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): November 28, 2022

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 Events.

Amerimmune Collaborative Development and Commercialization Agreement Arbitration

On November 28, 2022, Histogen Inc. (the "Company") received an Interim Award ("Interim Award") issued by the Arbitrator presiding over the demand for arbitration (the "Arbitration Demand") filed by the Company in the County of San Diego, against Amerimmune LLC ("Amerimmune") seeking a declaratory judgment that Amerimmune has materially breached the terms of the Collaborative Development and Commercialization Agreement to jointly develop emricasan for the potential treatment of COVID-19 entered into by and between the Company and Amerimmune on October 26, 2020 (the "Collaborative Agreement"), and that the Company is therefore entitled to terminate the Collaborative Agreement. In the Interim Award, the Arbitrator ruled in the Company's favor by finding that the Company lawfully and properly terminated the Collaboration Agreement and is entitled to declaratory relief and specific performance of the terms of the Collaborative Agreement on the finding that Amerimmune materially breached the terms of the Collaborative Agreement, and no affirmative defense excuses the breach by Amerimmune. Furthermore, the Arbitrator denied Amerimmune's request to exercise an option for additional license rights to develop additional products, as well as its claims for breach of the implied covenant of good faith and fair dealing, breach of contract, and tortious interference. The Interim Award further invited each party to consider whether there is authority for the award of any cost-shifting by the Arbitrator. Accordingly, each party has the right to submit a brief requesting attorney's fees and costs. If no party requests attorneys' fees or costs, the Company expects to receive the Final Award prior to the end of the calendar year 2022, which will make final the rulings set forth in the Interim Award and address any requests for fees and cost-shifting, as may be requested by the parties.

Once the parties receive the Final Award, the Company will have four years to confirm the award to judgment if it deems necessary. Amerimmune will have 100 days from the date it receives the final award to petition a court to vacate or correct the Final Award.

As affirmed by the Interim Award, the Company has terminated the Collaborative Agreement and all rights and licenses granted to Amerimmune by the Company have been terminated, and Amerimmune shall cease any and all development, manufacture and commercialization activities under the Agreement, and any and all rights granted by the Company to Amerimmune revert to the Company except any such rights that shall survive termination of the Collaborative Agreement.

Emricasan

The Company has completed its evaluation of emricasan for the potential treatment of skin bacterial infections including those related to MRSA, as well as other infectious diseases and anticipates initiating clinical development activities in the first half of 2023.

HST 003

In June of 2021, the Company initiated its Phase 1/2 clinical study of HST 003 to evaluate the safety and efficacy of human extracellular matrix, or hECM, implanted within microfracture interstices and the cartilage defect in the knee to regenerate hyaline cartilage in combination with a microfracture procedure. During the second half of 2021, the Company experienced significant recruitment challenges that the Company believed were due to both the specific nature of the study inclusion criteria and the impact of COVID-19 on the elective surgery environment. The Company added three additional clinical sites in the first quarter of 2022 in an attempt to help address the recruitment challenges. In the second quarter of 2022, the Company expanded its efforts in addressing the recruiting challenges, which included engaging a clinical research organization, or CRO, to evaluate both protocol changes and the potential of adding more clinical sites. In the third quarter of 2022, the Company implemented the protocol changes which the Company believes addressed the study inclusion criteria which should have improved the ability of the clinical sites to enroll patients. Despite these efforts, the clinical sites continue to be unsuccessful in recruiting and enrolling additional patients. Therefore, the Company has made the decision at this time to terminate the study for futility regarding patient recruitment and redirect efforts and funding away from HST 003 to other product candidates.

* * *

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 2, 2022

By: /s/ Susan A. Knudson

Name: Susan A. Knudson

Title: Executive Vice President, Chief Financial Officer & Corporate Secretary