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 5, 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))

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 November 5, 2019, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 5, 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: November 5, 2019

Chiasma, Inc.

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

Exhibit 99.1

Chiasma Reports Third Quarter 2019 Results

CHIASMA OPTIMAL trial, conducted under SPA and designed to support FDA approval, met the primary and all secondary endpoints

MYCAPSSA® NDA on track for submission by year-end 2019

MPOWERED™ Phase 3 trial, designed to support EU approval, progressing as planned with topline data expected in 2H 2020

Waltham, MA – November 5, 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 third quarter ended September 30, 2019 and provided a business update.

In July, Chiasma reported topline results from its CHIASMA OPTIMAL global Phase 3 clinical trial designed to support marketing approval of its oral octreotide capsules product candidate, conditionally trade named MYCAPSSA®, in the United States. The trial, which was conducted under a Special Protocol Assessment (SPA) agreement with the FDA, met the primary and all secondary endpoints. If approved, MYCAPSSA will be the first oral somatostatin analog that we believe has the potential to change the standard of pharmacological care in the management of patients with acromegaly.

Key CHIASMA OPTIMAL data highlights include:

Primary Endpoint:

- 58% of patients on octreotide capsules maintained biochemical control (IGF-1 ≤ 1.0 x ULN) at the end of study vs. 19% on placebo (p = 0.008). We believe this data is consistent with the efficacy physicians may expect for a potential maintenance treatment for acromegaly patients.

Secondary Endpoints:

- Of patients who were growth hormone (GH) responders at screening, 78% of patients on octreotide capsules maintained their GH response at the end of the core study versus 30% for placebo (p=0.001)
- Median time to loss of IGF-1 response (as defined by either >1.0 or ≥ 1.3 x ULN) was not reached (>36 Weeks) for patients on octreotide capsules vs. 16 weeks on placebo (p < 0.001)
- 25% of patients on octreotide capsules required rescue with SSA Injections vs. 68% on placebo (p = 0.003); stated otherwise, 75% of patients on octreotide capsules completed the trial (of which 90% elected to continue into the open label extension)

Exploratory Analysis:

- Mean IGF-1 values across all patients treated with octreotide capsules remained within normal limits (≤ 1.0 x ULN) up to the end of oral treatment
- 75% of patients on MYCAPSSA achieved an IGF-1 ≤ 1.1 x ULN at the end of treatment

Octreotide capsules appeared safe and well tolerated in the study population, and no new or unexpected safety signals were observed.

Chiasma remains on track to file its NDA by year end and expects possible FDA approval in mid-2020, following an expected six-month PDUFA review classification. In parallel, the company is conducting a Phase 3 study, MPOWERED™, which is designed to support an application for marketing approval in the European Union, and the company remains on track to report topline data in the second half of 2020.

In September, Chiasma hosted a Key Opinion Leader meeting for investors featuring Susan L. Samson, MD, PhD, FRCPC, FACE, Associate Professor at Baylor College of Medicine in Houston, Texas, and Jill Sisco, President of Acromegaly Community, Inc., a patient organization that helps educate patients and their families regarding this rare disease. The presentation by Dr. Samson and Ms. Sisco, which is available under the events and presentations section of the company's website, underscored the burdens that persist with the current standard-of-care, monthly SSA injections, including injection site pain and reactions. If marketing approval is granted by the FDA, MYCAPSSA would be the first approved oral somatostatin analog treatment in an injectables-only adult acromegaly maintenance treatment market.

"In our CHIASMA OPTIMAL trial, 90% of the patients who completed the trial on MYCAPSSA elected to continue into the open label extension, which we believe reflects the strong preference by acromegaly patients for an oral treatment option. We also observed that 75% of patients on MYCAPSSA achieved an IGF-1 ≤ 1.1 x ULN at the end of treatment, which we believe will be clinically meaningful to physicians. If approved, we believe MYCAPSSA would be well positioned to potentially become a new standard of pharmacological care for the management of acromegaly," said Raj Kannan, Chief Executive Officer of Chiasma. "We made significant progress in the third quarter with our commercial preparedness and have hired key talent in marketing and market access and also accelerated our hiring in medical affairs" Mr. Kannan concluded.

