Histogen Reports First Quarter 2022 Financial Results and Provides Business Update

May 12, 2022

Received $3.75 Million Payment from Allergan

Phase 1/2 Study of HST 003 for Cartilage Regeneration in the Knee Ongoing with Top-Line Data Anticipated in the First Half of 2023

SAN DIEGO, May 12, 2022 (GLOBE NEWSWIRE) -- Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company focused on developing both restorative therapeutics and pan-caspase and caspase selective inhibitors focused on treatments for infectious and inflammatory diseases, today reported financial results for the first quarter ended March 31, 2022 and provided an update on its clinical pipeline and other corporate developments.

"We continue to focus on clinical execution of HST-003 in knee cartilage repair, IND enabling activities for HST-004 in spinal disk regeneration, exploration of testing emricasan in animal studies for methicillin resistant staphylococcus aureus infections ("MRSA"), and evaluating our caspase-1 inhibitors that impact the inflammasome pathway," said Steven J. Mento, Ph.D., Interim President and Chief Executive Officer.

Highlights from the First Quarter 2022 and Business Updates

- **HST-003 –** Our Phase 1/2 clinical study of HST-003 to evaluate the safety and efficacy of human extracellular matrix (hECM) implanted within microfracture interstices and the cartilage defect in the knee to regenerate hyaline cartilage in combination with a microfracture procedure is on-going. In the first quarter of 2022, we added three additional clinical sites to help supplement enrollment of patients due to the recruitment challenges we have experienced related to both the specific nature of the study inclusion criteria and the impact of COVID-19 on the elective surgery environment. We continue to anticipate top line results in the first half of 2023, assuming we complete enrollment in the fourth quarter of 2022.

- **HST-004 –** Our initial preclinical research has shown that HST-004 stimulates stem cells from the spinal disc to proliferate and secrete aggrecan and collagen II, regenerate normal matrix and cell tissue structure and restores disc height. HST-004 was also shown to reduce inflammation and protease activity and upregulate aggrecan production in an ex vivo spinal disc model. We have initiated IND enabling activities for HST-004 and anticipate filing IND for HST-004 in the second half of 2023.

- **Emricasan COVID-19 Amerimmune Collaboration Agreement -** On March 3, 2022, we filed our demand for arbitration as we believe that Amerimmune has failed to undertake commercially reasonable efforts toward conducting and completing the Phase 2 study as required by the Collaborative Development and Commercialization Agreement that we previously entered into with Amerimmune in October of 2020.

- **Emricasan MRSA -** We continue to make progress on exploring the feasibility of testing emricasan in animal studies for MRSA. We expect to complete our feasibility assessment in the second half of 2022 and, subject to the outcome of the arbitration with Amerimmune, explore further development of emricasan for MRSA.

- **$3.75 Million Allergan Payment –** In March 2022, we received a one-time $3.75 million payment from Allergan pursuant to execution of a letter agreement entered into on March 18, 2022. The payment represents a full and final satisfaction of all monies due to the Company pursuant to the Allergan License Agreement.

First Quarter Ended March 31, 2022 Financial Highlights

Product, License, and Grant Revenues

For the three months ended March 31, 2022 and 2021, we recognized product revenues of $0 and $0.3 million, respectively. The revenue for the first quarter of 2021 was related to the additional supply of CCM to Allergan. As of March 31, 2021, all obligations of the Company related to the additional supply of CCM to Allergan under the Allergan Agreements have been completed.

For the three months ended March 31, 2022 and 2021, we recognized license revenue of $3.8 million and $12 thousand, respectively. The increase in the current period is due to a one-time payment of $3.8 million received in March 2022 as consideration for execution of the Allergan letter agreement.

For the three months ended March 31, 2022 and 2021, we recognized grant revenue of $0 and $0.1 million, respectively. The related revenue is associated with a research and development grant awarded to the Company from the NSF. As of March 31, 2021, all work required by the Company under the grant has been completed.

Cost of revenues for the three months ended March 31, 2022 and 2021, we recognized $0 and $0.2 million, respectively, for cost of product sold to Allergan under the Allergan Agreements.

Research and development expenses for the three months ended March 31, 2022 and 2021 were $1.9 million and $2.1 million, respectively. The decrease of $0.2 million was primarily due to decreases in development costs of our clinical and pre-clinical product candidates and personnel related expenses, partially offset by facility rent increases.

General and administrative expenses for the three months ended March 31, 2022 and 2021 were $2.5 million and $2.3 million, respectively. The increase of $0.2 million was primarily due to increases in royalty expenses and legal fees, offset by reductions in personnel related expenses.

