# 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): May 9, 2019**

# Chiasma, Inc.
**(Exact name of registrant as specified in its charter)**

| DELAWARE | 001-37500 | 76-0722250 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (I.R.S. Employer Identification No.) |

**460 Totten Pond Road, Suite 530**
**Waltham, Massachusetts 02451**
**(Address of principal executive office) (Zip Code)**

**(617) 928-5300**
**(Registrant's telephone number, including area code)**

**Not Applicable**
**(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))

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. ☒

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, $0.01 par value** | **CHMA** | **NASDAQ Global Select Market** |

**Item 2.02 Results of Operations and Financial Condition.**

On May 9, 2019, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2019 and providing a business update. The full text of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information under this Item 2.02 is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release of Chiasma, Inc. dated May 9, 2019 |

**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.

Date: May 9, 2019

**Chiasma, Inc.**

By: /s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
President, Chief Executive Officer, and Director

**Exhibit 99.1**

**Chiasma Reports First Quarter 2019 Results**

*CHIASMA OPTIMAL top-line data on track for Q3 2019 and, if positive, MYCAPSSA® NDA submission on track for year-end 2019*

**Waltham, MA – May 9, 2019** – Chiasma, Inc. (NASDAQ: CHMA), a clinical-stage biopharmaceutical company focused on improving the lives of patients with rare and serious chronic diseases, today reported financial results for the first quarter ended March 31, 2019 and provided a business update.

During the first quarter of 2019, Chiasma continued to advance its international Phase 3 clinical trial, referred to as CHIASMA OPTIMAL (**O**ctreotide capsules vs. **P**lacebo **T**reatment **I**n **M**ultination**AL** centers), which, if positive, could support potential regulatory approval in the United States of its investigational octreotide capsules, conditionally trade-named MYCAPSSA®, for the maintenance therapy of adult patients with acromegaly. Chiasma anticipates the release of top-line data from this trial during the third quarter of 2019, with an NDA resubmission planned by year-end 2019. If FDA determines the planned NDA to be complete, Chiasma expects a six-month PDUFA review classification.

Chiasma is also advancing its ongoing multi-national MPOWERED™ Phase 3 trial, which, if positive, could support potential regulatory approval in the E.U. The Company expects to report top-line data from this trial in the second half of 2020.

At ENDO 2019, the Endocrine Society's Annual Meeting, the Company presented three posters highlighting the ongoing challenges experienced by acromegaly patients being treated with the current standard of care injectable somatostatin analogs and underscoring the need for new treatment alternatives.

"We are on track with both of our Phase 3 clinical trials of MYCAPSSA®, and we look forward to the release of top-line data from CHIASMA OPTIMAL, which, if positive, is expected to form the basis of our planned NDA filing," said Mark Fitzpatrick, President and Chief Executive Officer of Chiasma. "As further demonstrated in our recent poster presentations at ENDO 2019 in March, acromegaly patients on the current standard of care, injectable somatostatin receptor ligands, continue to face significant treatment burdens which impact their quality of life, suggesting a significant unmet need in this patient population. If approved, MYCAPSSA would be the first orally-administered somatostatin analog for this rare but debilitating lifelong disease and is designed to potentially address some of the ongoing challenges of existing treatments. We also plan to continue our commercial readiness activities."

In April, Chiasma completed a follow-on public offering of 7,263,158 shares of its common stock that raised net proceeds of approximately $32.2 million. The Company believes its cash and investments are sufficient to fund its operations as currently planned into late 2020, including through the release of CHIASMA OPTIMAL top-line data and, if positive, through an anticipated mid-2020 PDUFA date.

