
**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 11, 2021

Histogen Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-36003
(Commission
File Number)

20-3183915
(IRS Employer
Identification No.)

10655 Sorrento Valley Road, Suite 200,
San Diego CA
(Address of principal executive offices)

92121
(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 11, 2021, Histogen Inc. (the “Company”) issued a press release announcing its financial results for the quarter and full year ended December 31, 2020. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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

<u>Exhibit Number</u>	<u>Exhibits</u>
99.1	Press Release, dated March 11, 2021

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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: March 11, 2021

By: /s/ Richard W. Pascoe

Name: Richard W. Pascoe

Title: President and Chief Executive Officer



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

Histogen Reports Fourth Quarter and Year-End 2020 Financial Results and Provides Business Update

Strengthened Balance Sheet with \$25.3 Million of Gross Proceeds from Financings and Warrant Exercises

Initiation of Phase 1 Study of Emricasan in Symptomatic COVID-19 Patients Anticipated in the First Quarter of 2021

HST 003 Trial Initiation for Cartilage Regeneration in the Knee Anticipated in the Second Quarter of 2021

Appointment of Industry Leader Dr. Susan Windham-Bannister to Board of Directors

SAN DIEGO, March 11, 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 fourth quarter and year ended December 31, 2020 and provided an update on its clinical pipeline and other corporate developments.

“Throughout 2020 and into 2021, we have transformed Histogen into a well-capitalized public company with a focus on advancing our novel pipeline in multiple therapeutic indications and building the strength and diversity of our team and board of directors,” said Richard W. Pascoe, President and Chief Executive Officer. Looking ahead, we will continue to focus on clinical execution with HST-001 in androgenic alopecia, HST-003 in cartilage repair and emricasan in COVID-19 with the overarching goal of restoring function and enhancing the lives of patients as we seek to drive value for our shareholders. Finally, I want to welcome Dr. Susan Windham-Bannister to our Board of Directors. Sue brings to our board relevant industry experience with a focus on strategic growth which will serve Histogen well during this pivotal time in our corporate evolution.”

Highlights from the Fourth Quarter and Year Ended 2020 and Business Updates

- **HST-001** – In February of 2021, we announced the final results from the week 26 assessments. 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 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 preparing for the next HST-
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001 clinical trial in men with androgenic alopecia and anticipate the trial will commence in the second half of 2021, subject to review and approval by the U.S. Food and Drug Administration (“FDA”).

- **HST-003*** – In the second half of 2020, Histogen submitted an Investigational New Drug (“IND”) application with the FDA for the initiation of a Phase 1/2 clinical trial of HST-003 to evaluate the safety and efficacy of human extracellular matrix (hECM:HST-003) implanted within microfracture Interstices and the cartilage defect in the knee to regenerate hyaline cartilage in combination with a microfracture procedure and was awarded a \$2 million grant by the Peer Reviewed Orthopedic Research Program (PRORP) of the U.S. Department of Defense (DoD) to help fund our planned HST 003 trial. In January of 2021, we announced that the FDA had notified the company that the IND for planned Phase 1/2 clinical trial of HST-003 was placed on clinical hold. The hold is due to additional CMC information required for the FDA to complete their review. Histogen submitted a complete response letter to the FDA on February 19, 2021 and will continue to work with the FDA to release the clinical hold. We anticipate initiating the HST-003 trial in the second quarter of 2021, pending FDA release of the clinical hold.
 - **Emricasan** – In the second half of 2020, we filed and received approval from the FDA for an IND to initiate a Phase 1 study of emricasan for the treatment of mild 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, anticipate the initiation of the Phase 1 study of emricasan in the first quarter of 2021 and expect top-line data to be available in the second quarter of 2021.
 - **Financings** – In November 2020, we received \$4.5 million of gross proceeds from a registered direct offering. In January 2021, we received \$14 million of gross proceeds from a public offering and as of March 18, 2021, an incremental \$6.8 million of gross proceeds from the exercise of warrants associated with the January 2021 public offering.
 - **Appointed Dr. Susan Windham-Bannister to the board of directors** - Dr. Windham-Bannister joined the Histogen board in March of 2021 and 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 and as immediate past President and CEO of the Massachusetts Life Sciences Center (MLSC), a state-funded investment organization charged with administering a \$1-billion Life Sciences investment fund created by Governor Deval Patrick in June 2008. These advisory firms and other organizations leverage Dr. Windham-Bannister’s experience as a business strategist.
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Fourth Quarter and Full-Year 2020 Financial Highlights

Fourth Quarter Ended December 31, 2020 and 2019

Product and Service Revenues for the three months ended December 31, 2020 and 2019 were \$0.5 million and \$1.6 million, respectively. The decrease of \$1.1 million was primarily due to a decrease in fulfillment of supply orders of CCM to Allergan.

