

Heron Therapeutics Announces Second Quarter 2015 Financial Results and Recent Corporate Progress

August 7, 2015 8:00 AM ET

REDWOOD CITY, Calif.--(BUSINESS WIRE)--Aug. 7, 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 second quarter 2015 financial results and highlighted recent corporate progress.

Recent Corporate Progress:

- In July 2015, Heron resubmitted its New Drug Application (NDA) for SUSTOL[®] (granisetron) Injection, extended release, for the prevention of acute and delayed chemotherapy-induced nausea and vomiting (CINV) associated with moderately emetogenic chemotherapy (MEC) and highly emetogenic chemotherapy (HEC) regimens, to the U.S. Food and Drug Administration (FDA).
- In June and July 2015, Heron initiated two Phase 2 clinical trials of HTX-011 for the prevention of post-operative pain, one in patients undergoing bunionectomy and one in patients undergoing inguinal hernia repair.
- In June 2015, Heron closed an underwritten public offering of 5,520,000 shares of common stock at a public offering price of \$24.75 per share. Heron received total net proceeds from the offering of approximately \$128.2 million.
- In May 2015, Heron reported positive, top-line results from its recently completed Phase 3 MAGIC study for SUSTOL. The MAGIC study evaluated the efficacy and safety of SUSTOL as part of a three-drug regimen with the intravenous (IV) neurokinin-1 (NK₁) receptor antagonist fosaprepitant and the corticosteroid dexamethasone for the prevention of delayed CINV associated with HEC regimens.
- In May 2015, the FDA accepted Heron's proposal to use the 505(b)(2) regulatory pathway for HTX-019, Heron's proprietary intravenous formulation of the NK₁ receptor antagonist aprepitant for the prevention of CINV. Utilizing the 505(b)(2) regulatory pathway to significantly reduce the costs and time required for development, Heron intends to file an NDA for HTX-019 in the second half of 2016.

"We have achieved several critical milestones since our last quarterly update, including the resubmission of the SUSTOL NDA to the FDA," commented Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "With a pipeline of four exciting product candidates with best-in-class potential and a healthy balance sheet following our successful financing in June, we are looking forward to an eventful and productive second half of 2015."

Results of Operations

As of June 30, 2015, Heron had approximately \$171.5 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 the June 2015 public offering noted above, partially offset by net cash used in operating activities.

Heron's net cash used for operating activities for the three and six months ended June 30, 2015 was \$15.8 million and \$35.5 million, respectively, compared to net cash used for operating activities of \$12.5 million and \$28.2 million, respectively, for the same periods in 2014. 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 loss for the three and six months ended June 30, 2015 was \$23.1 million and \$43.7 million, or \$0.74 per share and \$1.45 per share, respectively, compared to a net loss of \$19.0 million and \$36.5 million, or \$0.78 per share and \$1.52 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, as well as 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 medicines 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. 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[®] (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 and resubmitted its New Drug Application (NDA) for SUSTOL to the U.S. Food and Drug Administration (FDA) in July 2015. 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 (NK₁) 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, Heron's long-acting formulation of the local anesthetic bupivacaine in a fixed-dose combination with the anti-inflammatory meloxicam, is currently being evaluated in two Phase 2 clinical trials for the prevention of post-operative pain. Heron expects to report results from both of these trials in the second half of 2015. HTX-003, a long-acting formulation of buprenorphine, is being developed for the 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[®] 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.heronrx.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 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: the acceptance of the Company's resubmission of its New Drug Application (NDA) for SUSTOL, 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 ability to raise additional capital to fund future initiatives, 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. 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 Consolidated Statements of Operations
(in thousands, except per share amounts)

Three Months Ended Six Months Ended

	June 30, 2015	2014	June 30, 2015	2014
Operating expenses:				
Research and development	\$ 16,175	\$ 14,279	\$ 30,679	\$ 25,907
General and administrative	6,839	4,512	12,695	10,206
Total operating expenses	23,014	18,791	43,374	36,113
Loss from operations	(23,014)	(18,791)	(43,374)	(36,113)
Other expense, net	(93)	(220)	(303)	(436)
Net loss	\$(23,107)	\$(19,011)	\$(43,677)	\$(36,549)
Basic and diluted net loss per share	\$(0.74)	\$(0.78)	\$(1.45)	\$(1.52)
Shares used in computing basic and diluted net loss per share	31,035	24,266	30,218	23,989

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheet Data (in thousands)

	June 30, 2015	December 31, 2014
	(unaudited)	
Cash and cash equivalents	\$ 171,526	\$ 72,675
Total assets	176,456	76,682
Total stockholders' equity	\$ 159,866	\$ 63,062

View source version on businesswire.com: <http://www.businesswire.com/news/home/20150807005089/en/>

Source: Heron Therapeutics, Inc.

Heron Therapeutics, Inc.

Investor Relations Contact:

Jennifer Capuzelo, 858-703-6063

Sr. Manager, Investor Relations

jcapuzelo@herontx.com

Corporate Contact:

Barry D. Quart, Pharm D., 650-366-2626

Chief Executive Officer