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, 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 August 11, 2021, Histogen Inc. (the "Company") issued a press release announcing its results of operations for the three and six months ended June 30, 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 August 11, 2021
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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, 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 Second Quarter 2021 Earnings and Provides Business Update

Company to Focus its Regenerative Medicine Technology Platform on Developing Orthopedic Product Candidates

Initiated Phase 1/2 Study of HST 003 for Cartilage Regeneration in the Knee

HST 004 Selected as Product Candidate for Spinal Disc Repair with IND Enabling Activities Underway

Positive Top-Line Study Results from its Phase 1 Study of Emricasan in Mild Symptomatic COVID-19 Patients

SAN DIEGO, August 11, 2021 – Histogen Inc. (NASDAQ: HSTO), a clinical-stage 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 second quarter ended June 30, 2021 and provided an update on its clinical pipeline and other corporate developments.

"In the second quarter, we charted a more strategic course for our restorative therapeutics pipeline with a focus on orthopedic indications that we believe sit at the crossroads of pre-clinical and clinical proof-of-concept, significant commercial opportunity and unmet medical needs," said Richard W. Pascoe, President and Chief Executive Officer. "Moreover, we believe that there is a significant value-creating opportunity for emricasan as a COVID-19 therapeutic given the positive safety and efficacy signals we reported in the recently completed Phase 1 study in mild symptomatic patients. Looking forward, we will concentrate our efforts on achieving meaningful regulatory, pre-clinical and clinical milestones for our pipeline assets in an effort to create long-term value for the benefit of patients, the healthcare community and our shareholders."

Highlights from the Second Quarter Ended June 30, 2021 and Business Updates

- **Technology and Pipeline Focus –** In June 2021, we completed a strategic evaluation of our regenerative medicine platform technology and announced that our pipeline focus will be on what we believe to be high-value orthopedic indications, creating pipeline synergies and maximizing resources in an effort to further drive long-term shareholder value. Our current orthopedic development programs include HST 003 for cartilage regeneration in the knee and HST 004 for spinal disk repair. Histogen is also evaluating the potential for additional pipeline opportunities targeting other soft tissues such as the tendon and ligament.

- **HST 003 –** In June 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 anticipate having top-line results from this study in the second quarter of 2022.

- **HST 004 –** We recently initiated investigational new drug application (IND) enabling activities for HST 004, a CCM solution intended to be administered through an intradiscal injection for spinal disc repair. 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 restore disc height. HST 004 was also shown to both reduce inflammation and protease activity and upregulate aggrecan production in an ex vivo spinal disc model. We anticipate filing an IND for HST 004 in the second quarter of 2022.

- **Emricasan –** In June 2021, we, along with our partner 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 had a complete resolution of the symptoms most commonly associated in mild COVID-19, such as a cough, headache, and fatigue at day 7 and continued through Day 45. Patients in the placebo arm who completed the study did not experience COVID-19 symptom resolution at any time point out to day 45. We, along with our partner Amerimmune, are currently evaluating our clinical development plans for the emricasan program and expect to complete our evaluation in the third quarter of 2021.

Second Quarter 2021 Financial Highlights

Second Quarter Ended June 30, 2021 and 2020

License and Service Revenues in the second quarter of 2021 decreased nearly 100% to $5 thousand from $0.1 million in the second quarter of 2020. The decrease is primarily related to the completion of technology transfer obligations of Histogen under the Allergan Agreements. During both periods, $5 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.

Cost of Professional Services Revenues for the three months ended June 30, 2021 and 2020 were zero and $0.1 million, respectively.

Acquired In-Process Research and Development for the three months ended June 30, 2021 and 2020 were zero and $7.1 million, respectively. Histogen incurred $7.1 million for in-process research and development acquired during the three months ended June 30, 2020 in connection with the merger.

Research and Development Expenses for the three months ended June 30, 2021 and 2020 were $2.4 million and $1.4 million, respectively. The net increase of $1.0 million for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020 was primarily due to increases in expanded development costs of our product candidates partially offset by $0.2 million in qualifying expenses in connection with the Department of Defense grant and increases in personnel-related expenses.

