

Heron Therapeutics Announces Third Quarter and Year-to-Date 2014 Financial Results and Corporate Highlights

November 6, 2014

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Nov. 6, 2014-- <u>Heron Therapeutics</u>. Inc. (NASDAQ:HRTX), a biotechnology company, today reported third quarter and year-to-date 2014 financial results and highlighted recent corporate progress.

Third Quarter Highlights and Progress:

- Due to a slower rate of enrollment than projected over the last quarter for Heron's ongoing Phase 3 study of SUSTOL [®] (granisetron injection, extended release) for the prevention of delayed-onset chemotherapy induced nausea and vomiting (CINV) in patients receiving highly emetogenic chemotherapy (HEC) agents, the Company now anticipates completing enrollment in the first quarter of 2015, with the resubmission of the new drug application (NDA) to the U.S. Food and Drug Administration (FDA) shortly thereafter.
- The Company expects to initiate a Phase 1 study of HTX-011 in the coming weeks. HTX-011 is the Company's lead
 candidate in its pain management program, and is a combination of local anesthetic bupivacaine and the anti-inflammatory
 meloxicam in a novel formulation utilizing the Company's proprietary Biochronomer [®] polymer-based drug delivery platform.
- The Company has disclosed a new development program as part of its growing CINV franchise. HTX-019 is an intravenous (IV), polysorbate 80-free formulation of aprepitant, which is a substance P/neurokinin-1 (NK₁) receptor antagonist. NK₁ receptor antagonists, such as HTX-019, are used in combination with 5-HT₃ receptor antagonists in treatment of CINV, and are complimentary to the Company's SUSTOL program. Registration of HTX-019 is expected to use the 505(b)(2) regulatory approval pathway for new drug applications filed with the FDA, with potential commercial launch in 2016.

"While we are disappointed that the HEC study will be a few months late in completing, we continue to make significant progress with SUSTOL and our internal pipeline programs," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron Therapeutics. "The addition of an IV administrable NK₁ antagonist to our growing CINV franchise will help us to build a potentially dominant position in this segment of the oncology supportive care market which is estimated to be greater than \$500 million per year in the U.S. and potentially over \$1 billion worldwide. Further, with the impending initiation of a Phase 1 study of HTX-011, our development program in pain management continues to move forward."

Results of Operations

As of September 30, 2014, we had approximately \$86.2 million in cash, compared to \$72.3 million as of December 31, 2013. The net increase in cash was primarily due to the net proceeds received of \$58.9 million from the June 2014 public offering, partially offset by net cash used in operating activities of \$47.4 million for the nine months ended September 30, 2014.

Heron Therapeutics' net loss for the three and nine months ended September 30, 2014 was \$19.2 million and \$55.7 million, or \$0.66 per share and \$2.17 per share, respectively, compared to a net loss of \$12.9 million and \$41.2 million, or \$0.84 per share and \$2.69 per share, respectively, for the same periods in 2013.

The increase in net loss was primarily due to the initiation of the Phase 3 HEC study of SUSTOL in 2014 and expenses related to new product development, including our program targeting the relief of post-surgical pain, which was initiated in November 2013.

The decrease in net loss per share for the three and nine months ended September 30, 2014 compared to the same periods in 2013 was mainly due to the increase in shares outstanding in 2014 as a result of our November 2013 and June 2014 common stock offerings, partially offset by the increase in net loss.

About SUSTOL®

Heron's lead investigational product candidate, SUSTOL® (granisetron injection, extended release), is being developed for the prevention of both acute- and delayed-onset chemotherapy induced nausea and vomiting (CINV). One of the most debilitating side effects of cancer chemotherapy, CINV is a leading cause of premature discontinuation of treatment. There is only one injectable 5-HT₃ receptor antagonist approved for the prevention of delayed-onset CINV in patients receiving moderately emetogenic chemotherapy (MEC); none are approved for delayed-onset CINV in patients receiving highly emetogenic chemotherapy (HEC). SUSTOL contains the 5-HT₃ receptor antagonist granisetron formulated in the Company's proprietary Biochronomer® polymer-based drug delivery platform, which has been shown in clinical studies to maintain therapeutic drug levels of

SUSTOL for up to five days with a single subcutaneous injection. Currently available intravenous and oral formulations of granisetron are approved only for the prevention of acute-onset CINV. Granisetron was selected for SUSTOL because it is widely prescribed by physicians based on a well-established record of safety and efficacy.

About Heron's HTX-011 and HTX-019 Development Programs

The Company has initiated development of HTX-011 for pain management. HTX-011 is a combination of local anesthetic bupivacaine and the anti-inflammatory meloxicam in a novel formulation utilizing the proprietary Biochronomer polymer-based drug delivery platform.

HTX-019 is a proprietary intravenous formulation of aprepitant, an NK₁ receptor antagonist. HTX-019 does not contain polysorbate 80, which may cause hypersensitivity reactions in some patients. At present, there is only one intravenous NK₁ receptor antagonist approved in the U.S. for the prevention of CINV. NK₁ receptor antagonists are always used in combination with a 5-HT₃ receptor antagonist for the prevention of CINV.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. (formerly A.P. Pharma, Inc.) is a biotechnology company using its proprietary technology and innovative efforts to develop products to address unmet medical needs. The Company's proprietary Biochronomer polymer-based drug delivery platform is designed to improve the therapeutic profile of injectable pharmaceuticals by extending the duration of action of known active ingredients. The Company's product development program also focuses on identifying new delivery methods and formulations utilizing known compounds that may expand or extend the therapeutic effort, or eliminate the drawbacks of current therapies.

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 subject to certain risks and uncertainties that could cause actual results to differ materially. These risks and uncertainties include those associated with the timing of completion of the HEC study, and the results thereof, and the NDA resubmission for SUSTOL, potential regulatory approval of SUSTOL and the timing for such approval, if approved at all; risks relating to progress in research and development of HTX-019, HTX-011 and our other product candidate programs, including the timing of planned toxicology and clinical studies; the risk that safety and efficacy data from our clinical studies may not warrant further development of our product candidates, risks related to the launch and acceptance of new products generally; risks related to our financial position and our ability to raise additional capital to fund operations if necessary or to pursue additional business opportunities; risks related to strategic business alliances we may pursue or the potential acquisition of other products or technologies and other risks and uncertainties identified in the Company's filings with the Securities and Exchange Commission. We caution investors that forward-looking statements reflect our analysis only on their stated date. We do not intend to update them except as required by law.

HERON THERAPEUTICS, INC.

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

	Three Months Ended September 30,		Nine Months Ended	
			September 30,	
	2014	2013	2014	2013
Operating expenses:				
Research and development	\$ 14,731	\$ 6,216	\$ 40,929	\$ 24,162
General and administrative	4,222	6,448	14,137	16,464
Total operating expenses	18,953	12,664	55,066	40,626
Loss from operations	(18,953)	(12,664)	(55,066)	(40,626)
Interest and other expense	(241)	(209)	(677)	(614)
Net loss	\$(19,194)	\$(12,873)	\$(55,743)	\$(41,240)
Basic and diluted net loss per share	\$ (0.66)	\$ (0.84)	\$ (2.17)	\$ (2.69)
Shares used in computing basic and diluted net loss per share	29,004	15,375	25,679	15,305

HERON THERAPEUTICS, INC.

Condensed Balance Sheet Data (in thousands)

September 30,	December 31,
2014	2013
(unaudited)	

Cash \$ 86,212 \$ 72,287 92,282 75,937 Total assets Total stockholders' equity \$ 81,008 \$ 68,945

Source: Heron Therapeutics, Inc.

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