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 16, 2020

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.)

140 Kendrick Street, Building C East
Needham, Massachusetts 02494
(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))

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**

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 16, 2020, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 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 March 16, 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.

Date: March 16, 2020

Chiasma, Inc.

By: /s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
President

Chiasma Reports Fourth Quarter and Full Year 2019 Financial Results

MYCAPSSA® PDUFA Date Set for June 26, 2020; U.S. Commercial Launch Planned in Q4'20
First Industry Sponsored U.S. Disease State Registry for Acromegaly Began Enrolling Patients

Needham, MA – March 16, 2020 – Chiasma, Inc. (NASDAQ: CHMA), a clinical stage biopharmaceutical company focused on improving the lives of patients who face challenges associated with their existing treatments for rare and serious chronic diseases, today reported financial results for the fourth quarter and year ended December 31, 2019 and provided a business update.

"Our focus for 2020 is on obtaining U.S. regulatory approval for MYCAPSSA® as a maintenance treatment for adult patients with acromegaly and subsequently executing a successful launch," said Raj Kannan, Chief Executive Officer of Chiasma. "With our NDA resubmission accepted for review by the FDA, we are preparing for a commercial launch to establish the foundation needed for long-term growth."

Recent Business Highlights and Anticipated 2020 Milestones

- **MYCAPSSA NDA Acceptance**: Chiasma announced on January 13, 2020 that the U.S. Food and Drug Administration (FDA) accepted for review the New Drug Application (NDA) resubmission for its oral octreotide capsules investigational product candidate, conditionally trade named MYCAPSSA, for the treatment of adults with acromegaly. The FDA assigned a Prescription Drug User-Fee Act (PDUFA) target action date of June 26, 2020, which is a six-month review.
- **The Management of Acromegaly (MACRO) Registry**: Chiasma began enrolling patients in the first-ever industry sponsored U.S. disease state registry for acromegaly. The MACRO registry is designed to enroll patients from over 40 clinical sites in the U.S. and collect real-world data on treatment burden and effectiveness of various acromegaly treatments.
- **Publication of CHIASMA OPTIMAL Phase 3 Clinical Trial Results:** Chiasma plans to submit the positive results of the CHIASMA OPTIMAL trial to a peer-reviewed journal for expected publication in mid-2020.
- **MYCAPSSA Planned U.S. Commercial Launch:** Chiasma plans to launch MYCAPSSA in the United States in the fourth quarter of 2020, pending the FDA's timely approval of the NDA and either of the planned prior approval manufacturing supplements to the NDA.
- **Top-line MPOWERED Phase 3 Clinical Trial Results:** Chiasma expects to report top-line results from the MPOWERED (**M**aintenance of acromegaly **P**atients with **O**ctreotide capsules compared **W**ith injections – **E**valuation of **RE**sponse **D**urability) Phase 3 open-label clinical trial of octreotide capsules in the fourth quarter of 2020.
- **Pipeline Expansion Leveraging Transient Permeability Enhancer (TPE®) Technology**: Chiasma plans to announce its pipeline expansion plans to develop one or more oral therapies targeting diseases with unmet needs following the anticipated approval of MYCAPSSA for the maintenance treatment of adults with acromegaly.

