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): June 3, 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 8.01 Other Information.

On June 3, 2021, Histogen Inc. issued a news release providing an update for its development programs and pipeline focus. A copy of the news release is filed as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

Exhibit Number	Exhibits
99.1	Press Release, dated June 3, 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: June 3, 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 Provides Update on its Development Programs and Pipeline Focus

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

HST 003 Trial for Cartilage Regeneration in the Knee Remains On-Track with an Anticipated Phase 1/2 Study Initiation in June 2021

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

Top-line Data for Phase 1 Study of Emricasan in Mild-Symptomatic COVID-19 Patients Anticipated in June 2021

SAN DIEGO, June 3, 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 announced an update on its pipeline focus following a strategic evaluation of its regenerative medicine platform technology development programs with the goal of focusing on high value orthopedic indications, creating pipeline synergies and maximizing resources in an effort to further drive long-term shareholder value.

Development Program Updates

- **HST 001 –** we completed our strategic evaluation of the HST 001 program taking into consideration the results from our Phase 1b/2a clinical trial of HST 001 as announced earlier this year, and as a result, we will suspend development of this program. While HST 001 has demonstrated a favorable safety and tolerability profile in androgenic alopecia in men, the development resources required to potentially achieve an acceptable efficacy threshold are substantial in terms of cost and time. Therefore, we believe the best business decision at this time, is to redirect these resources towards our high value orthopedic programs.

- **HST 003 -** we are on track to initiate our Phase 1/2 clinical study of HST 003 in June 2021. The upcoming study is designed 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. 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.

- **HST 004** - We recently initiated an 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 in the second half of 2022.

- **Emricasan –** In May, we, along with our partner Amerimmune, completed enrollment of the Phase 1 study of emricasan for the treatment of mild-symptomatic COVID-19 patients. A total of 13 patients have been enrolled at our single site in New York City versus the initially targeted 40 patients. The decision to stop enrollment with a lesser number of patients was based solely upon the overall decline in COVID-19 cases in New York City and its negative impact on patient recruitment. To date, there have been no reports of serious adverse events, and we anticipate top-line safety, biomarker and patient reported outcomes data to be available in June 2021.

“Following the completion of our HST 001 Phase 1a/2b study in androgenic alopecia in men in the first quarter of this year, we embarked upon a strategic pipeline evaluation with the goal of determining the optimal value-creating opportunities for our regenerative medicine technology platform,” said Richard W. Pascoe, President and Chief Executive Officer. “As a result of our evaluation, we have charted a new course for Histogen 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. Moreover, we believe that by developing products that are therapeutically synergistic, we can be more efficient with our resources and create a strategic pipeline of novel therapeutics that has the potential to create long-term value for the benefit of our shareholders.”

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 joint cartilage regeneration, spinal disk repair, hair growth and dermal rejuvenation. 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 suspension of the HST 001 program, the commencement of the planned HST 003 Phase 1/2 clinical trial for regeneration of cartilage in the knee, the anticipated filing of the HST 004 IND for spinal disc repair and the completion and reporting of topline data for the Phase 1 study of emricasan for the treatment of COVID-19; 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, specifically given the strategic shift to orthopedic indications; 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 003, HST 004 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, 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, 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 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; 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.

# # #