Histogen Reports First Quarter 2023 Results and Provides Business Update

May 11, 2023

Received FDA Clearance of IND Application for Emricasan for the Treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI)

Emricasan Treatment has Therapeutic Effect Against Bacterial Skin Infection in Mice

Signed Exclusive Intellectual Property License Agreement with Johns Hopkins University

Steven J. Mento Ph.D. Appointed President and CEO

SAN DIEGO, May 11, 2023 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company focused on developing potential first-in-class clinical and preclinical small molecule pan-caspase and caspase selective inhibitors that protect the body's natural process to restore immune function, today reported financial results for the first quarter ended March 31, 2023, and provided an update on its pipeline and other corporate developments.

"The team has done a fantastic job of executing on critical milestones that support the development of emricasan as a potential treatment for ABSSSI," said Steven J. Mento, Ph.D., President and Chief Executive Officer. "We believe that emricasan has the potential to treat infections in a different way; by protecting the competence of the human body's immune system thereby restoring the body's natural process to combat invading organisms," stated Dr. Mento. "The previously reported positive results in the COVID clinical trial together with the compelling preclinical data in bacterial skin disease point to a potential broad opportunity for emricasan as a more generalized host-based immunotherapeutic treatment of both viral and bacterial infections without the risk of generating resistance."

Highlights from the First Quarter and Business Updates

- **Emricasan ABSSSI –** Emricasan is an orally available pan-caspase inhibitor designed to reduce the activities of human caspases, which are enzymes that mediate inflammation and apoptosis. Emricasan has completed extensive toxicology testing including chronic toxicology and clean carcinogenicity testing. This drug candidate has previously been shown to be well tolerated in multiple clinical studies involving approximately 1,000 subjects employing multiple doses ranging from 1 mg to 500 mg orally with treatment for up to two years, including a Phase 1 study in mild symptomatic COVID-19 patients to assess safety, tolerability, and preliminary efficacy.

  In April 2023, we announced the online publication of an abstract describing our preclinical study in mice showing that emricasan has therapeutic effect against bacterial skin infections. In the study, the role of the irreversible pan-caspase inhibitor emricasan alone and in combination with a standard-of-care antibiotic, doxycycline, was examined as a potential host-directed immunotherapy against bacterial infections in a mouse model commonly used to test the effectiveness of the innate immune response. Mice in four groups; placebo, placebo plus doxycycline, emricasan plus doxycycline, and emricasan alone were treated orally twice daily for 7 days after intradermal injection of the established CA-MRSA strain USA300 of Staphylococcus aureus in mice. The results of the study show that: (1) emricasan alone reduced both lesion size and bacterial burden versus placebo ($p<0.0001$); (2) emricasan alone showed efficacy superior to doxycycline alone in lesion size ($p=0.02$); and (3) emricasan alone and emricasan plus doxycycline showed comparable efficacy versus placebo in both lesion size and bacterial burden ($p<0.0001$).

  Additionally, in March 2023, we received notice from the FDA related to our recently filed IND for emricasan for the treatment of ABSSSI that the "Study May Proceed." Assuming we raise sufficient capital, we anticipate initiation of clinical development in the second half of 2023.

- **Exclusive Intellectual Property License Agreement with Johns Hopkins –** In April 2023, we signed an exclusive license agreement with Johns Hopkins University. The intellectual property associated with this license covers the use of emricasan for the treatment of disease in humans resulting from viral or bacterial infections (including, but not limited to, MRSA, VRSA, and SARS-CoV-2). The license agreement with Johns Hopkins is an instrumental addition to Histogen's intellectual property portfolio. Rights to these patent applications, together with recently issued internal patents, are expected to provide freedom to operate and exclusivity worldwide to the Histogen's entire caspase inhibitor portfolio.

- **Steven J. Mento Ph.D. appointed President and CEO –** In March 2023, Dr. Mento was appointed President and CEO. Dr. Mento served as Histogen's Executive Chairman and Interim President and CEO from November of 2021 to March 2023 and as a member of our Board since July 2005. Dr. Mento was one of Conatus' co-founders and served as Conatus' President and Chief Executive Officer from July 2005 until the merger with Histogen. From July 2005 until December 2012, Dr. Mento also served as Chairman of Conatus' Board of Directors. Dr. Mento has over 40 years of combined experience

in the biotechnology and pharmaceutical industries serving in a broad range of senior executive and scientific positions. He previously served as President, Chief Executive Officer, and a member of the Board of Directors of Idun Pharmaceuticals prior to its sale in 2005 to Pfizer.

First Quarter 2023 Financial Highlights: Three Months Ended March 31, 2023 and 2022

Revenues for the three months ended March 31, 2023 and 2022, we recognized license revenue of $5 thousand and $3.8 million, respectively. The decrease in the current period is due to a one-time payment of $3.75 million received in March 2022 as consideration for execution of the Allergan Letter Agreement.

