
**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 9, 2023

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 9, 2023, Histogen Inc. (the “Company”) issued a press release announcing its financial results for the year ended December 31, 2022. The full text of such press release is furnished as Exhibit 99.1 to this report.

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</u> <u>Number</u> | <u>Exhibits</u> |
|---------------------------------|---|
| 99.1 | Press Release, dated March 9, 2023 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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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 9, 2023

By: /s/ Susan A. Knudson

Name: Susan A. Knudson

Title: Executive Vice President and Chief Financial Officer



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

Histogen Reports Year-End 2022 Results and Provides Business Update

Pipeline Focus on Pan-Caspase and Caspase Selective Inhibitors for Infectious and Inflammatory Diseases

SAN DIEGO, March 9, 2023 – Histogen Inc. (NASDAQ: HSTO), a clinical-stage therapeutics company on developing potential first-in-class clinical and preclinical small molecule pan-caspase and caspase selective inhibitors that protect the body’s natural process to restore immune function, today reported financial results for the year ended December 31, 2022, and provided an update on its pipeline and other corporate developments.

“Our team is very excited about the new direction of the company. We remain focused on the development of emricasan as a potential treatment for acute bacterial skin and skin structure infections (ABSSSI), including those related to methicillin resistant staphylococcus aureus (“MRSA”) and our pre-clinical evaluations of our caspase-1 inhibitors that impact the inflammasome pathway,” said Steven J. Mento, Ph.D., Interim President and Chief Executive Officer.

Highlights from Year Ended 2022 and Business Updates

- **Emricasan ABSSSI** – Emricasan is an orally available pan-caspase inhibitor designed to reduce the activities of human caspases, which are enzymes that mediate inflammation and apoptosis. Emricasan has completed extensive toxicology testing including chronic toxicology and clean carcinogenicity testing. This drug candidate has previously been shown to be well tolerated in multiple clinical studies involving approximately 1,000 subjects employing multiple doses ranging from 1 mg to 500 mg orally with treatment for up to two years, including a Phase 1 study in mild symptomatic COVID-19 patients to assess safety, tolerability, and preliminary efficacy. In the fourth quarter of 2021, we completed our pre-clinical evaluation of emricasan for the potential treatment of acute bacterial skin infections, including those related to MRSA, and anticipate initiating clinical development activities for the treatment of ABSSSI in the first half of 2023.
- **Amerimmune Collaboration** – In November 2022, in accordance with an arbitration award, we terminated the Amerimmune Collaboration Agreement and all rights to emricasan, CTS-2090, and CTS-2096 were returned to us.
- **Appointed Alfred P. Spada, Ph.D. as Chief Scientific Officer** - In January 2023, Dr. Spada joined Histogen as its Executive Vice President and Chief Scientific Officer. Dr. Spada is a seasoned veteran of pharmaceutical discovery and development with over 35 years of combined experience in large Pharma and Biotech. He most recently served as President and CEO of Aya Biosciences. Prior to joining Aya Biosciences, Dr. Spada was co-founder, EVP of R&D and CSO of Conatus Pharmaceuticals until its merger with Histogen in May 2020. At Conatus, Dr. Spada was responsible for the management of all preclinical and early-stage development activities employed to support the company’s clinical assets. Prior to Conatus, Dr. Spada was the VP of Preclinical and Pharmaceutical Development at Idun Pharmaceuticals until its acquisition by Pfizer in 2005.

- **HST 003 and HST 004** – In December 2022, we announced the termination of our Phase 1/2 clinical study of HST 003 to evaluate the safety and efficacy of human extracellular matrix (hECM) to repair cartilage defects in the knee in combination with a microfracture procedure for fertility related to patient recruitment. In the third quarter of 2022, we announced suspending all IND enabling activities on our HST 004 program focused on spinal disc repair due to pipeline reprioritization.

Full-Year 2022 Financial Highlights

Twelve Months Ended December 31, 2022 and 2021

Revenues

For the years ended December 31, 2022 and 2021, we recognized license revenues of \$3.8 million and \$27 thousand, respectively. The increase in the current period is due to a one-time payment of \$3.75 million received in March 2022 as consideration for execution of the Allergan Letter Agreement.

For the years ended December 31, 2022 and 2021, we recognized product revenues of \$0 and \$0.9 million, respectively. The product revenue for the year ended December 31, 2021 was due to a one-time unanticipated sale of CCM to Allergan, unrelated to the Allergan Agreements. As of March 31, 2021, all obligations of the Company related to the additional supply of CCM to Allergan under the Allergan Agreements had been completed.

For the years ended December 31, 2022 and 2021, we recognized grant revenue of \$0 and \$0.1 million, respectively. The grant revenue for 2021 is associated with a research and development grant awarded to the Company from the NSF. As of March 31, 2021, all work required by the Company under the grant has been completed.

Cost of product revenues for the years ended December 31, 2022 and 2021, we recognized \$0 and \$0.2 million, respectively, for cost of product sold to Allergan under the Allergan Agreements.

Research and development expenses for the years ended December 31, 2022 and 2021 were \$5.0 million and \$8.5 million, respectively. The decrease of \$3.5 million was primarily due to decreases in personnel related expenses, the number of clinical and preclinical candidates in development and corresponding reduction of costs, partially offset by facility rent increases.