Fourth Quarter and Year Full Year 2019 Financial Results and Outlook

- **G&A Expenses:** General and administrative expenses were $5.9 million for the fourth quarter ended December 31, 2019, compared with $2.7 million for the same period of 2018. The current period results include increased pre-commercial activity and compensation related expenses which were primarily offset by a reduction in legal expenses. General and administrative expenses were $15.1 million for the year ended December 31, 2019, compared with $10.0 million for the year ended December 31, 2018. The increase was primarily driven by the initiation of pre-commercial activities and compensation related expenses which were primarily offset by a reduction in legal expenses.
- **R&D Expenses:** Research and development expenses were $6.4 million for the fourth quarter ended December 31, 2019, compared with $5.7 million for the same period of 2018. The increase was primarily driven by increased regulatory and manufacturing costs and offset by decreased clinical trials costs. Research and development expenses were $22.5 million for the year ended December 31, 2019, compared with $22.4 million for the year ended December 31, 2018. Though the change was immaterial, we observed an increase in regulatory and manufacturing costs offset by a decrease in clinical trials costs.
- **Net Loss:** For the quarter ended December 31, 2019, net loss was ($12.0) million, or ($0.29) per basic share, compared with ($8.1) million, or ($0.32) per basic share, for the same period of 2018. For the year ended December 31, 2019, net loss was ($36.3) million, or ($1.06) per basic share, compared with ($31.3) million, or ($1.28) per basic share, for the same period of 2018.
- **Cash Position and Outlook:** Cash, cash equivalents and marketable securities as of December 31, 2019, were $92.4 million, compared with $41.7 million as of December 31, 2018. The Company expects that its current cash, cash equivalents and marketable securities balance is sufficient to fund its operations as currently planned through at least 2020.

Conference Call and Webcast Information

Chiasma management will host a conference call and webcast to discuss the fourth quarter results in more detail today, March 16, 2020, at 5:00 pm ET. The dial-in number in the U.S. / Canada is 1-877-407-4018; for international participants, the dial-in number is 1-201-689-8471. For all callers, please refer to Conference ID 13699225. To access the live webcast, please use the following link: https://edge.media-server.com/mmc/p/b4e8rvsn

A live audio webcast of the call may also be accessed under “Events & Presentations” on the News & Investors section of the Company’s website, http://ir.chiasmapharma.com/events-presentations. An archived replay of webcast will be available on the Company’s website approximately two hours after the event. The archived webcast will be available for one year.

CHIASMA OPTIMAL Global Phase 3 Trial

The CHIASMA OPTIMAL trial was a randomized, double-blind, placebo-controlled, nine-month Phase 3 clinical trial of octreotide capsules that was conducted under a SPA agreement with the FDA. The trial enrolled 56 adult acromegaly patients whose disease was biochemically controlled by injectable somatostatin analogs based upon levels of IGF-1, a byproduct of increased growth hormone, or GH, levels caused by acromegaly (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 ³ 1.3 × ULN. Patients were randomized on a 1:1 basis, to octreotide capsules or placebo. Patients were dose titrated from 40 mg per day (equaling one capsule in the morning and one capsule in the evening) to up to a maximum of 80 mg per day (equaling two capsules in the morning and two capsules in the evening). Patients who met the predefined withdrawal criteria, or discontinued from oral treatment for any reason, in either treatment arm during the course of the trial were considered treatment failures, reverted to their original treatment of injections and monitored for the remainder of the trial. The primary endpoint of the trial was the proportion of patients who maintained their biochemical response 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 (assessed at weeks 34 and 36). Hierarchical secondary endpoints that are expected to be considered by the FDA in evaluating the totality of evidence for octreotide capsules treatment effect include: proportion of patients who maintain GH response at week 36 compared to screening; time to loss of response: IGF-1 of 2 consecutive visits is > 1.0 × ULN; time to loss of response: IGF-1 of 2 consecutive visits is ³ 1.3 × ULN; and proportion of patients requiring rescue treatment.

MPOWERED™ Phase 3 Trial

Chiasma is also conducting an international Phase 3 clinical trial under a protocol accepted by the EMA for the company's oral octreotide capsules for the maintenance treatment of adult patients with acromegaly. The trial, referred to as MPOWERED, is a randomized, open-label and active-controlled, 15-month trial intended to support regulatory approval in the European Union. Chiasma completed enrollment of 146 adult acromegaly patients into the trial in June 2019. In January 2020, the randomization of patients was completed. Of the 146 patients that entered the six-month run-in phase of the trial, 92 of these patients (or 63%) completed the run-in phase and were deemed to be responders to octreotide capsules per protocol (IGF-1 <1.3 x ULN and GH<2.5 ng/mL). Responders to octreotide capsules were randomized (2:3) per protocol to either go back to their original long-acting injectable somatostatin analog or remain on octreotide capsules at the dose identified during the run-in phase and then followed for an additional nine months. The trial 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. Chiasma expects to release top-line data from the MPOWERED Phase 3 clinical trial during the fourth quarter of 2020.

