

# Heron Therapeutics Announces Third Quarter 2015 Financial Results and Recent Corporate Progress

#### November 6, 2015

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Nov. 6, 2015-- Heron Therapeutics, Inc. (NASDAQ:HRTX), a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs, today reported third quarter 2015 financial results and highlighted recent corporate progress.

#### **Recent Corporate Progress:**

- In October 2015, Heron appointed Neil J. Clendeninn, M.D., Ph.D. as Senior Vice President and Chief Medical Officer. Dr. Clendeninn brings more than 25 years of drug development and clinical practice experience to his role at Heron. Prior to his appointment, Dr. Clendeninn advised Heron during the recently completed MAGIC study for SUSTOL<sup>®</sup> (granisetron) Injection, extended release and with the resubmission of Heron's New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA). Dr. Clendeninn, in addition to his experience as a practicing physician, has held academic positions, and served as a board member and scientific advisor for numerous institutions and companies within the oncology field.
- In September 2015, Heron reported positive, top-line results from its recently completed Phase 2 clinical study of HTX-011 in the management of post-operative pain in patients undergoing bunionectomy. In the study, HTX-011 showed a significant reduction in pain intensity, reduction in the need for opioid rescue medications, and increase in time to first use of rescue medications.
- In September 2015, the FDA accepted for review Heron's NDA resubmission for SUSTOL for the prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) associated with moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC) regimens. The FDA assigned a Prescription Drug User Fee Act (PDUFA) goal date of January 17, 2016.

#### **Business Updates:**

- Based on the positive Phase 2 results of HTX-011 in patients undergoing bunionectomy, the Company plans to expand target enrollment for its ongoing Phase 2 clinical trial of HTX-011 in patients undergoing inguinal hernia repair. The increased target enrollment to approximately 100 patients now is expected to provide 90% power to detect a statistical improvement (p < 0.05) in the study. The Company expects to report results from this study in the first half of 2016.
- Heron plans to study HTX-011 as part of a broad-based development program designed to target patients undergoing a wide range of surgeries who experience significant post-operative pain, potentially including abdominoplasty, orthopedic procedures, nerve block and further studies in inguinal hernia repair and bunionectomy.

"This has been an exciting quarter for Heron with the FDA's acceptance of the SUSTOL NDA and the release of positive, top-line results from our Phase 2 study of HTX-011 in patients undergoing bunionectomy," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "We look forward to a productive fourth quarter with the continuation of our activities in preparation for the potential commercial launch of SUSTOL, if approved by the FDA, and the expansion of our Phase 2 program for HTX-011 in anticipation of an End-of-Phase 2 meeting with the FDA in 2016."

#### **Results of Operations**

As of September 30, 2015, Heron had approximately \$153.0 million in cash and cash equivalents, compared to \$72.7 million as of December 31, 2014. The net increase in cash and cash equivalents was primarily due to Heron's June 2015 public equity offering resulting in total net proceeds to us of approximately \$128.2 million, partially offset by net cash used in operating activities. Based on current operating plans and projections, Heron believes that its current cash and working capital are sufficient to fund operations through 2016.

Heron's net cash used for operating activities for the three and nine months ended September 30, 2015 was \$19.9 million and \$55.4 million, respectively, compared to net cash used for operating activities of \$19.2 million and \$47.4 million, respectively, for the same periods in 2014.

Heron's net loss for the three and nine months ended September 30, 2015 was \$22.7 million and \$66.3 million, or \$0.63 per share and \$2.07 per

share, respectively, compared to a net loss of \$19.2 million and \$55.7 million, or \$0.66 per share and \$2.17 per share, respectively, for the same periods in 2014.

The increases in net cash used for operating activities and net loss in 2015 as compared to 2014 were primarily due to clinical and manufacturing costs related to our Phase 1 and Phase 2 clinical studies for HTX-011, costs associated with the development of HTX-019, as well as costs incurred in preparation for the commercial launch of SUSTOL, if approved by the FDA.

