

Heron Therapeutics Reports Financial Results for the Three and Nine Months Ended September 30, 2017 and Recent Corporate Progress

November 6, 2017

SAN DIEGO, Calif.--(BUSINESS WIRE)--Nov. 6, 2017-- Heron Therapeutics, Inc. (Nasdaq:HRTX) (the Company or Heron), a commercial-stage biotechnology company focused on developing novel, best-in-class treatments to address some of the most important unmet patient needs, today reported financial results for the three and nine months ended September 30, 2017 and highlighted recent corporate progress.

Recent Corporate Progress

Pain Franchise

- Initiated Phase 3 Program for HTX-011 in Postoperative Pain. Heron is enrolling patients in two pivotal Phase 3 efficacy studies in bunionectomy and hernia repair. Heron's Phase 3 program is designed to achieve a broad indication for the reduction in postoperative pain and the need for opioid analgesics for 72 hours following surgery. Heron anticipates completing the pivotal Phase 3 efficacy studies in the first half of 2018 and expects to file a New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) in 2018.
- Fast Track Designation Granted for HTX-011. The FDA has granted Fast Track designation for HTX-011 for local administration into the surgical site to reduce postoperative pain and the need for opioid analgesics for 72 hours. Fast Track designation is intended to facilitate the development and expedite the review of new therapies to treat serious conditions with unmet medical needs by providing sponsors with the opportunity for frequent interactions with the FDA. HTX-011 is the first opioid alternative for local administration into the surgical site to receive Fast Track designation.
- Patent Issued Covering Novel Bupivacaine/Meloxicam Combination. The U.S. Patent and Trademark Office issued to Heron U.S. Patent No. 9,801,945, which covers HTX-011 and all clinically relevant combinations of bupivacaine and meloxicam for the prevention of postoperative pain.

CINV Franchise

- SUSTOL[®] Sales. Net product sales of SUSTOL (granisetron) extended-release injection for the three and nine months ended September 30, 2017 were \$8.6 million and \$20.7 million, respectively. Heron commenced commercial sales of SUSTOL in October 2016. Guidance for full-year 2017 net product sales of SUSTOL remains \$25 million to \$30 million.
- CINVANTI[™] FDA Action Date in Q4 2017. The FDA set a Prescription Drug User Fee Act (PDUFA) goal date of November 12, 2017 for a decision on the Company's NDA for CINVANTI.

"Heron made good progress in the third quarter of 2017, highlighted by the start of Phase 3 studies for HTX-011, which recently has been granted Fast Track designation, and SUSTOL's continued commercial success, outperforming all other CINV new drug launches in the last decade," said Barry D. Quart, Pharm.D., Chief Executive Officer of Heron. "Looking ahead, we are focused on FDA approval of CINVANTI, which, if approved, we expect to launch in January 2018, reporting top-line Phase 3 results for HTX-011 in the first half of next year and filing an NDA for HTX-011 in 2018."

Financial Results

Net product sales of SUSTOL for the three months ended September 30, 2017 were \$8.6 million and totaled \$20.7 million for the nine months ended September 30, 2017. Heron commenced commercial sales of SUSTOL in October 2016.

Heron's net loss for the three and nine months ended September 30, 2017 was \$41.9 million and \$135.0 million, or \$0.77 per share and \$2.55 per share, respectively, compared to a net loss of \$48.5 million and \$125.2 million, or \$1.24 per share and \$3.34 per share, respectively, for the same periods in 2016. Net loss for the three and nine months ended September 30, 2017, included non-cash, stock-based compensation expense of \$7.5 million and \$23.6 million, respectively, compared to \$7.5 million and \$18.7 million, respectively, for the same periods in 2016.

Heron's cash, cash equivalents and short-term investments were \$74.0 million as of September 30, 2017. The Company also had accounts receivable of \$28.9 million, the majority of which the Company expects to collect in the fourth quarter of 2017 and the first quarter of 2018. Net cash used for operating activities for the three months ended September 30, 2017 was \$40.5 million, compared to \$36.1 million for the three months ended September 30, 2017 was \$40.5 million, compared to \$36.2017 was \$123.2 million, compared to \$95.6 million for the nine months ended September 30, 2016.

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 that address some of the most important unmet patient 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. 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, those associated with: our capital position and the sufficiency of our capital to fund our operations in future periods; the market opportunity for SUSTOL; whether the FDA approves the CINVANTI NDA as submitted; the timing for the commercial launch of CINVANTI, if approved; the timing of completion and results of the Phase 3 studies for HTX-011; the timing of the HTX-011 NDA filing and review; 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 September 30, (unaudited)		Nine Months Ended September 30, (unaudited)	
	2017	2016	2017	2016
Revenues:				
Net product sales	\$ 8,572	\$-	\$ 20,714	\$-
Operating expenses:				
Cost of product sales	1,051	-	3,250	-
Research and development	28,844	30,242	90,825	73,620
General and administrative	6,462	5,333	19,389	15,474
Sales and marketing	13,529	12,159	39,918	35,018
Total operating expenses	49,886	47,734	153,382	124,112
Loss from operations	(41,314)	(47,734)	(132,668)	(124,112)
Interest expense, net	(552)	(775)	(2,326)	(1,068)
Net loss	\$ (41,866)	\$ (48,509)	\$(134,994)	\$(125,180)
Basic and diluted net loss per share	\$ (0.77)	\$ (1.24)	\$ (2.55)	\$ (3.34)
Shares used in computing basic and diluted net loss per share	54,176	39,113	52,846	37,470

HERON THERAPEUTICS, INC.

Condensed Consolidated Balance Sheet Data (in thousands)

	September 30, 2017		December 31, 2016	
	(unaudited)			
Cash, cash equivalents and short-term investments	\$	74,016	\$	51,138
Accounts receivable, net		28,851		1,960
Total assets		118,196		67,482
Promissory note payable		25,000		50,000
Total stockholders' equity (deficit)		40,053		(21,251)

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Source: Heron Therapeutics, Inc.

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