Research and development expenses for the three months ended March 31, 2023 and 2022 were $1.0 million and $1.9 million, respectively. The decrease of $0.9 million was primarily due to decreases in outsourced manufacturing facility expenses, personnel related expenses, and the number of clinical and preclinical candidates in development and corresponding reduction of costs.

General and administrative expenses for both the three months ended March 31, 2023 and 2022 were $2.5 million. While there was no difference in expense between the periods, the change in the type of expenses for the period ended March 31, 2023 as compared to March 31, 2022 was primarily increases in stock-based compensation, outside services, and rent expenses, offset by reductions in royalty expenses, legal, insurance, and personnel related expenses.

Cash and cash equivalents as of March 31, 2023 were $9.7 million. Histogen believes that its existing cash and cash equivalents and cash inflow from operations will be sufficient to meet Histogen's anticipated cash needs into January of 2024.

About Histogen Inc.

Histogen Inc. is a clinical-stage therapeutics company focused on developing potential first-in-class clinical and preclinical small molecule pan-caspase and caspase selective inhibitors that protect the body's natural process to restore immune function. Currently, we are developing emricasan for acute bacterial skin and skin structure infections (ABSSSI) as well evaluating its use for other infectious diseases. Our pipeline also includes novel preclinical product candidates including CTS-2090 and other proprietary caspase inhibitors, which are selective small molecule inhibitors of caspase-1 designed for the treatment of certain inflammatory diseases. For more information, please visit www.histogen.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995 and other Federal securities laws. For example, we are using forward-looking statements when we discuss the potential benefits of the license with Johns Hopkins University and our expectation that the license will provide freedom to operate and exclusivity; the potential benefits of the preclinical study in mice showing that emricasan has therapeutic effect against bacterial skin infections; our future operations and our ability to successfully initiate, enroll and complete clinical trials, obtain clinical trial data, and achieve regulatory milestones and related timing, including those related to the timing of providing clinical development guidance on the development of emricasan and any further evaluation of CTS-2090. We may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Because such statements deal with future events and are based on our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of Histogen that could differ materially from those described in or implied by the statements in this press release, including: our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates; including its ability to carry out the development of emricasan and the potential for delays in the timing of regulatory approval and the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all; our expectations regarding the operation of our product candidates and related benefits; our beliefs regarding the success, cost and timing of our product candidate development and current and future clinical trials and studies; our beliefs regarding the potential markets for our product candidates; any impact of the COVID-19 pandemic, or responses to the pandemic, on our business, clinical trials or personnel; our beliefs regarding our industry; our ability to attract and retain key personnel; regulatory developments in the United States and foreign countries, with respect to our product candidates; the impact of any litigation proceedings on our business and market and other conditions. The foregoing review of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including those risks discussed in our filings with the Securities and Exchange Commission. Except as otherwise required by law, Histogen disclaims any intention or obligation to update or revise any forward-looking statements, which speak only as of the date hereof, whether as a result of new information, future events, or circumstances or otherwise.

HISTOGEN INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three Months Ended March 31,	
	2023	**2022**
Revenue		
License revenue	$ 5	$ 3,755
Total revenue	5	3,755
Operating expense		
Research and development	993	1,932
General and administrative	2,486	2,506

Total operating expense	3,479	4,438
Loss from operations	(3,474)	(683)
Other income (expense)		
Interest expense, net	—	(1)
Gain on sale of subsidiary	1	—
Net loss	(3,473)	(684)
Loss attributable to noncontrolling interest	3	11
Net loss available to common stockholders	$ (3,470)	$ (673)
Net loss per share available to common stockholders, basic and diluted	$ (0.81)	$ (0.27)
Weighted-average number of common shares outstanding used to compute net loss per share, basic and diluted	4,271,759	2,497,450

HISTOGEN INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share amounts)

	March 31, 2023	December 31, 2022
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 9,658	$ 12,109
Restricted cash	300	400
Accounts receivable, net	23	99
Prepaid and other current assets	627	848
Total current assets	10,608	13,456
Property and equipment, net	398	436
Right-of-use asset	4,576	4,658
Other assets	469	523
Total assets	$ 16,051	$ 19,073
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 441	$ 382
Accrued liabilities	629	595
Current portion of lease liabilities	251	238
Current portion of deferred revenue	19	19
Total current liabilities	1,340	1,234
Lease liabilities, non-current	4,312	4,379
Deferred revenue, non-current	74	79
Finance lease liability, non-current	3	5
Total liabilities	5,729	5,697
Commitments and contingencies (Note 8)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; no shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 4,271,759 shares issued and outstanding at March 31, 2023 and December 31, 2022	5	5
Additional paid-in capital	103,092	102,673
Accumulated deficit	(91,743)	(88,273)
Total Histogen Inc. stockholders' equity	11,354	14,405
Noncontrolling interest	(1,032)	(1,029)
Total equity	10,322	13,376
Total liabilities and stockholders' equity	$ 16,051	$ 19,073

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