General and administrative expenses for the years ended December 31, 2022 and 2021 were \$9.4 million and \$7.8 million, respectively. The increase of \$1.6 million was primarily due to increases in royalty expenses, legal fees, outside services, rent expenses and personnel expenses, partially offset by reductions in insurance and other administrative expenses.

Cash and cash equivalents as of December 31, 2022 were \$12.1 million. 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 January of 2024.

About Histogen Inc.

Histogen Inc. is a clinical-stage therapeutics company focused on developing potential first-in-class clinical and preclinical small molecule pan-caspase and caspase selective inhibitors that protect the body's natural process to restore immune function. Our product candidates include emricasan, CTS-2090 and CTS-2096. Currently, we are developing emricasan for acute bacterial skin and skin structure infections (ABSSSI) as well evaluating its use for other infectious diseases. Our pipeline also includes novel preclinical product candidates including CTS-2090 and CTS-2096, which are selective small molecule inhibitors of caspase-1 designed for the treatment of certain inflammatory diseases. 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, enroll and complete clinical trials, obtain clinical trial data, and achieve regulatory milestones and related timing, including those related to the timing of providing clinical development guidance on the development of emricasan and any further evaluation of CTS-2090 and CTS-2096. 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 Histogen that could differ materially from those described in or implied by the statements in this press release, including: our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates; including its ability to carry out the development of emricasan and the potential for delays in the timing of regulatory approval and the requirement for additional capital to continue to advance these product candidates, which may not be available on favorable terms or at all; our expectations regarding the operation of our product candidates and related benefits; our beliefs regarding the success, cost and timing of our product candidate development and current and future clinical trials and studies; our beliefs regarding the potential markets for our product candidates; any impact of the COVID-19 pandemic, or responses to the pandemic, on our business, clinical trials or personnel; our beliefs regarding our industry; our ability to attract and retain key personnel; regulatory developments in the United States and foreign countries, with respect to our product candidates; the impact of any litigation proceedings on our business and market and other conditions. 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, 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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HISTOGEN INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)

| | Years Ended December 31, | |
|--|--------------------------|--------------------|
| | 2022 | 2021 |
| Revenue | | |
| Product revenue | \$ — | \$ 892 |
| License revenue | 3,769 | 27 |
| Grant revenue | — | 113 |
| Total revenue | <u>3,769</u> | <u>1,032</u> |
| Operating expense | | |
| Cost of product revenue | — | 220 |
| Research and development | 5,021 | 8,473 |
| General and administrative | 9,391 | 7,796 |
| Total operating expense | <u>14,412</u> | <u>16,489</u> |
| Loss from operations | <u>(10,643)</u> | <u>(15,457)</u> |
| Other income (expense) | | |
| Interest expense, net | (1) | (10) |
| Other income, net | — | 458 |
| Net loss | <u>(10,644)</u> | <u>(15,009)</u> |
| Loss attributable to noncontrolling interest | 23 | 59 |
| Deemed dividend - accretion of discount and redemption feature of redeemable convertible preferred stock | (488) | — |
| Net loss available to common stockholders | <u>\$ (11,109)</u> | <u>\$ (14,950)</u> |
| Net loss per share available to common stockholders, basic and diluted | <u>\$ (3.46)</u> | <u>\$ (7.79)</u> |
| Weighted-average number of common shares outstanding used to compute net loss per share, basic and diluted | <u>3,211,139</u> | <u>1,918,176</u> |

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

| | December 31, | |
|--|--------------|-----------|
| | 2022 | 2021 |
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 12,109 | \$ 18,685 |
| Restricted cash | 400 | 400 |
| Accounts receivable, net | 99 | 165 |
| Prepaid and other current assets | 848 | 2,359 |
| Total current assets | 13,456 | 21,609 |
| Property and equipment, net | 436 | 399 |
| Right-of-use asset | 4,658 | 4,432 |
| Other assets | 523 | 805 |
| Total assets | \$ 19,073 | \$ 27,245 |
| Liabilities and stockholders' equity | | |
| Current liabilities | | |
| Accounts payable | \$ 382 | \$ 1,393 |
| Accrued liabilities | 595 | 791 |
| Current portion of lease liabilities | 238 | 127 |
| Current portion of deferred revenue | 19 | 19 |
| Total current liabilities | 1,234 | 2,330 |
| Lease liabilities, non-current | 4,379 | 4,617 |
| Deferred revenue, non-current | 79 | 98 |
| Finance lease liability, non-current | 5 | 14 |
| Total liabilities | 5,697 | 7,059 |
| Commitments and contingencies (Note 9) | | |
| Stockholders' equity | | |
| Preferred stock, \$0.0001 par value; 10,000,000 shares authorized at December 31, 2022 and 2021; no shares issued and outstanding at December 31, 2022 and 2021 | — | — |
| Common stock, \$0.0001 par value; 200,000,000 shares authorized at December 31, 2022 and 2021; 4,271,759 and 2,497,450 shares issued and outstanding at December 31, 2022 and 2021, respectively | 5 | 5 |
| Additional paid-in capital | 102,673 | 98,839 |
| Accumulated deficit | (88,273) | (77,652) |
| Total Histogen Inc. stockholders' equity | 14,405 | 21,192 |
| Noncontrolling interest | (1,029) | (1,006) |
| Total equity | 13,376 | 20,186 |
| Total liabilities and stockholders' equity | \$ 19,073 | \$ 27,245 |

