Heron Therapeutics Announces Financial Results for the Three and Nine Months Ended September 30, 2021 and Highlights Recent Corporate Updates

November 3, 2021

- ZYNRELEF® net product sales of $2.1 million in its first quarter of launch with 160 unique accounts already purchasing ZYNRELEF and 50% of those accounts reordering -

- ZYNRELEF has received 126 formulary approvals, representing over a 91% hospital approval rate -

- CMS has issued a specific C-code for ZYNRELEF to support separate reimbursement for Medicare patients in the ASC setting of care -

SAN DIEGO, Nov. 3, 2021 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced financial results for the three and nine months ended September 30, 2021 and highlighted recent corporate updates.

Recent Corporate Updates

Acute Care Franchise

- **ZYNRELEF Now Available:**
  - 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. ZYNRELEF became commercially available in the U.S. on July 1, 2021, and net product sales for the three and nine months ended September 30, 2021 were $2.1 million.
  - During the first quarter of commercial launch, 160 unique accounts purchased ZYNRELEF with 50% of those accounts reordering the product.
  - As of October 31, 2021, ZYNRELEF has received 126 formulary approvals, representing over a 91% hospital approval rate, and an additional 150 formulary review meetings are scheduled before the end of 2021.
  - Multiple commercial and Medicaid payers covering over 88 million lives have agreed to reimburse ZYNRELEF outside of the surgical bundle payment for surgeries performed in ambulatory surgical centers (ASC), with many of these covered lives also having their hospital outpatient procedures reimbursed outside the surgical bundle payment. Commercial and Medicaid payers represent >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. Medicare is currently reimbursing ZYNRELEF in outpatient settings of care under a miscellaneous C-code at 95% of the Average Wholesale Price until December 31, 2021.
  - Heron announced on October 4, 2021, the filing of a supplemental NDA (sNDA) for expansion of the ZYNRELEF indication statement based on the outcome of a Type C meeting with the FDA. At this meeting, Heron aligned with the FDA on the content of this sNDA to support the proposed revised indication statement to include foot and ankle, small–to–medium open abdominal, and lower extremity total joint arthroplasty surgical procedures.
  - At the Type C meeting, Heron also aligned with the FDA on the data needed to support a future sNDA to further expand the ZYNRELEF indication statement to broadly include soft tissue and orthopedic surgical procedures with pharmacodynamic, pharmacokinetic and safety data from a limited number of additional procedures. The studies in these additional surgeries are already in progress with the plan to submit the next sNDA in the second half of 2022.
  - Heron recently received FDA approval in less than 4 months of a manufacturing supplement to the NDA for ZYNRELEF to add a large-scale secondary supplier of our proprietary polymer, which will allow for the manufacturing of millions of doses of ZYNRELEF annually at a significantly reduced cost of products sales.
- **NDA for HTX-019 for Prevention of PONV in Adults Planned in Late 2021:** A 505(b)(2) NDA for HTX-019 is planned for the prevention of postoperative nausea and vomiting (PONV) in adults. A Pre-NDA meeting with the FDA was held in August 2021 and the NDA is on track for filing in the fourth quarter of this year.

Oncology Care Franchise

- **2021 Oncology Care Franchise Net Product Sales:** For the three and nine months ended September 30, 2021, oncology care franchise net product sales were $21.1 million and $63.6 million, respectively, compared to $20.0 million and $68.0

million, respectively, for the same periods in 2020. During 2021, Heron's oncology care franchise net product sales have stabilized. Key factors influencing our results are the lower rate of new cancer patient treatment starts due to the continued impact of the COVID-19 pandemic, resulting in fewer clinic anti-emetic administrations during the first nine months of 2021 compared to the prior year, and the impact of value-based payer reimbursement.

  - **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and nine months ended September 30, 2021 were $18.0 million and $56.2 million, respectively, compared to $19.8 million and $67.6 million, respectively, for the same periods in 2020.
  - **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and nine months ended September 30, 2021 were $3.1 million and $7.4 million, respectively, compared to $0.2 million and $0.4 million, respectively, for the same periods in 2020.
- **2021 Oncology Care Franchise Net Product Sales Guidance:** Heron currently expects fourth quarter of 2021 net product sales for the oncology care franchise in the range of $20 million to $22 million.

"The approval and commercial launch of ZYNRELEF, the first and only FDA-approved extended-release dual-acting local anesthetic, is an important advancement in the field of pain management. Laying the groundwork for long-term growth, we have had excellent success with the pharmacy and therapeutics committee approvals in our first quarter of launch and the number of accounts already ordering the product. With agreement from the FDA, we have submitted the first of our planned sNDAs designed to expand the ZYNRELEF label, which we believe will substantially expand the commercial opportunity for ZYNRELEF," said Barry Quart, Pharm.D., Chairman and Chief Executive Officer of Heron. "For our oncology care franchise, we have stabilized sales in a market dominated by generics and expect to see moderate growth in net product sales in 2022. Overall, we have reduced the net cash used for operating activities by 15% compared to the prior quarter and we expect to continue to further reduce it by more than 10% next quarter."

