UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 11, 2022

Histogen Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36003**	**20-3183915**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(IRS Employer Identification No.)**
10655 Sorrento Valley Road, Suite 200, San Diego CA		**92121**
(Address of principal executive offices)		**(Zip Code)**

(858) 526-3100
(Registrant's telephone number, including area code)

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value	HSTO	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 11, 2022, Histogen Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2022. The full text of such press release is furnished as Exhibit 99.1 to this report.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall expressly be set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Exhibits
99.1	Press Release, dated August 11, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* * *

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Histogen Inc.

Date: August 11, 2022

By: /s/ Susan A. Knudson
Name: Susan A. Knudson
Title: Executive Vice President and Chief Financial Officer

CONTACT:
Susan A. Knudson
Executive Vice President & CFO
Histogen Inc.
ir@histogen.com

Histogen Reports Second Quarter 2022 Financial Results and Provides Business Update

Closed $5M Financing in July

Regained Compliance with Nasdaq Minimum Bid Price Requirement

SAN DIEGO, Aug 11, 2022 – Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company focused on developing both restorative therapeutics for orthopedic indications and pan-caspase and caspase selective inhibitors focused on treatments for infectious and inflammatory diseases, today reported financial results for the second quarter ended June 30, 2022 and provided an update on its clinical pipeline and other corporate developments.

“We continue to focus on execution of IND enabling activities for HST 004 in spinal disc 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. “We also initiated a feasibility evaluation of our ongoing HST 003 study for cartilage regeneration in the knee, including implementation of protocol modifications, adding more sites, and other study resources given the continued recruitment challenges stemming from both the study protocol and impact of COVID-19 on the elective surgery environment and expect to complete our evaluation in the fourth quarter of 2022.”

Highlights from the Second 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. Despite adding three additional clinical sites in the first quarter of 2022, we continue to experience recruitment challenges due to both the specific nature of the study inclusion criteria and the impact of COVID-19 on the elective surgery environment. We are currently evaluating the overall feasibility of the ongoing HST 003 trial, including implementing protocol modifications, adding more sites, and other study resources. We expect to complete our feasibility evaluation 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, regenerates 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 continue to execute on IND enabling activities for HST-004 and anticipate filing IND for HST-004 in the second half of 2023.

- **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 third quarter of 2022.

- **Regained Compliance with Nasdaq Minimum Bid Listing Requirement** - On June 2, 2022, we effected a 1-for-20 reverse stock split of the Company's issued and outstanding common stock, par value $0.0001 per share. Subsequently, we received written notice from the Listing Qualifications Department of the Nasdaq Stock Market stating that the Company has regained compliance with the Nasdaq minimum bid price listing requirement.

- **$5 Million Financing –** In July 2022, we closed a $5 million private placement financing. We anticipate that the net proceeds, in addition to our cash of $12.6M as of June 30, 2022, will support our operations through December 2023.

Six Months Ended June 30, 2022 Financial Highlights

Product, License, and Grant Revenues

For the six months ended June 30, 2022 and 2021, we recognized product revenues of $0 and $0.3 million, respectively. The revenue for the first six months of 2021 was related to the additional supply of cell conditioned medium (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 six months ended June 30, 2022 and 2021, we recognized license revenue of $3.8 million and $17 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 six months ended June 30, 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 National Science Foundation (NSF). As of March 31, 2021, all work required by the Company under the grant has been completed.

Cost of revenues for the six months ended June 30, 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 six months ended June 30, 2022 and 2021 were $3.0 million and $4.5 million, respectively. The decrease of $1.5 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 six months ended June 30, 2022 and 2021 were $4.8 million and $4.2 million, respectively. The increase of $0.6 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 June 30, 2022 were $12.6 million which excludes gross proceeds of approximately $5 million from the private placement financing closed in July 2022. Histogen believes that

its existing cash and cash equivalents and cash inflow from operations will be sufficient to meet Histogen's anticipated cash needs through December 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 obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates; our expectations regarding the arbitration and judicial proceedings 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 impact of any arbitration and 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.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue				
Product revenue	$ —	$ —	$ —	$ 306
License revenue	5	5	3,760	17
Grant revenue	—	—	—	113
Total revenue	5	5	3,760	436
Operating expense				
Cost of product revenue	—	—	—	220
Research and development	1,093	2,376	3,025	4,528
General and administrative	2,306	1,822	4,812	4,154
Total operating expense	3,399	4,198	7,837	8,902
Loss from operations	(3,394)	(4,193)	(4,077)	(8,466)
Other income (expense)				
Interest expense, net	—	(2)	(1)	(7)
Other Income	—	475	—	475
Net loss	(3,394)	(3,720)	(4,078)	(7,998)
Loss attributable to noncontrolling interest	6	16	17	24
Deemed dividend - accretion of discount and redemption feature of redeemable convertible preferred stock	(488)	—	(488)	—
Net loss available to common stockholders	$ (3,876)	$ (3,704)	$ (4,549)	$ (7,974)
Net loss per share available to common stockholders, basic and diluted	$ (1.55)	$ (1.99)	$ (1.82)	$ (4.64)
Weighted-average number of common shares outstanding used to compute net loss per share, basic and diluted	2,497,450	1,859,770	2,497,450	1,719,925

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

	June 30, 2022	December 31, 2021
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 12,598	$ 18,685
Restricted cash	400	400
Accounts receivable, net	88	165
Prepaid and other current assets	1,941	2,359
Total current assets	15,027	21,609
Property and equipment, net	510	399
Right-of-use asset	4,816	4,432
Other assets	692	805
Total assets	$ 21,045	$ 27,245
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 534	$ 1,393
Accrued liabilities	372	791
Current portion of lease liabilities	212	127
Current portion of deferred revenue	19	19
Total current liabilities	1,137	2,330
Lease liabilities, non-current	4,504	4,617
Noncurrent portion of deferred revenue	89	98
Finance lease liability, non-current	9	14
Total liabilities	5,739	7,059
Commitments and contingencies (Note 8)		
Stockholders' Equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at June 30, 2022 and December 31, 2021; no shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 2,497,450 shares issued and outstanding at June 30, 2022 and December 31, 2021	5	5
Additional paid-in capital	98,037	98,839
Accumulated deficit	(81,713)	(77,652)
Total Histogen Inc. stockholders' equity	16,329	21,192
Noncontrolling interest	(1,023)	(1,006)
Total equity	15,306	20,186
Total liabilities and stockholders' equity	$ 21,045	$ 27,245