Third Quarter 2019 Financial Results

- **G&A Expenses:** General and administrative expenses were $4.1 million for the third quarter ended September 30, 2019, compared with $2.3 million for the same period of 2018. The current period results include increased compensation related expenses, the initiation of pre-commercial activities, and increased insurance premiums which were primarily offset by a reduction in legal costs.

- **R&D Expenses:** Research and development expenses were $4.1 million for the third quarter ended September 30, 2019, compared with $5.5 million for the same period of 2018. The decrease was primarily driven by a decrease in clinical trial costs and was offset by increased manufacturing and regulatory costs.

- **Net Loss:** For the quarter ended September 30, 2019, net loss was ($7.7) million, or ($0.20) per basic share, compared with ($7.5) million, or ($0.31) per basic share, in the same period of 2018.

- **Financial Position:** In August, Chiasma completed a follow-on offering of common stock that raised net proceeds of approximately $52.3 million. Chiasma ended the third quarter with cash, cash equivalents and marketable securities of $102.7 million.

Conference Call and Webcast Information:

Chiasma management will host a conference call and webcast to discuss the third quarter results in more detail today, November 5, 2019, at 5:00 pm EDT. The dial-in number in the U.S. / Canada is 855-327-6837;

for international participants, the number is 631-891-4304. For all callers, please refer to Conference ID 10007821. To access the live webcast, please use the following link: http://public.viavid.com/index.php?id=136495

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 Trial Design

The CHIASMA OPTIMAL trial was a randomized, double-blind, placebo-controlled, nine-month clinical trial of octreotide capsules that was conducted under a special protocol assessment, or SPA, agreement with the FDA. The trial enrolled 56 adult acromegaly patients whose disease was biochemically controlled by injectable somatostatin analogs (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. Patients were randomized on a 1:1 basis, to octreotide capsules or placebo. Patients were 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 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 and 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 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 ≥ 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 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 completed enrollment of 146 adult acromegaly patients into the trial in June 2019, of which at least 80 patients who are responders to octreotide capsules per the protocol following a six-month run-in were 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 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 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 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. 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 and potential commercialization of octreotide capsules, conditionally named MYCAPSSA, for the treatment of acromegaly, the data from the CHIASMA OPTIMAL trial and whether the data will support the submission of an NDA for octreotide capsules and ultimately regulatory approval, statements regarding the timing of NDA submission and regulatory review, including the company's anticipated eligibility for a six-month PDUFA review cycle, statements concerning the nature of the FDA's review of any such NDA submission and whether the data submission will be sufficient to support regulatory approval, 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, the Company's ability to release top-line data from the MPOWERED trial during the second half of 2020, and statements concerning the market potential and the ability to become a standard of care of MYCAPSSA. 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.

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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 nine months ended	
	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Operating expenses:				
General and administrative	$ 4,116	$ 2,256	$ 9,210	$ 7,317
Research and development	4,110	5,462	16,103	16,630
Total operating expenses	8,226	7,718	25,313	23,947
Loss from operations	(8,226)	(7,718)	(25,313)	(23,947)
Other income, net	(549)	(275)	(1,074)	(785)
Loss before income taxes	(7,677)	(7,443)	(24,239)	(23,162)
Provision for income taxes	6	27	34	24
Net loss	$ (7,683)	$ (7,470)	$ (24,273)	$ (23,186)
Earnings per share of common stock:				
Basic	$ (0.20)	$ (0.31)	$ (0.77)	$ (0.95)
Diluted	$ (0.20)	$ (0.31)	$ (0.77)	$ (0.95)
Weighted-average shares outstanding:				
Basic	38,490,768	24,389,666	31,569,731	24,385,328
Diluted	38,490,768	24,389,666	31,569,731	24,385,328

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

	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 19,665	$ 13,060
Marketable securities	83,030	28,602
Insurance recovery	—	18,288
Prepaid expenses and other current assets	2,987	2,237
Property and equipment, net	209	111
Other assets	992	958
Total assets	$ 106,883	$ 63,256
Accounts payable	$ 2,737	$ 2,029
Estimated settlement liability	—	18,750
Accrued expenses	6,557	7,848
Other current liabilities	204	—
Long-term liabilities	645	505
Total liabilities	10,143	29,132
Total stockholders' equity	96,740	34,124
Total liabilities and stockholders' equity	$ 106,883	$ 63,256