Financial Results

Net product sales for the three and nine months ended September 30, 2021 were $23.2 million and $65.7 million, respectively, compared to $20.0 million and $68.0 million, respectively, for the same periods in 2020.

Heron's net loss for the three and nine months ended September 30, 2021 was $52.4 million and $166.0 million, or $0.51 per share and $1.71 per share, respectively, compared to $58.2 million and $165.0 million, or $0.64 per share and $1.82 per share, respectively, for the same periods in 2020. Net loss for the three and nine months ended September 30, 2021 included non-cash, stock-based compensation expense of $11.2 million and $34.0 million, respectively, compared to $11.1 million and $34.2 million, respectively, for the same periods in 2020.

As of September 30, 2021, Heron had cash, cash equivalents and short-term investments of $202.8 million, compared to $208.5 million as of December 31, 2020. Net cash used for operating activities for the nine months ended September 30, 2021 was $158.1 million, compared to $132.3 million for the same period in 2020. The increase in our net cash used for operating activities was primarily due to changes in working capital related to the launch of ZYNRELEF in July 2021, including manufacturing of commercial inventory. We expect net cash used for operating activities of $45 million to $48 million in the fourth quarter of 2021, and we anticipate that our net cash usage will continue to moderate lower in 2022 as net product sales increase and we realize cost savings from anticipated larger-scale manufacturing.

Conference Call and Webcast

Heron will host a conference call and webcast on November 3, 2021 at 4:15 p.m. ET. The conference call can be accessed by dialing 877-311-5906 for domestic callers and 281-241-6150 for international callers. Please provide the operator with the passcode 7242566 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 modified-release local anesthetic to be classified by the FDA as an "extended-release" product because ZYNRELEF is also 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 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. Safety and efficacy have not been established in highly vascular surgeries, such as intrathoracic, large multilevel spinal, and head and neck procedures. At a Type C meeting with the FDA, following the ZYNRELEF NDA approval, we aligned with the FDA on the content of an sNDA for proposed expansion of the ZYNRELEF indication statement to include foot and ankle, small–to–medium open abdominal, and lower extremity total joint arthroplasty surgical procedures without the need for additional clinical studies. The sNDA is based on the consistent safety, efficacy and pharmacokinetic data from previously completed clinical trials and was submitted to the FDA in late September 2021. 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.

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, 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. A successful Pre-NDA

meeting with the FDA was held in August 2021 and the NDA is on track for filing in the fourth quarter of this year.

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 is 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 best-in-class treatments to address some of the most important unmet patient needs. 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 timing of the commercial launch of ZYNRELEF in Europe; the potential market opportunities for ZYNRELEF in the U.S. and Europe; the timing and results of studies for the potential expansion of the U.S. label for ZYNRELEF and for the HTX-019 development program; whether the FDA approves ZYNRELEF for additional indications; the timing of the NDA filing and 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)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(Unaudited)			
Revenues:				
Net product sales	$ 23,230	$ 19,965	$ 65,691	$ 68,033
Operating expenses:				
Cost of product sales	11,351	7,170	35,080	26,797
Research and development	28,595	49,182	101,944	130,080
General and administrative	9,786	9,482	30,266	29,723
Sales and marketing	25,206	12,515	62,692	48,300
Total operating expenses	74,938	78,349	229,982	234,900
Loss from operations	(51,708)	(58,384)	(164,291)	(166,867)
Other income (expense)	(700)	156	(1,746)	1,870
Net loss	$ (52,408)	$ (58,228)	$ (166,037)	$ (164,997)
Basic and diluted net loss per share	$ (0.51)	$ (0.64)	$ (1.71)	$ (1.82)
Shares used in computing basic and diluted net loss per share	101,906	90,849	97,290	90,671

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

	September 30, 2021	December 31, 2020
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 159,570	$ 105,138
Short-term investments	43,250	103,353
Accounts receivable, net	43,086	41,850
Inventory	41,502	41,905
Prepaid expenses and other current assets	27,644	21,950
Total current assets	315,052	314,196
Property and equipment, net	22,788	22,737
Right-of-use lease assets	14,202	16,277
Other assets	346	346
Total assets	$ 352,388	$ 353,556
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,885	$ 525
Accrued clinical and manufacturing liabilities	17,151	49,962
Accrued payroll and employee liabilities	16,006	13,597
Other accrued liabilities	30,003	28,369
Current lease liabilities	3,251	2,997
Convertible notes payable to related parties	—	7,053
Total current liabilities	72,296	102,503
Non-current lease liabilities	12,217	14,561
Non-current convertible notes payable, net	149,032	—
Total liabilities	233,545	117,064
Stockholders' equity:		
Common stock	1,019	913
Additional paid-in capital	1,676,613	1,628,070
Accumulated other comprehensive income	(4)	257
Accumulated deficit	(1,558,785)	(1,392,748)
Total stockholders' equity	118,843	236,492
Total liabilities and stockholders' equity	$ 352,388	$ 353,556

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View original content:https://www.prnewswire.com/news-releases/heron-therapeutics-announces-financial-results-for-the-three-and-nine-months-ended-september-30-2021-and-highlights-recent-corporate-updates-301415716.html

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