#### About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicines that address major unmet medical needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to alreadyapproved pharmacological agents. Heron's goal is to build on therapeutics with well-known pharmacology by improving their tolerability and efficacy as well as broadening their potential field of use. Heron is currently developing four pharmaceutical products for patients suffering from cancer or pain.

SUSTOL<sup>®</sup> (granisetron) Injection, extended release is being developed for the prevention of both acute and delayed chemotherapy-induced nausea and vomiting (CINV) associated with moderately emetogenic chemotherapy (MEC) or highly emetogenic chemotherapy (HEC). CINV is one of the most debilitating side effects of chemotherapy and is a leading cause of premature discontinuation of cancer treatment. Heron recently reported positive, top-line results from its Phase 3 MAGIC study. In July 2015, Heron resubmitted its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA), and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) goal date of January 17, 2016. HTX-019, also being developed for the prevention of CINV, has the potential to become the first polysorbate 80-free, intravenous formulation of aprepitant, a neurokinin-1 (NK<sub>1</sub>) receptor antagonist. Heron intends to file an NDA for HTX-019 using the 505(b)(2) regulatory pathway in the second half of 2016. HTX-011 is Heron's long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam. In September 2015, Heron reported positive, top-line results from a Phase 2 study of HTX-011 in patients undergoing bunionectomy. In this study, HTX-011 significantly reduced pain intensity and the need for opioid rescue medications. HTX-011 is the subject of a broad-based development program designed to target the many patients undergoing a wide range of surgeries who experience significant post-operative pain. HTX-003, a long-acting formulation of buprenorphine, is being developed for the potential management of chronic pain and opioid addiction.

All of Heron's product candidates utilize Heron's innovative science and technology platforms, including its proprietary Biochronomer <sup>®</sup> drug delivery technology, which can deliver therapeutic levels of a wide range of otherwise short-acting pharmacological agents over a period of days to weeks with a single injection.

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. These risks and uncertainties include, but are not limited to, those associated with: whether the U.S. Food and Drug Administration (FDA) approves the SUSTOL NDA as submitted or supports as broad of a labeled indication for SUSTOL as requested, the progress in the research and development of HTX-019, HTX-011, HTX-003 and our other programs, including the timing of preclinical, clinical, and manufacturing activities, safety and efficacy results from our studies that may not justify the pursuit of further development of our product candidates, the launch and acceptance of SUSTOL and new products generally, our financial position and our ability to raise additional capital to fund operations, if necessary, or to pursue additional business opportunities, strategic business alliances we may pursue or the potential acquisition of products or technologies, and our ability to grow our organization to sustain the commercial launch for SUSTOL, and other risks and uncertainties identified in the Company's filings with the 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.

## Condensed Consolidated Statements of Operations (in thousands, except per share amounts)

		nths Ended nber 30,	Nine Months Ended September 30,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	\$ 14,241	\$ 14,731	\$ 44,920	\$ 40,638
General and administrative	8,250	4,222	20,945	14,428
Total operating expenses	22,491	18,953	65,865	55,066
Loss from operations	(22,491)	(18,953)	(65,865)	(55,066)
Other expense, net	(181)	(241)	(484)	(677)
Net loss	\$(22,672)	\$(19,194)	\$(66,349)	\$(55,743)
Basic and diluted net loss per share	\$ (0.63)	\$ (0.66)	\$ (2.07)	\$ (2.17)
Shares used in computing basic and diluted net loss per share	35,773	29,004	32,090	25,679

#### HERON THERAPEUTICS, INC.

### Condensed Consolidated Balance Sheet Data

(in thousands)

	September 30, December 31,					
	2	2015		2014		
	(unaudited)					
Cash and cash equivalents	\$	152,989 \$	\$7	2,675		
Total assets		158,151	7	76,682		
Total stockholders' equity	\$	141,701 \$	\$6	63,062		

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Source: Heron Therapeutics, Inc.

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