# Heron Therapeutics Announces Financial Results for the Three and Twelve Months Ended December 31, 2019 and Highlights Recent Corporate Updates

March 2, 2020

SAN DIEGO, March 2, 2020 /PRNewswire/ -- Heron Therapeutics, Inc. (Nasdaq: HRTX), a commercial-stage biotechnology company focused on improving the lives of patients by developing best-in-class treatments to address some of the most important unmet patient needs, today announced financial results for the three and twelve months ended December 31, 2019 and highlighted recent corporate updates.

**Recent Corporate Updates**

***Pain Management Franchise***

- **New Drug Application for HTX-011:** In September 2019, Heron resubmitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for HTX-011, an investigational agent for the management of postoperative pain. In February 2020, Heron announced that the FDA has extended the review period for the NDA for HTX-011 by up to three months. The new Prescription Drug User Fee Act (PDUFA) goal date is June 26, 2020.
- **Contract Manufacturing Site for HTX-011:** In February 2020, Heron announced that the contract manufacturing site used to manufacture HTX-011 has been reinspected by the FDA with no Form 483 observations issued and with a recommendation by the FDA inspector for approval of the site. Heron has not been informed of any other manufacturing concerns.
- **Marketing Authorisation Application for HTX-011 in the European Union:** In March 2019, Heron's Marketing Authorisation Application (MAA) for HTX-011 for the management of postoperative pain was validated by the European Medicines Agency (EMA) for review under the Centralised Procedure. An opinion from the EMA's Committee for Medicinal Products for Human Use (CHMP) is anticipated in the second quarter of 2020.
- **New Drug Submission for HTX-011 in Canada:** In December 2019, Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status and accepted by Health Canada. Health Canada's Priority Review status provides an accelerated 6-month review target for the NDS. A decision by Health Canada is anticipated in the third quarter of 2020.

***CINV Franchise***

- **CINV 2019 Net Product Sales:** For the three months ended December 31, 2019, chemotherapy-induced nausea and vomiting (CINV) franchise net product sales were $35.1 million, up 22% from the same period in 2018. For the twelve months ended December 31, 2019, CINV franchise net product sales were $146.0 million, up 88% from the same period in 2018.
    - **CINVANTI® Net Product Sales:** Net product sales of CINVANTI (aprepitant) injectable emulsion for the three and twelve months ended December 31, 2019 were $34.6 million and $132.2 million, respectively, compared to $23.4 million and $56.2 million, respectively, for the same periods in 2018.
    - **SUSTOL® Net Product Sales:** Net product sales of SUSTOL (granisetron) extended-release injection for the three and twelve months ended December 31, 2019 were $0.5 million and $13.8 million, respectively, compared to $5.4 million and $21.3 million for the same periods in 2018. On October 1, 2019, the Company made a business decision to discontinue all discounting of SUSTOL, which resulted in significantly lower SUSTOL net product sales.
- **2020 Net Product Sales Guidance:** Heron expects 2020 net product sales for the CINV franchise of $70 million to $80 million and the CINV franchise to return to growth in 2021 and beyond.

"We have made important advances in 2019 in both our pain management and CINV franchises, highlighted by the advancement of HTX-011 toward marketing approvals and strong sales for our CINV franchise," said Barry Quart, Pharm.D., President and Chief Executive Officer of Heron Therapeutics. "We look forward to launching HTX-011 for postoperative pain management in the second half of 2020, pending FDA approval."

**Financial Results**

Net product sales for the three and twelve months ended December 31, 2019 were $35.1 million and $146.0 million, respectively, compared to $28.8 million and $77.5 million, respectively, for the same periods in 2018.

Heron's net loss for the three and twelve months ended December 31, 2019 was $57.9 million and $204.7 million, or $0.65 per share and $2.50 per share, respectively, compared to $49.6 million and $178.8 million, or $0.63 per share and $2.44 per share, respectively, for the same periods in 2018. Net loss for the three and twelve months ended December 31, 2019 included non-cash, stock-based compensation expense of $11.1 million and $51.4 million, respectively, compared to $9.8 million and $33.4 million, respectively, for the same periods in 2018.

As of December 31, 2019, Heron had cash, cash equivalents and short-term investments of $391.0 million compared to $332.4 million as of December 31, 2018. Net cash used for operating activities for the twelve months ended December 31, 2019 was $124.6 million, compared to $191.8 million for the same period in 2018. Heron expects that its current cash, cash equivalents and short-term investments will be sufficient to fund its operations into 2022.

