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 8, 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 Rd, Suite 530 **Waltham, MA** **(Address of principal executive offices)**	**02451** **(Zip Code)**

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

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. ☑

Item 2.02 Results of Operations and Financial Condition.

On March 8, 2019, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended December 31, 2018 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. (concerning financial results) dated March 8, 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: March 8, 2019

Chiasma, Inc.

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

Exhibit 99.1

Chiasma Reports Fourth Quarter and Year End 2018 Results

On track for top-line data from Phase 3 CHIASMA OPTIMAL trial of octreotide capsules, conditionally trade-named MYCAPSSA®, expected in Q3 2019

Assuming positive OPTIMAL data, NDA submission expected by year-end 2019

Waltham, MA – March 8, 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 fourth quarter and year ended December 31, 2018 and provided a business update.

On October 1, 2018, Chiasma announced that it had completed enrollment of 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), randomizing a total of 56 patients. This trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) to 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 and, if positive, a New Drug Application (NDA) submission is expected by year-end 2019. Chiasma currently expects the FDA will aim to complete its review of the anticipated NDA, if resubmitted and determined complete, in six months.

Chiasma also continues to advance its ongoing multinational MPOWERED™ (**M**aintenance of acromegaly **P**atients with **O**ctreotide capsules compared **W**ith injections – **E**valuation of **RE**sponse **D**urability) Phase 3 trial designed to support potential regulatory approval in the European Union. In October 2018, Chiasma completed the randomization of the required minimum 80 patients into the nine-month randomized controlled phase of the trial. As it previously announced, the Company continues to enroll up to an additional 15 U.S.-based patients in MPOWERED in order to gain further U.S. investigator and patient experience with octreotide capsules. Chiasma expects to complete enrollment in MPOWERED in the second quarter of 2019 and to report top-line data from this trial in the second half of 2020.

“With CHIASMA OPTIMAL progressing as planned, we are approaching a significant milestone for our Company with the anticipated release of top-line data from this important U.S. trial during the third quarter of this year,” said Mark Fitzpatrick, President and Chief Executive Officer of Chiasma. “If approved, we believe MYCAPSSA® will potentially become a standard of care for the maintenance treatment of adults suffering from acromegaly. We look forward to our expected filing of an NDA by year-end and to the potential for approval and commercial launch in 2020. In anticipation of positive clinical trial results in 2019, we intend to meaningfully advance our commercial readiness planning this year,” Mr. Fitzpatrick concluded.

Fourth Quarter 2018 Financial Results

- **G&A Expenses:** General and administrative expenses were $2.7 million for the fourth quarter ended December 31, 2018, compared with $1.8 million for the same period of 2017. The current period results include increased legal costs which were primarily offset by a reduction in facility costs.
- **R&D Expenses:** Research and development expenses were $5.7 million for the fourth quarter ended December 31, 2018, compared with $4.3 million for the same period of 2017. The increase was primarily due to costs related to the CHIASMA OPTIMAL clinical trial, which completed enrollment in October 2018.
- **Net Loss:** For the quarter ended December 31, 2018, net loss was ($8.1) million, or ($0.32) per basic share, compared with ($6.1) million, or ($0.25) per basic share, in the same period of 2017.
- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2018 were $41.7 million, compared with $66.9 million as of December 31, 2017, primarily reflecting the Company's operating expenditures for the year. The Company anticipates that its current cash balance is sufficient to fund its operations as currently planned through the release of CHIASMA OPTIMAL top-line data and into early 2020.

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 ≤ 1.0 × 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 1.3 × 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 ≤ 1.0 × 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 Acromegaly

Acromegaly typically develops when a benign tumor of the pituitary gland produces too much growth hormone (GH), ultimately leading to significant health problems and early death if untreated. There are an estimated 69,000 individuals with acromegaly worldwide. In 13 studies of acromegaly prevalence since 1980, an average of approximately 75 cases per million was determined, suggesting roughly 24,000 individuals with acromegaly in the United States, of which an estimated 8,000 are treated chronically with somatostatin analog injections. However, previous data suggest that pituitary tumors may be more prevalent than previously thought, and that the global prevalence of acromegaly may be higher, between 85 and 118 cases per million people. National Institutes of Health (NIH) also cites an annual incidence of three to four new cases per million each year. Because symptoms often develop slowly, diagnosis may be delayed by years or decades, making it difficult to determine the total number of people with the disease.

Common features of acromegaly are facial changes, intense headaches, joint pain, impaired vision and enlargement of the hands, feet, tongue and internal organs. Serious health conditions associated with the progression of acromegaly include type 2 diabetes, hypertension, respiratory disorders and cardiac and cerebrovascular disease.

Current treatment options include surgery to remove the pituitary tumor, radiation therapy, which destroys any lingering tumor cells, and/or medical treatment in cases where these approaches are not possible or fully effective. Today's medical treatments include dopamine agonists, GH antagonists, and injectable somatostatin analogs, which are the current standard of care.

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 trade-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 and anticipated regulatory review and commercial launch timing in the U.S., 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 the 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 early 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:

Ashley R. Robinson
LifeSci Advisors, LLC
617-535-7742
arr@lifesciadvisors.com

Chiasma, Inc.

Condensed Consolidated Statements of Operations

(amounts in thousands except share and per share data)

(unaudited)

	For the three months ended		For the twelve months ended	
	December 31, 2018	December 31, 2017	December 31, 2018	December 31, 2017
Operating expenses:				
General and administrative	$ 2,657	$ 1,793	$ 9,974	$ 9,146
Research and development	5,732	4,323	22,362	17,948
Restructuring charges	—	1,038	—	1,038
Total operating expenses	8,389	7,154	32,336	28,132
Loss from operations	(8,389)	(7,154)	(32,336)	(28,132)
Other income, net	(259)	(160)	(1,044)	(716)
Loss before income taxes	(8,130)	(6,994)	(31,292)	(27,416)
Benefit from Income Taxes	(55)	(891)	(31)	(590)
Net loss	$ (8,075)	$ (6,103)	$ (31,261)	$ (26,826)
Earnings per share of common stock:				
Basic	$ (0.32)	$ (0.25)	$ (1.28)	$ (1.10)
Diluted	$ (0.32)	$ (0.25)	$ (1.28)	$ (1.10)
Weighted-average shares outstanding:				
Basic	24,442,370	24,378,930	24,399,706	24,366,681
Diluted	24,442,370	24,378,930	24,399,706	24,366,681

Chiasma, Inc.

Condensed Consolidated Balance Sheets Information

(amounts in thousands)

(unaudited)

	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 13,060	$ 14,603
Marketable securities	28,602	52,336
Insurance recovery	18,288	—
Prepaid expenses and other current assets	2,237	1,768
Property and equipment, net	111	193
Other assets	958	983
Total assets	$ 63,256	$ 69,883
Accounts payable	$ 2,029	$ 1,017
Estimated settlement liability	18,750	—
Accrued expenses	7,848	4,033
Other current liabilities	—	1,695
Long-term liabilities	505	664
Total liabilities	29,132	7,409
Total stockholders' equity	34,124	62,474
Total liabilities and stockholders' equity	$ 63,256	$ 69,883