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): March 10, 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 March 10, 2022, Histogen Inc. (the "Company") issued a press release announcing its financial results for the quarter and full year ended December 31, 2021. 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 March 10, 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: March 10, 2022

By: /s/ Steven J. Mento, Ph.D.
Name: Steven J. Mento, Ph.D.
Title: Executive Chairman, Interim President and Chief Executive Officer

Exhibit 99.1

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

Histogen Reports Fourth Quarter and Year-End 2021 Financial Results and Provides Business Update

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, March 10, 2022 – 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 fourth quarter and year ended December 31, 2021 and provided an update on its clinical pipeline and other corporate developments.

"We have a diverse pipeline of biologics and small molecule product candidates that we believe address large unmet market needs," said Steven J. Mento, Ph.D., Interim President and Chief Executive Officer. "Looking ahead, we will continue to focus on clinical execution with HST-003 in cartilage repair, and emricasan in COVID-19 with our partner Amerimmune while we explore the feasibility of testing emricasan in animal studies for methicillin resistant staphylococcus aureus infections (MRSA), and continue to evaluate our caspase-1 inhibitors that impact the inflammasome pathway. These activities support our overarching goal of enhancing the lives of patients as we seek to build value for our shareholders."

Highlights from the Fourth Quarter and Year Ended 2021 and Business Updates

- **HST-003 –** In the second half of 2021, we initiated 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. We have experienced recruitment challenges due to both the specific nature of the study inclusion criteria and the impact of COVID-19 on the elective surgery environment. Additional qualified clinical sites have been added to help supplement recruitment and we will continue to evaluate the need to add more sites and study resources. We now 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. In the second half of 2021, we initiated toxicology studies and other IND enabling activities for HST-004. However, due to pipeline program prioritization, we now anticipate filing IND for HST-004 in the second half of 2023.

- **Emricasan COVID-19 –** In June 2021, we, jointly with Amerimmune LLC (“Amerimmune”), announced positive results from the Phase 1 study of emricasan in mild symptomatic COVID-19 patients. Emricasan was shown to be safe and well-tolerated during the 14 days of dosing and at the day 45 follow-up, as compared to placebo with no reports of serious adverse events. Patients who completed treatment with emricasan showed a statistically significant complete resolution of the symptoms most commonly associated in mild COVID-19, such as a cough, headache, and fatigue at day 7 which continued through day 45. No patients in the placebo arm experienced COVID-19 associated symptom resolution at any time point out to day 14. The mean number of days to recovery for patients in the emricasan arm was 4.8 days compared to 37.5 days in the placebo arm (p=0.001). In March 2022, we filed our demand for arbitration (“Arbitration Demand”) 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 (the “Collaborative Agreement”). As part of our Arbitration Demand, we are seeking a declaratory judgement from the arbitrator to terminate the Collaborative Agreement, which would result in us regaining all rights that we licensed to Amerimmune under the Collaborative Agreement. In such event, we intend to conduct and complete the Phase 2 study independently. If the Collaborative Agreement is not terminated, we will likely continue to jointly develop emricasan pursuant to the terms of the Collaborative Agreement. In either case, we anticipate a Phase 2 study could be initiated in the second half of 2022.

- **Emricasan MRSA** - We are exploring the feasibility of testing emricasan in animal studies of other infectious diseases, initially focused on methicillin-resistant staphylococcus aureus (“MRSA”). We anticipate completing the feasibility assessment in the second half of 2022.

- **CEO Transition** - In November of 2021, the board appointed Steven J. Mento, Ph.D. as Executive Chairman and Interim President and Chief Executive Officer.

Fourth Quarter and Full-Year 2021 Financial Highlights

Fourth Quarter Ended December 31, 2021 and 2020

Product and Service Revenues for the three months ended December 31, 2021 and 2020 were $0 and $0.5 million, respectively. The decrease of $0.5 million was due to fulfillment timing of CCM supply orders to Allergan PLC (“Allergan”). Our obligation to supply CCM to Allergan was satisfied in 2021, and we have no additional purchase orders with Allergan for fulfillment.

Cost of revenues for the three months ended December 31, 2021 and 2020, we recognized cost of product revenue of $0 and $0.3 million, respectively. The decrease of $0.3 million for the three months ended December 31, 2021 as compared to the three months ended December 31, 2020 was due to the decrease in product sales to Allergan.

Research and development expenses for the three months ended December 31, 2021 and 2020 were $1.6 million and $1.9 million, respectively. The decrease of $0.3 million for the three months ended December 31, 2021 as compared to the three months ended December 31, 2020 was primarily due to decreases related to personnel related expenses.

General and administrative expenses for the three months ended December 31, 2021 and 2020 were $1.5 million and $1.8 million, respectively. The $0.3 million decrease for the three months ended December

31, 2021 as compared to the three months ended December 31, 2020 was primarily due to decrease in personnel related expenses and rent expense decrease, partially offset by an increase in legal and other administrative expenses.

Twelve Months Ended December 31, 2021 and 2020

Revenues

For the years ended December 31, 2021 and 2020, we recognized license revenues of $27 thousand and $0.9 million, respectively. The revenue recognized in both periods is associated with the Allergan Agreements. During the period ended December 31, 2021, $19 thousand of deferred revenue was recognized in relation to the Potential Future Improvements remaining performance obligation currently being amortized over the remaining 9-year patent life. The year-over-year decrease is primarily attributable to the recognition of the allocated proceeds received upon the transfer of the expanded license to Allergan in January 2020.