**First Quarter 2019 Financial Results**

- **G&A Expenses:** General and administrative expenses were $2.5 million for the quarter ended March 31, 2019, compared with $2.4 million for the same period of 2018. The current period results include increased professional services fees which were primarily offset by a reduction in legal costs.
- **R&D Expenses:** Research and development expenses were $6.5 million for the quarter ended March 31, 2019, compared with $4.9 million for the same period of 2018. The increase was primarily due to an increase in manufacturing costs.
- **Net Loss:** For the quarter ended March 31, 2019, net loss was ($8.8) million, or ($0.36) per basic share, compared with ($7.0) million, or ($0.29) per basic share, in the same period of 2018.
- **Cash Position:** Chiasma ended the quarter with cash, cash equivalents and marketable securities of $33.9 million. In April, the Company completed a follow-on offering of common stock that raised net proceeds of approximately $32.2 million. The Company anticipates that its current cash and investments balance is sufficient to fund operations as currently planned into late 2020, including through CHIASMA OPTIMAL top-line data and, if positive, through an anticipated mid-2020 PDUFA date.

**Conference Call and Webcast Information:**

Chiasma management will host a conference call and webcast to discuss the first quarter results in more detail today, May 9, 2019, at 5:00 pm EDT.

The dial-in number in the U.S./Canada is 877-407-4018; for international participants, the number is 201-689-8471. For all callers, please refer to Conference ID 13690157.

To access the live webcast, please use the following link: http://public.viavid.com/index.php?id=134279

**CHIASMA OPTIMAL Phase 3 Trial**

The CHIASMA OPTIMAL trial is a randomized, double-blind, placebo-controlled, nine-month clinical trial of octreotide capsules being conducted under a SPA agreement with the FDA. The trial enrolled 56 adult acromegaly patients whose disease was biochemically controlled, based upon levels of IGF-1, a byproduct of increased growth hormone (GH) levels caused by acromegaly, by injectable somatostatin receptor ligands at baseline (average IGF-1 $\leq 1.0 \times$ upper limit of normal (ULN)). The patients also had confirmed active acromegaly following their last surgical intervention based upon an elevated IGF-1 at that time of $\geq 1.3 \times$ ULN. The trial was randomized on a 1:1 basis, octreotide capsules versus placebo. Patients are being dose titrated from 40 mg per day to up to a maximum of 80 mg per day, equaling two capsules in the morning and two capsules in the evening. Patients who meet predefined withdrawal criteria or withdraw from oral treatment in either treatment arm for any reason during the course of the trial will be considered treatment failures; those patients will be offered their original treatment of injections and monitored for the remainder of the trial. The primary endpoint of the trial is the proportion of patients who maintain their biochemical response compared to placebo at the end of the nine-month, double-blind, placebo-controlled period as measured using the average of the last two IGF-1 levels $\leq 1.0 \times$ ULN. Chiasma anticipates the release of top-line data from this Phase 3 clinical trial in the third quarter of 2019.

**MPOWERED™ Phase 3 Trial**

Chiasma is conducting an international Phase 3 clinical trial under a protocol accepted by the EMA for the Company's octreotide capsules product candidate for the maintenance therapy of adult patients with acromegaly. The trial, referred to as MPOWERED, is a global, randomized, open-label and active-controlled, 15-month trial intended to support approval in the European Union. Chiasma plans to enroll up to 150 adult acromegaly patients into the trial, of which at least 80 patients who are responders to octreotide capsules following a six-month run-in will be randomized to either octreotide capsules or injectable somatostatin receptor ligands (octreotide LAR or lanreotide autogel), and then followed for an additional nine months. The trial was initiated in March 2016, has enrolled 135 patients as of July 2018 (of which the EMA-required minimum of 80 responder patients have been randomized) and is designed to evaluate the proportion of patients who maintain their biochemical response to octreotide capsules and patient-reported outcomes in patients treated with octreotide capsules, compared to patients treated with standard of care injectable somatostatin receptor ligands. In November 2018, Chiasma announced that it had elected to resume enrollment in the trial in an effort to enroll up to 15 additional patients exclusively located in the United States in order to gain further U.S. investigator and patient experience with octreotide capsules. Chiasma now anticipates the trial to complete enrollment into the run-in phase in the second quarter of 2019 and expects to release top-line data from this Phase 3 clinical trial during the second half of 2020.

