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): December 1, 2020

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 December 1, 2020, Histogen Inc. issued a news release announcing preliminary week 18 results from its Phase 1b/2a clinical trial of HST-001 in male patients with androgenic alopecia. 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 December 1, 2020

* * *

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: December 1, 2020

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

Histogen Announces Preliminary Week 18 HST-001 Study Results for the Treatment of Androgenic Alopecia in Men

HST-001 Demonstrated Separation from Placebo at Week 18 Primary Efficacy Endpoint Assessment

HST-001 Found to be Safe and Well Tolerated with No Serious Adverse Events

Week 26 Final Study Results for HST-001 Expected in Early First Quarter of 2021

SAN DIEGO, December 1, 2020 (GLOBE NEWSWIRE) — Histogen Inc. (NASDAQ: HSTO), today announced preliminary week 18 results from its Phase 1b/2a clinical trial of HST-001 in male patients with androgenic alopecia. At the week 18 primary efficacy endpoint, patients treated with HST-001 demonstrated separation from placebo patients for absolute change from baseline in total hairs (terminal and vellus) in the target area (TAHC) in the vertex as measured by Canfield's Hairmetrix macrophotography system. HST-001 was also shown to be safe and well tolerated at week 18 as compared to placebo with no reports of serious adverse events.

"While HST-001 did not achieve statistical significance at the week 18 primary endpoint assessment, we are encouraged that these results demonstrated separation from placebo and that patients treated with HST-001 grew new hairs in the vertex region of the scalp while placebo patients lost hairs in the same region during the 18 week evaluation period," said Richard W. Pascoe, Histogen's President and CEO. "We look forward to completing the study and reporting the final results from the week 26 assessments, along with our plans for further clinical development of HST-001, in early first quarter of 2021."

About the HST-001 Phase 1a/2b Trial

This 2:1 randomized, blinded, placebo controlled, single site study has enrolled 36 male patients with androgenic alopecia with mild to moderate hair loss on a Norwood-Hamilton (N-H) Scale (3V, 4, 5). It is designed to assess the safety and tolerability of HST-001, as well as indicators of efficacy at weeks 18 and 26. The primary study endpoint is absolute change from baseline versus week 18 in total hairs (terminal and vellus) in the (TAHC) of the vertex as measured by Canfield's Hairmetrix macrophotography system. Secondary endpoints include absolute change from baseline in total hairs (terminal and vellus), new terminal and vellus hair count, hair thickness density as well as percent change from baseline in TAHC and terminal and vellus hair counts in the vertex and right temporal regions at weeks 18 and 26, all as measured by Canfield's Hairmetrix macrophotography system. At each treatment timepoint (Weeks 0, 6 and 12), patients received a total of 20 injections, 10 in the vertex scalp region and 5 in each temporal region for a total dose of 2mL. Final study results post week 26 assessments are expected in early first quarter of 2021.

About HST-001

HST-001, or Hair Stimulating Complex (HSC), is intended to be a physician-administered therapeutic for hair loss. HSC is anticipated to be a relatively safe, minimally invasive treatment that promotes new hair growth where existing treatments only reduce hair loss. HSC is manufactured to enrich for growth factors including KGF, VEGF and follistatin, which are involved in signaling stem cells in the body and have been shown to be important in hair formation and the stimulation of resting hair follicles.

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 our future operations and our ability to successfully initiate and complete clinical trials, obtain clinical trial data and achieve regulatory milestones and related timing, including those related to the reporting of week 26 study data for the ongoing HST-001 Phase 1a/2b trial for androgenic alopecia in men; the potential for HST-001 to be a first-in-class product; the nature, strategy and focus of our business; the sufficiency of our cash resources and ability to achieve value for our stockholders; and the development and commercial potential and potential benefits of any of our product candidates, including HST-001. We 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 our current expectations, they are subject to various risks and uncertainties and actual results, performance or achievements of ours 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 our product candidates, including potential delays in the commencement, enrollment and completion of clinical trials, the potential that earlier clinical trials and studies of Histogen's product candidates may not be predictive of future results, such as the week 18 data results from the HST-001 Phase 1a/2b clinical trial; risks related to business interruptions, including the outbreak of COVID-19 coronavirus, which could seriously harm our 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 our filings with the Securities and Exchange Commission. Except as otherwise required by law, we disclaim 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.

CONTACT:

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

# # #