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): May 13, 2021

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 May 13, 2021, Histogen Inc. (the "Company") issued a press release announcing its results of operations for the three months ended March 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 May 13, 2021
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: May 13, 2021

By: /s/ Richard W. Pascoe
Name: Richard W. Pascoe
Title: President and Chief Executive Officer

Exhibit 99.1

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

Histogen Reports First Quarter 2021 Earnings and Provides Business Update

Strengthened Balance Sheet with $20.8 Million of Gross Proceeds from Financing and Warrant Exercises

Initiated Phase 1 Study of Emricasan in Symptomatic COVID-19 Patients with Top-Line Data Anticipated in the Second Quarter of 2021

Initiation of Phase 1/2 Study of HST-003 for Cartilage Regeneration in the Knee Expected in the Second Quarter of 2021

Appointment of Industry Leaders Dr. Susan Windham-Bannister and Rochelle Furhmann to our Board of Directors

SAN DIEGO, May 13, 2021 – Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company focused on developing potential first-in-class restorative therapeutics that ignite the body's natural process to repair and maintain healthy biological function, today reported financial results for the first quarter ended March 31, 2021 and provided an update on its clinical pipeline and other corporate developments.

"We continue to focus on advancing our novel pipeline and are pleased to have initiated the emricasan study for treatment of mild symptomatic COVID-19 patients and are on track to initiate the HST-003 study for knee cartilage repair in the second quarter of 2021," said Richard W. Pascoe, President and Chief Executive Officer. We also welcomed Dr. Susan Windham-Bannister and Rochelle Fuhrmann to our Board of Directors. Both Sue and Rochelle bring to our board relevant industry experience with respective expertise in strategic growth and financial management, which will serve Histogen well. Looking forward, we will continue to focus on the initiation and execution of the HST-003 study, delivering top-line results of the emricasan COVID-19 trial, and completing our evaluation of the clinical development plans for the HST 001 program."

Highlights from the First Quarter Ended March 31, 2021 and Business Updates

- **HST-001 –** In February 2021, we announced the final results from the week 26 assessments of our study of HST-001 for the treatment of androgenic alopecia in men. These results supported that HST-001 was shown to be safe and well tolerated as compared to placebo with no reports of serious adverse events but did not achieve statistical significance at week 26 as compared to placebo. Additional observations at week 26 included that 84% of patients treated with HST-001, as compared to baseline, demonstrated a statistically significant change in total hairs (terminal and vellus) within the target area (TAHC) of the vertex as measured by Canfield's Hairmetrix macrophotography system. We are currently evaluating our clinical development plans for the HST-001 program and expect to complete our evaluation in the second quarter of 2021.

- **HST-003 –** In March 2021, we announced that the U.S. Food and Drug Administration ("FDA") confirmed that we can proceed with the initiation of our planned 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 anticipate enrollment to commence in the second quarter of 2021. Patients will be enrolled at three sites: Oasis MD in San Diego, CA, The Steadman Clinic in Vail, CO, and Walter Reed Medical Center in Bethesda, MD.

- **Emricasan –** In March 2021, we, in collaboration with our partner Amerimmune, announced dosing the first patient in the Phase 1 study of emricasan for the treatment of mild symptomatic COVID-19 patients. The study is designed to assess safety and tolerability and will also include various clinical and laboratory measures and patient reported outcomes (PROs) using the FDA COVID-19 Related Symptoms in Outpatient Adult and Adolescent Subjects in Clinical Trials of Drugs and Biological Products for COVID-19 Prevention or Treatment Assessment tool. We, along with our partner Amerimmune, expect top-line data to be available in the second quarter of 2021.

- **Appointed Dr. Susan Windham-Bannister and Rochelle Furhmann to the board of directors –** In March 2021, we continued to strengthen and diversify our board with the appointment of Dr. Windham-Bannister and Rochelle Fuhrmann. Dr. Windham-Bannister is an internationally recognized expert in innovation, market access and market optimization strategies. She has been recognized by *Biosphere* as one of the "10 Most Prominent African American Science Leaders," the *Boston Globe* as one of the "10 Most Influential Women in Biotech," by *Boston Magazine* as one of the "50 Most Powerful Women in Boston" and is the President of the National Board of Directors of the Association for Women in Science (AWIS). Dr. Windham-Bannister currently serves as Managing Partner of Biomedical Innovation Advisors LLC, which she founded with Dr. Harvey Lodish, co-founder of Genzyme, and member of the Whitehead Institute, MIT. She also serves as the President and CEO of Biomedical Growth Strategies, LLC. Ms. Fuhrmann currently serves as the Vice President Audit and Enterprise Risk Management at Becton Dickinson (BD). In 2016, Ms. Fuhrmann helped establish the BD Foundation, and she presently serves as Treasurer and as a member of its Board of Trustees. She joined BD in July 2015 as Senior Vice President and Chief Financial Officer, BD Life Sciences. Prior to joining BD, Rochelle held various positions responsible for the management of financial functions, including accounting and financial reporting, investor relations, corporate finance, risk management and treasury, primarily in the pharmaceutical industry with companies such as Amneal Pharmaceuticals and Warner Chilcott plc. She previously served as a member of the Board of Directors of Concordia International Corp. and held the position of Audit Committee Chairperson for three years.

- **Financings –** In January 2021, we received $14 million of gross proceeds from an S-1 offering and as of March 31, 2021, an incremental $6.8 million of gross proceeds from the exercise of warrants associated with the January 2021 public offering.

