Heron Therapeutics Announces Fourth Quarter and Full Year 2015 Financial Results and Recent Corporate Progress

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REDWOOD CITY, Calif.--(BUSINESS WIRE)--Feb. 19, 2016-- Heron Therapeutics, Inc. (NASDAQ:HRTX), a biotechnology company focused on improving the lives of patients by developing best-in-class medicine that address major unmet medical needs, today reported fourth quarter and full year 2015 financial results and highlighted recent corporate progress.

Recent Corporate Progress:

- In February 2016, Heron successfully demonstrated bioequivalence of HTX-019 to intravenous (IV) fosaprepitant in a study that included 100 healthy volunteers. In this study, HTX-019 demonstrated a substantially improved safety profile compared to IV fosaprepitant, which contains polysorbate 80. HTX-019, a polysorbate 80-free, IV formulation of the neurokinin-1 (NK_1) receptor antagonist aprepitant, is being developed for the prevention of chemotherapy-induced nausea and vomiting (CINV).
- In February 2016, Heron initiated a placebo-controlled, dose-finding, Phase 2 clinical trial of HTX-011 for the treatment of post-operative pain in approximately 100 patients undergoing abdominoplasty. HTX-011 is a long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam formulated with Heron's Biochronomer® drug delivery technology.
- In January 2016, the U.S. Food and Drug Administration (FDA) informed Heron that it has not yet completed its review of the New Drug Application (NDA) of SUSTOL® (granisetron) Injection, extended release and was unable to take action by the Prescription Drug User Fee Act (PDUFA) goal date of January 17, 2016. The FDA stated that it is targeting taking action in late February 2016.

"While we were disappointed that the FDA was unable to complete the review of the SUSTOL NDA by the original January 2016 PDUFA goal date, we appreciate the work of the FDA and remain confident in the potential of SUSTOL as an important option for the prevention of CINV in patients with cancer," commented Barry D. Quart, Chief Executive Officer of Heron Therapeutics. "Earlier this month, we achieved important milestones for our pipeline programs. We confirmed bioequivalence for HTX-019 compared with IV fosaprepitant and showed substantially improved tolerability of HTX-019, our polysorbate 80-free, IV formulation of aprepitant. In addition, we initiated our third Phase 2 study of HTX-011, which is evaluating HTX-011 in patients undergoing abdominoplasty."

Results of Operations

As of December 31, 2015, Heron had approximately $131.2 million in cash, cash equivalents and short-term investments, compared to $72.7 million as of December 31, 2014. The net increase in cash, cash equivalents and short-term investments was primarily due to Heron's June 2015 public equity offering that resulted in total net proceeds to us of approximately $128.2 million, partially offset by net cash used in operating activities in 2015. Based on current operating plans and projections, Heron believes that its current working capital is sufficient to fund operations through 2016.

Heron's net cash used for operating activities for the quarter and year ended December 31, 2015 was $23.2 million and $78.5 million, respectively, compared to net cash used for operating activities of $12.9 million and $60.3 million, respectively, for the same periods in 2014.

Heron's net loss for the quarter and year ended December 31, 2015 was $31.2 million and $97.6 million, or $0.87 per share and $2.95 per share, respectively, compared to a net loss of $20.6 million and $76.4 million, or $0.71 per share and $2.87 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

costs incurred in preparation for the commercial launch of SUSTOL, as well as clinical and manufacturing costs related to our Phase 1 and Phase 2 clinical studies for HTX-011 and costs associated with the development of HTX-019.

About Heron Therapeutics, Inc.

Heron Therapeutics, Inc. is a biotechnology company focused on improving the lives of patients by developing best-in-class medicine that address major unmet medical needs. Heron is developing novel, patient-focused solutions that apply its innovative science and technologies to already-approved pharmacological agents for patients suffering from cancer or pain. 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. 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 FDA completes its review of the SUSTOL NDA within the anticipated time period, whether the FDA approves the SUSTOL NDA as submitted and supports the requested labeled indication for SUSTOL, the potential market opportunity for SUSTOL and the expected timing of the commercial launch, the research and development progress of HTX-019, HTX-011 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, 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, our ability to grow our organization to sustain the commercial launch for SUSTOL, if approved, 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)

	Three Months Ended December 31, (unaudited)		Years Ended December 31,	
	2015	2014	2015	2014
Operating expenses:				
Research and development	$16,263	$14,195	$61,183	$54,833
General and administrative	14,797	5,300	35,742	19,728
Total operating expenses	31,060	19,495	96,925	74,561
Loss from operations	(31,060)	(19,495)	(96,925)	(74,561)
Other expense, net	(182)	(1,129)	(666)	(1,806)

Net loss	$(31,242)	$(20,624)	$(97,591)	$(76,367)
Basic and diluted net loss per share	$(0.87)	$(0.71)	$(2.95)	$(2.87)
Shares used in computing basic and diluted net loss per share	36,022	29,210	33,081	26,569

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Condensed Consolidated Balance Sheet Data
(in thousands)

	December 31, 2015	December 31, 2014
Cash, cash equivalents and short-term investments	$ 131,166	$ 72,675
Total assets	137,845	76,682
Total stockholders' equity	$ 118,110	$ 63,062

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