**About HTX-011 for Postoperative Pain**

HTX-011, an investigational agent, is a dual-acting, fixed-dose combination of the local anesthetic bupivacaine with a low dose of the nonsteroidal anti-inflammatory drug meloxicam. It is the first and only extended-release local anesthetic to demonstrate in Phase 3 studies significantly reduced pain and opioid use through 72 hours compared to bupivacaine solution, the current standard-of-care local anesthetic for postoperative pain control. HTX-011 was granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2017 and Breakthrough Therapy designation in the second quarter of 2018. Heron submitted a New Drug Application (NDA) to the FDA for HTX-011 in October of 2018 and received Priority Review designation in December of 2018. A Complete Response Letter (CRL) was received from the FDA regarding the NDA for HTX-011 on April 30, 2019 relating to chemistry, manufacturing and controls and non-clinical information. No issues related to clinical efficacy or safety were noted. Heron resubmitted an NDA to the FDA for HTX-011 in September 2019. The Prescription Drug User Fee Act (PDUFA) goal date is June 26, 2020. A Marketing Authorisation Application (MMA) for HTX-011 was validated by the European Medicines Agency (EMA) in March 2019 for review under the Centralised Procedure. Heron's New Drug Submission (NDS) for HTX-011 for the management of postoperative pain was granted Priority Review status by Health Canada in October 2019 and accepted by Health Canada in November 2019.

**About CINVANTI (Aprepitant) Injectable Emulsion**

CINVANTI, in combination with other antiemetic agents, is indicated in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin as a single-dose regimen, delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC) as a single-dose regimen, and nausea and vomiting associated with initial and repeat courses of MEC as a 3-day regimen. CINVANTI is an IV formulation of aprepitant, a substance P/neurokinin-1 ($NK_1$) receptor antagonist (RA). CINVANTI is the first IV formulation to directly deliver aprepitant, the active ingredient in EMEND® capsules. Aprepitant (including its prodrug, fosaprepitant) is the only single-agent $NK_1$ RA to significantly reduce nausea and vomiting in both the acute phase (0–24 hours after chemotherapy) and the delayed phase (24–120 hours after chemotherapy). The FDA-approved dosing administration included in the United States prescribing information for CINVANTI is a 30-minute IV infusion or a 2-minute IV injection.

Please see full prescribing information at www.CINVANTI.com.

**About SUSTOL (Granisetron) Extended-Release Injection**

SUSTOL is indicated in combination with other antiemetics in adults for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic chemotherapy (MEC) or anthracycline and cyclophosphamide (AC) combination chemotherapy regimens. SUSTOL is an extended-release, injectable 5-$HT_3$ receptor antagonist that utilizes Heron's Biochronomer® drug delivery technology to maintain therapeutic levels of granisetron for ≥5 days. The SUSTOL global Phase 3 development program was comprised of two, large, guideline-based clinical studies that evaluated SUSTOL's efficacy and safety in more than 2,000 patients with cancer. SUSTOL's efficacy in preventing nausea and vomiting was evaluated in both the acute phase (0–24 hours after chemotherapy) and delayed phase (24–120 hours after chemotherapy).

Please see full prescribing information at www.SUSTOL.com.

**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 to 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 pain or cancer.

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: whether the U.S. Food and Drug Administration (FDA) approves the New Drug Application (NDA) for HTX-011; the timing of the commercial launch of HTX-011; the timing of the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) review process for HTX-011; whether the European Commission (EC) authorizes the Marketing Authorisation Application (MAA) for HTX-011; the timing of Health Canada's New Drug Submission (NDS) review process for HTX-011; whether Health Canada issues a Notice of Compliance for the NDS for HTX-011; the expected future balances of Heron's cash, cash equivalents and short-term investments; the expected duration over which Heron's cash, cash equivalents and short-term investments balances will fund its operations; and other risks and uncertainties identified in the Company's filings with the U.S. 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.**
Consolidated Balance Sheets
(In thousands, except par value amounts)

| | December 31, 2019 | December 31, 2018 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 71,898 | $ 31,836 |
| Short-term investments | 319,074 | 300,535 |
| Accounts receivable, net | 39,879 | 64,652 |
| Inventory | 24,968 | 39,032 |
| Prepaid expenses and other current assets | 23,245 | 11,193 |
| Total current assets | 479,064 | 447,248 |
| Property and equipment, net | 19,618 | 14,677 |
| Right-of-use lease assets | 13,754 | — |
| Other assets | 346 | 254 |
| Total assets | $ 512,782 | $ 462,179 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable | $ 2,758 | $ 16,863 |
| Accrued clinical and manufacturing liabilities | 34,614 | 24,470 |
| Accrued payroll and employee liabilities | 15,248 | 13,397 |
| Other accrued liabilities | 36,535 | 32,715 |
| Current lease liabilities | 1,926 | — |
| Convertible notes payable to related parties, net of discount | 5,624 | 4,574 |
| Total current liabilities | 96,705 | 92,019 |
| Non-current lease liabilities | 12,242 | — |
| Total liabilities | 108,947 | 92,019 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.01 par value: 2,500 shares authorized; no shares issued or outstanding at December 31, 2019 and 2018 | — | — |
| Common stock, $0.01 par value: 150,000 shares authorized; 90,304 and 78,174 shares issued and outstanding at December 31, 2019 and 2018, respectively | 903 | 782 |
| Additional paid-in capital | 1,568,317 | 1,330,186 |
| Accumulated other comprehensive income (loss) | 85 | (87) |
| Accumulated deficit | (1,165,470) | (960,721) |
| Total stockholders' equity | 403,835 | 370,160 |
| Total liabilities and stockholders' equity | $ 512,782 | $ 462,179 |

