutics-announces-financial-results-for-the-three-months-ended-march-31-2022-and-highlights-recent-corporate-updates-301542760.html

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