About Acromegaly

Acromegaly typically develops when a benign tumor of the pituitary gland produces too much growth hormone, ultimately leading to significant health problems. 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. We believe that approximately 8,000 adult acromegaly patients are chronically treated with somatostatin analogs in the United States.

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 July 2019, the company reported positive topline data from its CHIASMA OPTIMAL 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. In January 2020, the FDA accepted the company's NDA resubmission seeking marketing approval of MYCAPSSA in the U.S. The PDUFA target action date is June 26, 2020. Chiasma is headquartered in Needham, 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, statements regarding the timing of regulatory filings and reviews and potential approvals, statements concerning the nature of the FDA's review of the NDA resubmission, statements concerning the commercial or therapeutic potential of MYCAPSSA, if approved, statements regarding the company's plan to submit two manufacturing supplements for an additional API manufacturer and an additional API manufacturing site following a potential NDA approval and the company's expectations regarding the availability of product supply, statements concerning the timing of potential commercial launch of MYCAPSSA in the United States, statements regarding the release of top-line results from the MPOWERED Phase 3 trial, statements regarding the company's cash forecasts and need for capital, including that it has sufficient existing cash and investments on hand to fund its operations through at least 2020, and announcements of pipeline expansion plans. Such statements are subject to numerous important factors, risks and uncertainties, many of which are beyond the company's control, that may cause actual events or results to differ materially from the company's current expectations. Management's expectations and, therefore, any forward-looking statements in this press release could be affected by risks and uncertainties relating to a number of factors, including the following: the content and timing of decisions made by the FDA, including with respect to the NDA and any manufacturing supplements to the NDA the company may submit to the FDA, the results of any inspections of the company's third-party manufacturers, the company's reliance on third parties to manufacture API and commercial octreotide capsules, the company's ability to obtain and retain requisite regulatory approvals for the commercial launch of octreotide capsules in the United States, and the timing and costs involved in establishing a commercial organization. Furthermore, the company will require additional capital to fund its planned operations beyond 2020, which may not be available to it on attractive terms or at all. If the company is unable to secure additional capital, it may be forced to delay, limit, reduce or terminate its development and planned commercialization of MYCAPSSA. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause the company's 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, 2019. 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.

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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		For the twelve months ended	
	December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Operating expenses:				
General and administrative	$ 5,912	$ 2,657	$ 15,122	$ 9,974
Research and development	6,354	5,732	22,457	22,362
Total operating expenses	12,266	8,389	37,579	32,336
Loss from operations	(12,266)	(8,389)	(37,579)	(32,336)
Other income, net	(469)	(259)	(1,543)	(1,044)
Loss before income taxes	(11,797)	(8,130)	(36,036)	(31,292)
Benefit from Income Taxes	250	(55)	284	(31)
Net loss	$ (12,047)	$ (8,075)	$ (36,320)	$ (31,261)
Earnings per share of common stock:				
Basic	$ (0.29)	$ (0.32)	$ (1.06)	$ (1.28)
Diluted	$ (0.29)	$ (0.32)	$ (1.06)	$ (1.28)
Weighted-average shares outstanding:				
Basic	42,022,030	24,442,370	34,204,284	24,399,706
Diluted	42,022,030	24,442,370	34,204,284	24,399,706

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

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 27,855	$ 13,060
Marketable securities	64,520	28,602
Insurance recovery	—	18,288
Prepaid expenses and other current assets	3,881	2,237
Property and equipment, net	334	111
Other assets	2,236	958
Total assets	$ 98,826	$ 63,256
Accounts payable	$ 3,253	$ 2,029
Estimated settlement liability	—	18,750
Accrued expenses	7,576	7,848
Other current liabilities	546	—
Long-term liabilities	1,682	505
Total liabilities	13,057	29,132
Total stockholders' equity	85,769	34,124
Total liabilities and stockholders' equity	$ 98,826	$ 63,256