**HERON THERAPEUTICS, INC.**
Condensed Consolidated Statements of Operations
(In thousands, except per share amounts)

| | Three Months Ended December 31, | | Twelve Months Ended December 31, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| | (unaudited) | | | |
| **Revenues:** | | | | |
| Net product sales | $ 35,083 | $ 28,844 | $ 145,968 | $ 77,474 |
| **Operating expenses:** | | | | |
| Cost of product sales | 15,874 | 11,572 | 61,619 | 27,512 |
| Research and development | 48,277 | 39,891 | 167,382 | 140,032 |
| General and administrative | 9,874 | 8,738 | 37,897 | 29,263 |
| Sales and marketing | 20,420 | 19,957 | 89,764 | 64,604 |
| Total operating expenses | 94,445 | 80,158 | 356,662 | 261,411 |
| Loss from operations | (59,362) | (51,314) | (210,694) | (183,937) |
| Other income, net | 1,442 | 1,755 | 5,945 | 5,097 |
| Net loss | $ (57,920) | $ (49,559) | $ (204,749) | $ (178,840) |
| Basic and diluted net loss per share | $ (0.65) | $ (0.63) | $ (2.50) | $ (2.44) |
| Shares used in computing basic and diluted net loss per share | 89,112 | 78,086 | 81,779 | 73,193 |

**HERON THERAPEUTICS, INC.**
Consolidated Statements of Cash Flows
(In thousands)

| | Years Ended December 31, | | |
|---|---|---|---|
| | **2019** | **2018** | **2017** |
| **Operating activities:** | | | |
| Net loss | $(204,749) | $(178,840) | $(197,484) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | | |
| Stock-based compensation expense | 51,411 | 33,367 | 30,538 |
| Depreciation and amortization | 2,044 | 1,513 | 1,531 |
| Amortization of debt discount | 1,050 | 890 | 773 |
| Accretion of discount on short-term investments | (3,730) | (3,412) | (278) |
| Realized gain on available-for-sale investments | (8) | — | — |
| Impairment of property and equipment | 107 | 72 | — |
| Loss on disposal of property and equipment | 62 | 29 | 39 |
| Change in operating assets and liabilities: | | | |
| Accounts receivable | 24,773 | (22,778) | (39,914) |
| Prepaid expenses and other assets | (12,052) | (7,482) | 3 |
| Inventory | 14,064 | (29,122) | (4,768) |
| Accounts payable | (14,105) | (1,906) | 11,955 |
| Accrued clinical and manufacturing liabilities | 10,144 | (3,614) | 13,713 |
| Accrued payroll and employee liabilities | 1,851 | 4,537 | 446 |
| Deferred revenue | — | — | 1,664 |
| Other accrued liabilities | 4,558 | 14,941 | 11,482 |
| Net cash used for operating activities | (124,580) | (191,805) | (170,300) |
| **Investing activities:** | | | |
| Purchases of short-term investments | (477,035) | (497,104) | (121,570) |
| Maturities and sales of short-term investments | 462,406 | 227,700 | 131,783 |
| Purchases of property and equipment | (7,154) | (9,171) | (2,553) |
| Proceeds from the sale of property and equipment | — | 25 | 78 |
| Net cash (used for) provided by investing activities | (21,783) | (278,550) | 7,738 |
| **Financing activities:** | | | |
| Net proceeds from sale of common stock and/or pre-funded warrants | 162,151 | 363,128 | 306,279 |
| Proceeds from purchases under the Employee Stock Purchase Plan | 2,109 | 1,179 | 989 |
| Proceeds from stock option exercises | 22,164 | 18,301 | 11,463 |
| Proceeds from warrant exercises | 1 | — | — |
| Repayment of promissory note payable to related party | — | (25,000) | (25,000) |
| Net cash provided by financing activities | 186,425 | 357,608 | 293,731 |
| Net increase (decrease) in cash and cash equivalents | 40,062 | (112,747) | 131,169 |
| Cash and cash equivalents at beginning of year | 31,836 | 144,583 | 13,414 |
| Cash and cash equivalents at end of year | $ 71,898 | $ 31,836 | $ 144,583 |
| **Supplemental disclosure of cash flow information:** | | | |
| Interest paid | $ — | $ 1,183 | $ 2,789 |
| Cumulative effect of adoption of new accounting standard | $ — | $ 1,574 | $ — |

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