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 7, 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 May 7, 2020, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2020 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 7, 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: May 7, 2020

Chiasma, Inc.

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

Chiasma Reports First Quarter 2020 Financial Results

Remain on Track with MYCAPSSA® Anticipated June 26, 2020 PDUFA Date and Planned U.S. Commercial Launch in Q4'20

Needham, MA – May 7, 2020 – Chiasma, Inc. (NASDAQ: CHMA), a clinical, late-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 first quarter of 2020 and provided a business update.

"Chiasma continues to execute on our mission to develop and commercialize alternative options to injectable therapies," said Raj Kannan, Chief Executive Officer of Chiasma. "The COVID-19 global pandemic has changed the way we currently conduct business; however, we remain on track with our organizational readiness to execute a successful launch with MYCAPSSA in the fourth quarter of this year. If MYCAPSSA is approved, we believe that as the first oral somatostatin analog for acromegaly, it also has the potential to address a growing preference for non-medically administered products in the current environment."

COVID-19 Business Impact – Projected 2020 Milestones Unchanged

Chiasma is closely monitoring the impact of COVID-19 on its business and has implemented steps to ensure the well-being of its employees as well as patients and health care professionals involved in the MPOWERED study and the MACRO Registry.

- **MYCAPSSA PDUFA Target Action Date:** The U.S. Food and Drug Administration (FDA) has not notified Chiasma of any expected delays to its June 26, 2020 Prescription Drug User-Fee Act (PDUFA) target action date for our investigational oral octreotide capsules product candidate, conditionally trade-named MYCAPSSA.
- **MYCAPSSA Supply and Manufacturing:** Chiasma has not observed any significant disruptions to the MYCAPSSA manufacturing supply chain. The company believes it will have sufficient commercial supply of MYCAPSSA to support its planned U.S. commercial launch in the fourth quarter of 2020, pending the FDA's timely approval of the NDA and a planned prior approval manufacturing supplement to the NDA.
- **MPOWERED Phase 3 Clinical Trial:** Chiasma has been working with patients and health care professionals at MPOWERED (**M**aintenance of acromegaly **P**atients with **O**ctreotide capsules compared **W**ith injections – **E**valuation of **RE**sponse **D**urability) clinical trial sites to implement safety protocols for the remaining patients in the randomized controlled (RCT) phase of the trial. Of the 92 patients randomized into the nine-month RCT phase, 83 have completed the trial and six remain active in RCT. Additionally, the trial has met the European Medicines Agency (EMA) requirement of a minimum of 80 patients being randomized into the nine-month, randomized, controlled phase of the trial. The primary endpoint will be calculated with time weighted average (TWA) analysis, therefore missing monthly IGF-1 values are not anticipated to affect the completion of the primary endpoint analysis. The MPOWERED trial is designed to support an application for marketing approval of MYCAPSSA in the European Union. Chiasma remains on track to report top-line results in the fourth quarter of 2020.

Recent Business Highlights and Anticipated 2020 Milestones

- **Anand Varadan Appointed Chief Commercial Officer (CCO):** Mr. Varadan was appointed Executive Vice President, Chief Commercial Officer in April 2020. Mr. Varadan leads Chiasma's commercial strategy and operations. He brings more than 20 years of relevant U.S. and international experience in leading both successful launches and in building commercial organizations.
- **Commenced Enrollment of the Management of Acromegaly (MACRO) Registry**: Chiasma began enrollment, during the first quarter of 2020, in the MACRO registry which is targeting 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.
- **Presentation and Publication of CHIASMA OPTIMAL Phase 3 Clinical Trial Results:** Chiasma plans to present the positive results of the CHIASMA OPTIMAL trial through virtual platforms hosted by the Endocrine Society (ENDO) and American Association of Clinical Endocrinologists (AACE), in the second quarter of 2020. The company also plans to submit these positive results 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 a planned prior approval manufacturing supplement.
- **Top-line MPOWERED Phase 3 Clinical Trial Results:** Chiasma expects to report top-line results from the MPOWERED Phase 3 open-label clinical trial of octreotide capsules in the fourth quarter of 2020.
- **HealthCare Royalty Partners (HCR) $75 Million Revenue Interest Financing Agreement:** Chiasma entered into a revenue interest financing agreement with HCR, in April 2020, for up to $75 million to strengthen our current cash position, extend our cash runway if funding conditions are met, and to support our ongoing MYCAPSSA launch efforts.