First Quarter 2021 Financial Highlights

First Quarter Ended March 31, 2021 and 2020

Product and Service Revenues in the first quarter of 2021, revenue decreased 56% to $0.4 million from $1.0 million in the first quarter of 2020. The decrease is primarily related to revenue recognized during the first quarter of 2020 associated with the Allergan License Agreement amendments offset by first quarter 2021 revenue related to the final supply of cell conditioned medium ("CCM") to Allergan under the Allergan License Agreements.

Cost of revenues for the three months ended March 31, 2021 and 2020 were $0.2 million and $0.3 million, respectively. The cost of product revenue during the first quarter of 2021 is related to the final supply of CCM sold to Allergan as compared to $0.2 million of scrapped inventory and $0.1 million of costs associated with professional services during the first quarter of 2020.

Research and development expenses for the three months ended March 31, 2021 and 2020 were $2.2 million and $1.4 million, respectively. The net increase of $0.8 million for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020 was primarily due to increases in expanded development costs of our product candidates partially offset by $0.2 million in qualifying reimbursable expenses in connection with the Department of Defense grant and increases in personnel related expenses.

General and administrative expenses for the three months ended March 31, 2021 and 2020 were $2.3 million and $1.2 million, respectively. The $1.1 million increase for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020 was primarily due to incremental costs related to the transition from a private to a public exchange traded entity, such as legal, accounting and insurance fees and increases in personnel related expenses.

Cash and cash equivalents as of March 31, 2021 were $21.7 million. We believe that Histogen's existing cash and cash equivalents and cash inflow from operations will be sufficient to meet its anticipated cash needs through the second quarter of 2022.

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 Histogen's future operations and its ability to successfully initiate and complete clinical trials, obtain clinical trial data and achieve regulatory milestones and related timing, including those related to the commencement of the planned HST-003 Phase 1/2 clinical trial for regeneration of cartilage in the knee, the completion and reporting of topline data for the Phase 1 study of emricasan for the treatment of COVID-19 and the timing of providing guidance on the HST- 001 clinical program targeting male androgenic alopecia; the nature, strategy and focus of Histogen's business; the sufficiency of Histogen's cash resources and its ability to achieve value for its stockholders; the sufficiency of Amerimmune's cash resources and its ability to complete the Phase 1 study of emricasan and achieve value for Histogen's stockholders; and the development and commercial potential and potential benefits of any of Histogen's product candidates, such as HST-001 and

HST-003, and the Collaborative Development and Commercialization Agreement with Amerimmune and any other collaboration agreements. Histogen 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 Histogen's 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: 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, such as the planned HST-003 Phase 1/2 clinical trial for regeneration of cartilage in the knee and the reporting of guidance on the HST- 001 clinical program targeting androgenic alopecia in men and Amerimmune's ability to further develop emricasan for the treatment of COVID-19, including the complexity and length of studies required to commercialize emricasan for COVID-19 and potential delays in the completion of clinical trials, such as the emricasan Phase 1 study for the treatment of COVID-19; Histogen's dependence on its collaboration partner, Amerimmune, to carry out the development of emricasan and the potential for delays in the timing of regulatory approval; competition in the COVID-19 market and other markets in which Histogen and its collaboration partner operate; the potential that earlier clinical trials and studies of Histogen's 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 Histogen's financial condition and increase its costs and expenses; and the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all. 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 Histogen's 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
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)

	March 31, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 21,743	$ 6,763
Restricted cash	10	10
Accounts receivable, net	188	144
Inventories	61	300
Prepaid and other assets	906	1,183
Total current assets	22,908	8,400
Property and equipment, net	248	271
Right-of-use assets	4,491	4,411
Other assets	1,166	1,931
Total assets	$ 28,813	$ 15,013
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 496	$ 539
Accrued liabilities	1,148	1,880
Current portion of lease liabilities	157	28
Payroll protection program loan, current	156	97
Financed insurance premiums, current	—	193
Current portion of deferred revenue	19	48
Total current liabilities	1,976	2,785
Payroll protection program loan, non-current	310	369
Lease liabilities, non-current	4,763	4,806
Noncurrent portion of deferred revenue	113	118
Other liabilities	20	22
Total liabilities	7,182	8,100
Commitments and contingencies (Note 10)		
Stockholders' Equity (Deficit)		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at March 31, 2021 and December 31, 2020; no shares issued and outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at March 31, 2021 and December 31, 2020; 35,744,457 and 15,030,757 shares issued and outstanding at March 30, 2021 and December 31, 2020, respectively	4	1
Additional paid-in capital	89,554	70,561
Accumulated deficit	(66,972)	(62,702)
Total Histogen Inc. stockholders' equity (deficit)	22,586	7,860
Noncontrolling interest	(955)	(947)
Total equity (deficit)	21,631	6,913
Total liabilities and stockholders' equity (deficit)	$ 28,813	$ 15,013

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

	Three Months Ended March 31,	
	2021	2020
	(unaudited)	
Revenues:		
Product	$ 306	$ —
Grant	113	—
License	12	867
Professional services	—	111
Total revenues	431	978
Operating expenses:		
Cost of product revenue	220	161
Cost of professional services revenue	—	97
Research and development	2,153	1,391
General and administrative	2,331	1,183
Total operating expenses	4,704	2,832
Loss from operations	(4,273)	(1,854)
Other income (expense):		
Interest income (expense), net	(5)	—
Total other income (expense)	(5)	—
Net loss	(4,278)	(1,854)
Net loss attributable to noncontrolling interest	8	10
Net loss attributable to common stockholders	$ (4,270)	$ (1,844)
Net loss per share available to common stockholders, basic and diluted	$ (0.14)	$ (0.55)
Weighted-average number of common shares outstanding used to compute net loss per share, basic and diluted	31,571,676	3,343,357