**About Chiasma**

Chiasma is focused on improving the lives of patients who face challenges associated with their existing treatments for rare and serious chronic diseases. Employing its Transient Permeability Enhancer (TPE®) technology platform, Chiasma seeks to develop oral medications that are currently available only as injections. In October 2018, the Company completed enrollment in CHIASMA OPTIMAL, its third Phase 3 clinical trial for its octreotide capsules product candidate, conditionally trade-named Mycapssa, for the maintenance therapy of adult patients with acromegaly in whom prior treatment with somatostatin analogs has been shown to be effective and tolerated. Prior to trial initiation, the Company reached agreement with the FDA on the design of the trial through a special protocol assessment. Chiasma is headquartered in Waltham, MA with a wholly-owned subsidiary in Israel. Mycapssa, TPE and CHIASMA are registered trademarks of Chiasma. For more information, please visit the Company's website at www.chiasma.com.

**Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding the Company's development of octreotide capsules, conditionally named MYCAPSSA, for the treatment of acromegaly, the Company's efforts to potentially obtain regulatory approval in the United States by conducting the Phase 3 CHIASMA OPTIMAL clinical trial under a Special Protocol Assessment, the Company's efforts to potentially obtain regulatory approval in the European Union by conducting the ongoing MPOWERED Phase 3 clinical trial, the timing of receipt and announcement of top-line and other clinical data and submission of regulatory filings, including the Company's ability to release top-line data from the CHIASMA OPTIMAL trial in the third quarter of 2019, and if positive, to resubmit its NDA by year-end 2019, and the Company's ability to release top-line data from the MPOWERED trial during the second half of 2020, and the Company's cash forecasts, including the expectation that it has sufficient existing cash and investments on hand to fund its operations through its anticipated release of top-line data from the Phase 3 CHIASMA OPTIMAL clinical trial in the third quarter of 2019 and that its cash and investments balance is sufficient to fund operations as currently planned into late 2020. Any forward-looking

statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in Chiasma's Annual Report on Form 10-K for the year ended December 31, 2018, and in subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Chiasma undertakes no duty to update this information unless required by law.

**Contact:**

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**Chiasma, Inc.**
**Condensed Consolidated Statements of Operations**
**(amounts in thousands except share and per share data)**
**(unaudited)**

| | For the three months ended | |
|---|---|---|
| | **March 31, 2019** | **March 31, 2018** |
| Operating expenses: | | |
| General and administrative | $ 2,450 | $ 2,434 |
| Research and development | 6,471 | 4,863 |
| Total operating expenses | 8,921 | 7,297 |
| Loss from operations | (8,921) | (7,297) |
| Other income, net | (184) | (230) |
| Loss before income taxes | (8,737) | (7,067) |
| Provision (benefit) for income taxes | 13 | (24) |
| Net loss | $ (8,750) | $ (7,043) |
| Earnings per share of common stock: | | |
| Basic | $ (0.36) | $ (0.29) |
| Diluted | $ (0.36) | $ (0.29) |
| Weighted-average shares outstanding: | | |
| Basic | 24,466,617 | 24,381,924 |
| Diluted | 24,466,617 | 24,381,924 |

**Chiasma, Inc.**
**Condensed Consolidated Balance Sheets Information**
**(amounts in thousands)**
**(unaudited)**

| | March 31, 2019 | December 31, 2018 |
|---|---|---|
| Cash and cash equivalents | $ 10,074 | $ 13,060 |
| Marketable securities | 23,783 | 28,602 |
| Insurance recovery | 18,288 | 18,288 |
| Prepaid expenses and other current assets | 1,364 | 2,237 |
| Property and equipment, net | 102 | 111 |
| Other assets | 1,262 | 958 |
| Total assets | $ 54,873 | $ 63,256 |
| Accounts payable | $ 3,829 | $ 2,029 |
| Estimated settlement liability | 18,750 | 18,750 |
| Accrued expenses | 5,442 | 7,848 |
| Other current liabilities | 169 | — |
| Long-term liabilities | 650 | 505 |
| Total liabilities | 28,840 | 29,132 |
| Total stockholders' equity | 26,033 | 34,124 |
| Total liabilities and stockholders' equity | $ 54,873 | $ 63,256 |