Cash and cash equivalents as of March 31, 2022 were $17.8 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 the third quarter of 2023.

About Histogen Inc.

Histogen Inc. is a clinical-stage therapeutics company focused on developing both potential first-in-class restorative therapeutics that ignite the body's natural process to repair and maintain healthy biological function as well as a pipeline of clinical and preclinical small molecule pan-caspase and caspase selective inhibitors focused on treatments for infectious and inflammatory diseases. Under our biologics technology platform, our product candidates in development are HST-003, a treatment for joint cartilage repair, and HST-004, a treatment for spinal disc repair. In addition, within our small molecule pipeline, our product candidates include emricasan, CTS-2090 and CTS-2096. Currently, emricasan is being developed jointly with our collaboration partner, Amerimmune, for the treatment of COVID-19, and we are evaluating the use of emricasan for other infectious diseases including the treatment of MRSA. We also have preclinical product candidates, CTS-2090 and CTS-2096, novel, potent, orally bioavailable, and highly 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 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 initiation, completion and reporting of top line results for HST-003 Phase 1/2 clinical trial for regeneration of cartilage in the knee, the completion of IND enabling activities and the anticipated filing of the HST-004 IND for spinal disc repair and the timing of providing clinical development guidance on the emricasan and any further evaluation of CTS-2090 and CTS-2096. 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 regain compliance with Nasdaq's continued listing requirements; our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates; our expectations regarding the potential benefits of our strategy and technology, our expectations regarding the arbitration proceeding related to emricasan and the joint development with Amerimmune for COVID-19 and other infectious and inflammatory diseases, 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, collaborations and related benefits; our beliefs regarding the success, cost and timing of our product candidate development and collaboration activities and current and future clinical trials and studies; our beliefs regarding the potential markets for our product candidates, collaborations and our collaborators' ability to serve those markets; any impact of the COVID-19 pandemic, or responses to the pandemic, on our business, collaborations, 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 expected impact of any arbitration and litigation proceedings on our business, cash resources and the time required by management to address such proceedings. 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,	
	2022	**2021**
Revenue		
Product revenue	$ —	$ 306
License revenue	3,755	12
Grant revenue	—	113
Total revenue	3,755	431
Operating expense		
Cost of product revenue	—	220
Research and development	1,932	2,153
General and administrative	2,506	2,331
Total operating expense	4,438	4,704
Loss from operations	(683)	(4,273)
Other income (expense)		

Interest expense, net	(1)	(5)
Net loss	(684)	(4,278)
Loss attributable to noncontrolling interest	11	8
Net loss available to common stockholders	$ (673)	$ (4,270)
Net loss per share available to common stockholders, basic and diluted	$ (0.01)	$ (0.14)
Weighted-average number of common shares outstanding used to compute net loss per share, basic and diluted	49,950,212	31,571,676

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

	March 31, 2022	December 31, 2021
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 17,848	$ 18,685
Restricted cash	400	400
Accounts receivable, net	67	165
Prepaid and other current assets	2,694	2,359
Redeemable convertible preferred stock financing proceeds held in escrow	4,762	—
Total current assets	25,771	21,609
Property and equipment, net	527	399
Right-of-use asset	4,451	4,432
Other assets	748	805
Total assets	$ 31,497	$ 27,245
Liabilities, mezzanine and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,274	$ 1,393
Accrued liabilities	1,382	791
Current portion of lease liabilities	200	127
Current portion of deferred revenue	19	19
Total current liabilities	2,875	2,330
Lease liabilities, non-current	4,563	4,617
Noncurrent portion of deferred revenue	94	98
Finance lease liability, non-current	11	14
Total liabilities	7,543	7,059
Commitments and contingencies (Note 8)		
Mezzanine Equity		
Redeemable Convertible Preferred Stock, $0.0001 par value; 10,000,000 shares authorized at March 31, 2022 and December 31, 2021; 5,000 and 0 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	4,296	—
Total mezzanine equity	4,296	—
Stockholders' Equity		
Common stock, $0.0001 par value; 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 49,950,212 shares issued and outstanding at March 31, 2022 and December 31, 2021	5	5
Additional paid-in capital	98,995	98,839
Accumulated deficit	(78,325)	(77,652)
Total Histogen Inc. stockholders' equity	20,675	21,192
Noncontrolling interest	(1,017)	(1,006)
Total equity	19,658	20,186
Total liabilities, mezzanine equity, and stockholders' equity	$ 31,497	$ 27,245