For the years ended December 31, 2021 and 2020, we recognized product revenues of $0.9 million and $0.8 million, respectively. The increase of $0.1 million for the year ended December 31, 2021, as compared to the year ended December 31, 2020 was due to a larger quantity of CCM sales to Allergan.

Grant revenue for the years ended December 31, 2021 and 2020 was $0.1 million and $0, respectively, all of which was related to an NSF research grant awarded to us in 2017. In March 2021, the Company completed all obligations under the NSF development grant and, as such, no longer generates any revenues in connection with the research and development grant.

For the year ended December 31, 2020, we recognized professional services revenue of $0.3 million, related to the transfer of certain technology and know-how, which was completed during 2020. As such, no additional professional services revenue was recognized during the year ended December 31, 2021.

Cost of Revenues

Cost of revenues for the years ended December 31, 2021 and 2020 were $0.2 million and $0.7 million, respectively. The decrease of $0.5 million for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was primarily due to the sale of CCM to Allergan in September 2021 that was originally designated for research and development purposes and therefore had no cost of goods associated with it, and costs related to scrapped inventory.

For the years ended December 31, 2021 and 2020, we recognized costs of professional services of $0 and $0.3 million, respectively, related to the completion of technology transfer obligations of Histogen under the Allergan Agreements

In-process research and development expenses were $7.1 million for the year ended December 31, 2020 for in-process research and development acquired in connection with the Merger in May of 2020.

Research and development expenses for the years ended December 31, 2021 and 2020 were $8.5 million and $6.2 million, respectively. The increase of $2.3 million for the year ended December 31, 2021, as compared to the year ended December 31, 2020 was primarily due to increases in development costs of our clinical and pre-clinical product candidates and personnel related expenses, partially offset by $0.7 million in qualifying reimbursable expenses in connection with the DoD grant.

General and administrative expenses for the years ended December 31, 2021 and 2020 were $7.8 million and $6.6 million, respectively. This increase of $1.2 million for the year ended December 31, 2021 as

compared to the year ended December 31, 2020 was primarily due to increases in personnel related expenses, legal fees and insurance costs.

Cash and cash equivalents as of December 31, 2021 were $18.7 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 the second 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 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, the impact of the arbitration proceedings 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 intention to independently assess our caspase selective inhibitors for inflammatory diseases; the uncertainties associated with the clinical development and regulatory approval of Histogen's product candidates, including potential delays in the commencement, enrollment and completion of clinical trials; competition in the orthopedics market, COVID-19 market and other markets in which we and our collaboration partner operate; the potential that earlier clinical trials and studies of our product candidates may not be predictive of future results; risks related to business

interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our financial condition and increase its costs and expenses; 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
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

	Three Months Ended December 31, (unaudited)		Years Ended December 31,	
	2021	2020	2021	2020
Revenues:				
Product	$ —	$ 426	$ 892	$ 845
License	5	5	27	882
Grant	—	—	113	—
Professional services	—	47	—	332
Total revenues	5	478	1,032	2,059
Operating expenses:				
Cost of product revenue	—	255	220	679
Cost of professional services revenue	—	41	—	289
Acquired in-process research and development	—	—	—	7,144
Research and development	1,607	1,857	8,473	6,219
General and administrative	1,532	1,833	7,796	6,586
Total operating expenses	3,139	3,986	16,489	20,917
Income (loss) from operations	(3,134)	(3,508)	(15,457)	(18,858)
Other income (expense):				
Change in fair value of warrant liabilities	—	—	(10)	(64)
Interest income (expense), net	(19)	(14)	458	105
Net loss	(3,153)	(3,522)	(15,009)	(18,817)
Net loss attributable to noncontrolling interest	18	14	59	48
Net loss attributable to common stockholders	$ (3,135)	$ (3,508)	$ (14,950)	$ (18,769)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.07)	$ (0.26)	$ (0.39)	$ (2.08)
Weighted-average common shares used to compute net loss per share attributable to common stockholders, basic and diluted	42,800,932	13,763,713	38,364,711	9,018,376

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

	December 31, 2021	December 31, 2020
Assets		
Current assets		
Cash and cash equivalents	$ 18,685	$ 6,763
Restricted cash	400	10
Accounts receivable, net	165	144
Inventories	—	300
Prepaid and other current assets	2,359	1,183
Total current assets	21,609	8,400
Property and equipment, net	399	271
Right-of-use asset	4,432	4,411
Other assets	805	1,931
Total assets	$ 27,245	$ 15,013
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable	$ 1,393	$ 539
Accrued liabilities	791	1,880
Current portion of lease liabilities	127	28
Current portion of deferred revenue	19	48
Financed insurance premiums, current	—	193
Payroll protection program loan, current	—	97
Total current liabilities	2,330	2,785
Lease liabilities, non-current	4,617	4,806
Payroll protection program loan, non-current	—	369
Noncurrent portion of deferred revenue	98	118
Finance lease liability, non-current	14	22
Total liabilities	7,059	8,100
Commitments and contingencies (Note 10)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at December 31, 2021 and 2020; no shares issued and outstanding at December 31, 2021 and 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at December 31, 2021 and 2020; 49,950,212 and 15,030,757 shares issued and outstanding at December 31, 2021 and 2020, respectively	5	1
Additional paid-in capital	98,839	70,561
Accumulated deficit	(77,652)	(62,702)
Total Histogen Inc. stockholders' equity	21,192	7,860
Noncontrolling interest	(1,006)	(947)
Total equity	20,186	6,913
Total liabilities and stockholders' equity	$ 27,245	$ 15,013