First Quarter 2020 Financial Results and Outlook

- **G&A Expenses:** General and administrative expenses were $7.6 million for the first quarter ended March 31, 2020, compared with $2.5 million for the same period of 2019. The current period results include our continuing pre-commercial activities, an increase in compensation-related expenses, and increased other administrative costs as we prepare for the potential commercialization of octreotide capsules.
- **R&D Expenses:** Research and development expenses were $8.1 million for the first quarter ended March 31, 2020, compared with $6.5 million for the same period of 2019. The increase was primarily driven by the manufacturing of octreotide capsules to support our commercial launch, if approved, costs associated with our disease state registry, scientific literature publications and increased regulatory costs which were offset by a decrease in clinical trial costs.

- **Net Loss:** For the quarter ended March 31, 2020, net loss was ($15.4) million, or ($0.36) per basic share, compared with a net loss of ($8.8) million, or ($0.36) per basic share, for the same period of 2019.
- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2020, were $79.3 million, compared with $92.4 million as of December 31, 2019. In April 2020, the company received the initial $25.0 million payment, less certain transaction expenses, from HCR under the previously announced revenue interest financing agreement. Under this agreement, Chiasma is entitled to an additional $25.0 million upon FDA approval of MYCAPSSA, $15.0 million upon the availability of commercial drug supply and first commercial sale of MYCAPSSA and $10 million in early 2022 subject to the achievement of a commercial milestone.

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 7, 2020, at 5:00 pm ET. The dial-in number in the U.S. / Canada is 1-800-949-2175; for international participants, the dial-in number is 1-856-344-9283. For all callers, please refer to Conference ID 3434236. To access the live webcast, please use the following link: https://edge.media-server.com/mmc/p/whqk8h8r

A live audio webcast of the call may also be accessed under “Events & Presentations” on the News & Investors section of the Company’s website, https://ir.chiasma.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. As previously announced, CHIASMA OPTIMAL met the primary endpoint and all secondary endpoints.

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 has met the EMA's requirement of a minimum of 80 patients being randomized into the nine-month, randomized, controlled phase of the trial. 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 prior approval manufacturing supplements following a potential NDA approval and the company’s expectations regarding the availability of product supply, statements concerning the timing and success of a potential commercial launch of MYCAPSSA in the United States, and statements regarding the release of top-line results from the MPOWERED Phase 3 trial. 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 prior approval 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 and the impact the ongoing COVID-19 crisis may have on the company’s business, including its expected development, manufacturing, regulatory and commercialization timelines for 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2020, 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	
	March 31, 2020	March 31, 2019
Operating expenses:		
General and administrative	$ 7,582	$ 2,450
Research and development	8,125	6,471
Total operating expenses	15,707	8,921
Loss from operations	(15,707)	(8,921)
Other income, net	(398)	(184)
Loss before income taxes	(15,309)	(8,737)
Provision for income taxes	77	13
Net loss	$ (15,386)	$ (8,750)
Earnings per share of common stock:		
Basic	$ (0.36)	$ (0.36)
Diluted	$ (0.36)	$ (0.36)
Weighted-average shares outstanding:		
Basic	42,187,694	24,466,617
Diluted	42,187,694	24,466,617

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

	March 31, 2020	December 31, 2019
Cash and cash equivalents	$ 42,555	$ 27,855
Marketable securities	36,707	64,520
Prepaid expenses and other current assets	4,877	3,881
Property and equipment, net	590	334
Other assets	1,993	2,236
Total assets	$ 86,722	$ 98,826
Accounts payable	$ 5,450	$ 3,253
Accrued expenses	7,238	7,576
Other current liabilities	716	546
Long-term liabilities	1,575	1,682
Total liabilities	14,979	13,057
Total stockholders' equity	71,743	85,769
Total liabilities and stockholders' equity	$ 86,722	$ 98,826