General and Administrative Expenses for the three months ended June 30, 2021 and 2020 were $1.8 million and $1.6 million, respectively. The $0.2 million increase for the three months ended June 30, 2021 as compared to the three months ended June 30, 2020 was primarily due to increases in personnel-related expenses and insurance fees offset by other expenses, such as legal and accounting fees.

Cash and Cash Equivalents as of June 30, 2021 were $23.1 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 into the fourth 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 completion and reporting of top-line data for the 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 clinical program for the treatment of COVID-19; the nature, strategy and focus of Histogen's business; the sufficiency of Histogen's cash resources based on anticipated cash needs and its ability to achieve value for its stockholders, specifically given the strategic shift to orthopedic indications; the Amerimmune's ability to further develop 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 003 and HST 004. 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 completion and reporting of top-line data for the 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 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; 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 orthopedics market, 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; the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all; 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 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)

	June 30, 2021	December 31, 2020
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 23,140	$ 6,763
Restricted cash	10	10
Accounts receivable, net	118	144
Inventories	61	300
Prepaid and other assets	1,802	1,183
Total current assets	25,131	8,400
Property and equipment, net	270	271
Right-of-use assets	4,291	4,411
Other assets	1,109	1,931
Total assets	$ 30,801	$ 15,013
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 586	$ 539
Accrued liabilities	1,523	1,880
Current portion of lease liabilities	—	28
Payroll protection program loan, current	—	97
Financed insurance premiums, current	—	193
Current portion of deferred revenue	19	48
Total current liabilities	2,128	2,785
Payroll protection program loan, non-current	—	369
Lease liabilities, non-current	4,587	4,806
Non-current portion of deferred revenue	108	118
Other liabilities	18	22
Total liabilities	6,841	8,100
Commitments and contingencies (Note 10)		
Stockholders' Equity (Deficit)		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized at June 30, 2021 and December 31, 2020; no shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 200,000,000 shares authorized at June 30, 2021 and December 31, 2020; 41,729,257 and 15,030,757 shares issued and outstanding at June 30, 2021 and December 31, 2020, respectively	4	1
Additional paid-in capital	95,603	70,561
Accumulated deficit	(70,676)	(62,702)
Total Histogen Inc. stockholders' equity (deficit)	24,931	7,860
Noncontrolling interest	(971)	(947)
Total equity (deficit)	23,960	6,913
Total liabilities and stockholders' equity (deficit)	$ 30,801	$ 15,013

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,	
	2021	2020	2021	2020
Revenues:				
Product	$ —	$ —	$ 306	$ —
Grant	—	—	113	—
License	5	5	17	872
Professional services	—	103	—	214
Total revenues	5	108	436	1,086
Operating expenses:				
Cost of product revenue	—	—	220	161
Cost of professional services revenue	—	89	—	186
Acquired in-process research and development	—	7,144	—	7,144
Research and development	2,376	1,437	4,528	2,828
General and administrative	1,822	1,588	4,154	2,771
Total operating expenses	4,198	10,258	8,902	13,090
Loss from operations	(4,193)	(10,150)	(8,466)	(12,004)
Other income (expense):				
Interest income (expense), net	(2)	(28)	(7)	(28)
Other income	475	—	475	—
Total other income (expense)	473	(28)	468	(28)
Net loss	(3,720)	(10,178)	(7,998)	(12,032)
Net loss attributable to noncontrolling interest	16	10	24	20
Net loss attributable to common stockholders	$ (3,704)	$ (10,168)	$ (7,974)	$ (12,012)
Net loss per share available to common stockholders, basic and diluted	$ (0.10)	$ (1.52)	$ (0.23)	$ (2.39)
Weighted-average number of common shares outstanding used to compute net loss per share, basic and diluted	37,196,606	6,710,490	34,399,680	5,026,923