Cost of revenues for the three months ended December 31, 2020 and 2019, we recognized cost of product revenue of \$0.3 million and \$1.0 million, respectively. The decrease of \$0.7 million for the three months ended December 31, 2020 as compared to the three months ended December 31, 2019 was commensurate with the decrease in product sales to Allergan as well as a write-off of inventory of \$0.2 million related to the termination of the supply agreement with Edge Systems LLC in 2019.

Research and development expenses for the three months ended December 31, 2020 and 2019 were \$1.9 million and \$1.4 million, respectively. The increase of \$0.5 million for the three months ended December 31, 2020 as compared to the three months ended December 31, 2019 was primarily due to increases related to expanded development costs of our product candidates and increases in personnel related expenses due to changes in duties and responsibilities of existing personnel.

General and administrative expenses for the three months ended December 31, 2020 and 2019 were \$1.8 million and \$1.6 million, respectively. The \$0.2 million increase for the three months ended December 31, 2020 as compared to the three months ended December 31, 2019 was primarily due to increases in insurance, rent and legal and accounting fees, offset by decreases in personnel related expenses due to changes in duties and responsibilities of existing personnel.

Twelve Months Ended December 31, 2020 and 2019

Revenues

For the years ended December 31, 2020 and 2019, we recognized license revenues of \$0.9 million and \$7.5 million, respectively. The \$7.5 million recognized in the year ended December 31, 2019 related to an upfront payment received in connection with the execution of the 2019 Allergan Agreement amendment. In the year ended December 31, 2020, we received a \$1.0 million upfront payment in connection with an amendment to the 2019 Allergan Agreement of which approximately \$28,000 remains in deferred revenue at December 31, 2020.

For the years ended December 31, 2020 and 2019, we recognized product revenues of \$0.8 million and \$3.4 million, respectively. The decrease of \$2.6 million for the year ended December 31, 2020, as compared to the year ended December 31, 2019 was primarily due to a decrease of supply orders of CCM to Allergan and one additional customer.

Grant revenue for the years ended December 31, 2020 and 2019 was \$0 and \$0.2 million, respectively, all of which was related to an NSF research grant awarded to us in 2017 and resulted from the acceptance of milestone reports in 2019.

For the years ended December 31, 2020 and 2019, we recognized professional services revenue of \$0.3 million and \$0.4 million, respectively.

Cost of Revenues

For the years ended December 31, 2020 and 2019, we recognized cost of product revenue of \$0.7 million and \$1.9 million, respectively. The decrease of \$1.2 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019 was commensurate with the decrease in product sales in 2020, coupled with a \$0.2 million write-off of inventory.

For the years ended December 31, 2020 and 2019, we recognized costs of professional services of \$0.3 million.

In-process research and development expenses increased \$4.9 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019. In the year ended December 31, 2020, we incurred \$7.1 million for in-process research and development acquired in connection with the Merger and in the year ended December 31, 2019, we incurred \$2.3 million for in-process research and development related to the acquisition of HST-003 and HST-004 from PUR.

Research and development expenses for the years ended December 31, 2020 and 2019 were \$6.2 million and \$4.1 million, respectively. The increase of \$2.1 million for the year ended December 31, 2020, as compared to the year ended December 31, 2019 was primarily due to expanded development costs of our product candidates HST-001 and HST-003.

General and administrative expenses for the years ended December 31, 2020 and 2019 were \$6.6 million and \$6.2 million, respectively. This increase of \$0.4 million for the year ended December 31, 2020 was primarily due to increases in insurance and other professional fees of \$1.2million, offset by a decrease in success-based fees related to license revenue received of approximately \$0.8 million.

Cash and cash equivalents as of December 31, 2020 were \$6.8 million. The \$6.8 million is exclusive of gross proceeds of \$14 million from a public offering that we closed in January 2021 and gross proceeds of \$6.8 million from the exercise of outstanding warrants in connection with the January 2021 public offering. 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 2022.

About Histogen Inc.

