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): January 15, 2021

Histogen Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36003**	**20-3183915**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

10655 Sorrento Valley Road, Suite 200, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (858) 526-3100

(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 240.13a-4(c))

Title of each class:	Trading symbol:	Name of each exchange on which registered:
Common Stock, par value $0.0001 per share	**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 January 19, 2021, the Company issued a news release announcing an update for its HST-003 knee cartilage regeneration program. 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	News Release of Histogen Inc., dated January 19, 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: January 19, 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 FDA Clinical Hold for Planned Phase 1/2 Trial of HST-003 for Knee Cartilage Regeneration

SAN DIEGO, January 19, 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 that the U.S. Food and Drug Administration (FDA) has verbally notified the company that it has additional questions about the company's Investigational New Drug ("IND") application package for the planned Phase 1/2 clinical trial of HST-003, which is intended 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.

Histogen has not yet received the written notice of its clinical hold from the FDA, which the FDA expects to provide to the company by February 12, 2021. Based upon the verbal communication with FDA, they indicated that the clinical hold is due to pending CMC information that is required to complete their review. Histogen plans to work diligently with the FDA to seek the release of the clinical hold and provide updated guidance on any potential impact to the HST-003 program once the written notice from FDA is received.

About HST-003

Histogen's human extracellular matrix, or hECM, is intended for regenerating hyaline cartilage for the treatment of articular cartilage defects with a novel malleable scaffold that stimulates the body's own stem cells. In multiple preclinical models, HST-003 has been shown to regenerate mature cartilage and well vascularized bone, indicating therapeutic potential in the sports medicine, spinal disc repair, orthopedic, and dental areas. Studies conducted by outside experts have demonstrated that HST-003 is anti-inflammatory, angiogenic, and can stimulate the growth of stem cells in damaged areas to induce tissue regeneration. The most extensive in vivo work in animals has focused on the regeneration of new hyaline cartilage and bone in full thickness knee injuries.

About Histogen

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 and achieve regulatory milestones and related timing, including those related to its efforts to work with the FDA to seek a release of the clinical hold placed on the planned Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee and its plans to initiate enrolment if and when such clinical hold is released; the nature, strategy and focus of Histogen’s business; and the development and commercial potential and potential benefits of any of Histogen’s product candidates, including HST-003. 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 release of the clinical hold placed on the planned Phase 1/2 clinical trial of HST-003 for regeneration of cartilage in the knee and the subsequent commencement, enrollment and completion of clinical trials if and when such hold is released; 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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