Histogen Inc. is 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. Histogen's innovative technology platform utilizes cell conditioned media and extracellular matrix materials produced by hypoxia-induced multipotent cells. Histogen's proprietary, reproducible manufacturing process provides targeted solutions across a broad range of therapeutic indications including hair growth, dermal rejuvenation, joint cartilage regeneration and spinal disk repair. 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 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-001 clinical trial for androgenic alopecia in men, approval of a HST-003 IND for the planned Phase 1/2 clinical trial for regeneration of cartilage in the knee and the commencement of such trial and the commencement of the planned Phase 1 study of emricasan for the treatment of COVID-19 and receipt of top-line data; the nature, strategy and focus of Histogen's business; the sufficiency of Histogen's cash resources and Histogen's ability to achieve value for its stockholders; the sufficiency of Amerimmune's cash resources and its ability to commence, enroll and complete the planned 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-001 clinical trial for androgenic alopecia in men, approval of the HST-003 IND for the planned Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee 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 commencement, enrollment and completion of clinical trials, such as the planned 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.

*The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702, is the awarding and administering acquisition office. The U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick MD 21702, is the awarding and administering acquisition office.

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

	<u>Three Months Ended December 31,</u>		<u>Years Ended December 31,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Revenues:				
License	\$ 5	\$ 4	\$ 882	\$ 7,519
Product	426	1,459	845	3,415
Grant	—	—	—	150
Professional services	47	98	332	370
Total revenues	<u>478</u>	<u>1,561</u>	<u>2,059</u>	<u>11,454</u>
Operating expenses:				
Cost of product revenue	255	1,020	679	1,893
Cost of professional services revenue	41	85	289	322
Acquired in-process research and development	—	—	7,144	2,250
Research and development	1,857	1,379	6,219	4,095
General and administrative	1,833	1,605	6,586	6,212
Total operating expenses	<u>3,986</u>	<u>4,089</u>	<u>20,917</u>	<u>14,772</u>
Income (loss) from operations	(3,508)	(2,528)	(18,858)	(3,318)
Other income (expense):				
Change in fair value of warrant liabilities	—	—	—	276
Interest income (expense), net	(14)	4	41	40
Net loss	(3,522)	(2,325)	(18,817)	(3,002)
Net loss attributable to noncontrolling interest	14	15	48	36
Net loss attributable to common stockholders	<u>\$ (3,508)</u>	<u>\$ (2,310)</u>	<u>\$ (18,769)</u>	<u>\$ (2,966)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.26)</u>	<u>\$ (0.70)</u>	<u>\$ (2.08)</u>	<u>\$ (0.89)</u>
Weighted-average common shares used to compute net				
loss per share attributable to common stockholders, basic and diluted	<u>13,763,713</u>	<u>3,343,356</u>	<u>9,018,376</u>	<u>3,332,281</u>

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

	December 31,	
	2020	2019
Assets		
Current assets		
Cash and cash equivalents	\$ 6,763	\$ 2,065
Restricted cash	10	10
Accounts receivable, net	144	110
Inventories	300	106
Prepaid and other current assets	1,183	167
Total current assets	8,400	2,458
Property and equipment, net	271	320
Right-of-use asset	4,411	95
Other assets	1,931	69
Total assets	<u>\$ 15,013</u>	<u>\$ 2,942</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities		
Accounts payable	\$ 539	\$ 808
Accrued liabilities	1,880	446
Current portion of lease liabilities	28	108
Current portion of deferred revenue	48	19
Financed insurance premiums, current	193	—
Payroll protection program loan, current	97	—
Total current liabilities	2,785	1,381
Lease liabilities, non-current	4,806	—
Payroll protection program loan, non-current	369	—
Noncurrent portion of deferred revenue	118	138
Other liabilities	22	321
Total liabilities	8,100	1,840
Commitments and contingencies		
Convertible preferred stock, \$0.001 par value, authorized shares — no shares and 73,000,000 shares at December 31, 2020 and 2019, respectively; issued and outstanding shares — no shares and 5,046,154 shares at December 31, 2020 and 2019, respectively; liquidation preference — \$0 and \$40,294 at December 31, 2020 and 2019, respectively	—	39,070
Stockholders' equity (deficit)		
Preferred stock, \$0.0001 par value; 10,000,000 shares and no shares authorized at December 31, 2020 and 2019; no shares issued and outstanding at December 31, 2020 and 2019	—	—
Common stock, \$0.0001 par value; 200,000,000 shares and 105,000,000 shares authorized at December 31, 2020 and 2019; respectively; 15,030,757 and 3,343,356 shares issued and outstanding at December 31, 2020 and 2019, respectively	1	—
Additional paid-in capital	70,561	6,864
Accumulated deficit	(62,702)	(43,933)
Total Histogen Inc. stockholders' equity (deficit)	7,860	(37,069)
Noncontrolling interest	(947)	(899)
Total equity (deficit)	6,913	(37,968)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 15,013</u>	<u>\$ 2,942</u>