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, 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 November 5, 2020, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 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 November 5, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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, 2020

Chiasma, Inc.

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

Chiasma Reports Third Quarter 2020 Results and Provides MYCAPSSA Launch Update

Launched MYCAPSSA® in U.S. earlier than expected and recognized first net product revenues in September

Well capitalized to support the MYCAPSSA launch

On track to announce MPOWERED™ Phase 3 trial topline data this month

Company to host conference call today, November 5, 2020 at 5:00pm ET

NEEDHAM, Mass., November 5, 2020 – Chiasma, Inc. (NASDAQ: CHMA), a commercial-stage biopharmaceutical company utilizing its delivery platform technology to develop and commercialize oral therapies to improve the lives of patients with rare diseases on burdensome and painful injections, today announced financial results for the third quarter ended September 30, 2020 and provided an update on its recent phased launch of MYCAPSSA® in the United States as the first and only oral somatostatin analog for the maintenance treatment of people with acromegaly.

Recent Business Highlights and Upcoming Milestones

- Launched MYCAPSSA in September, the first and only oral somatostatin analog (SSA) with the potential to become the new standard of pharmacological care in the long-term maintenance treatment of patients with acromegaly;
- Announced publication of CHIASMA OPTIMAL Phase 3 clinical trial results in the prestigious *Journal of Clinical Endocrinology & Metabolism*;
- Continued to enroll patients in the MACRO registry, the first ever industry-sponsored acromegaly disease state registry in the United States;
- Exited the third quarter with $177.1 million of cash, cash equivalents, marketable securities and restricted cash; and
- MPOWERED Phase 3 clinical trial topline data expected later this month that, if positive, are expected to provide head-to-head data against injectable octreotide and lanreotide and support a planned regulatory submission for MYCAPSSA for the treatment of acromegaly in the European Union.

“I am pleased that we were able to launch MYCAPSSA earlier than expected. I commend the dedicated team at Chiasma for the launch progress we have made to date. During this initial phase, our customer-facing team has made solid progress reaching targeted healthcare providers, generating patient enrollment forms, and gaining access for MYCAPSSA with payers,” stated Raj Kannan, chief executive officer of Chiasma. “As expected, and incorporated into our phased launch plans, headwinds from COVID-19 continue to be challenging; however, we expect strong revenue growth in the fourth quarter of 2020 and beyond.”

Third Quarter 2020 Financial Results

Product Revenues, Net: Net product revenues were approximately $142,000 in the third quarter of 2020, net of sales discounts and allowances, related to MYCAPSSA sales following the early-September launch**.** As is common in rare disease markets with specialized products, healthcare providers initiate a MYCAPSSA prescription by sending a consented patient enrollment form into our dedicated, in-house patient services group, for which the processing time may be up to six weeks or more to convert to a revenue generating patient. Nonetheless, we anticipate that by the end of 2020 over 100 million lives in the United States will be covered on formulary for MYCAPSSA which we believe has the potential to reduce the length of time in converting prescriptions to revenue generating patients.

SG&A Expenses: Selling, general and administrative expenses were $13.0 million for the third quarter ended September 30, 2020, compared with $4.1 million for the same period of 2019. The current year results include $6.6 million of commercial activities, an increase in compensation-related expenses, and increased other administrative costs to support the commercialization of MYCAPSSA in the United States.

R&D Expenses: Research and development expenses were $4.5 million for the third quarter ended September 30, 2020, compared with $4.1 million for the same period of 2019. The increase in current period results was primarily driven by costs associated with our MACRO registry and increased regulatory costs.

Net Loss: For the quarter ended September 30, 2020, net loss was ($18.5) million, or ($0.30) per basic share, compared with ($7.7) million, or ($0.20) per basic share, in the same period of 2019.

Cash Position: Chiasma ended the third quarter with cash, cash equivalents, marketable securities and restricted cash of $177.1 million, compared with $92.4 million as of December 31, 2019. In July and September, the company received an additional $25 million and $15 million, respectively, through our revenue interest finance agreement with Healthcare Royalty Partners, triggered by the FDA approval and first commercial sale of MYCAPSSA, respectively. Additionally, as previously announced in July, Chiasma raised approximately $75 million in net proceeds from our underwritten public offering of common stock and pre-funded warrants.

Conference Call and Webcast Information

Chiasma management will host a conference call and webcast to discuss its third quarter results in more detail today, November 5, 2020, at 5:00 pm ET. The dial-in number in the U.S. / Canada is 855-327-6837; for international participants, the dial-in number is 631-891-4304. For all callers, please refer to Conference ID 10011435. To access the live webcast, please use the following link: http://public.viavid.com/index.php?id=141919

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.

MPOWERED™ Phase 3 Clinical 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 completed enrollment of 146 adult acromegaly patients into the trial in June 2019, of which 92 patients who were deemed 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 in November 2020.

About MYCAPSSA

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

MYCAPSSA (octreotide) delayed-release capsules, for oral use, is a somatostatin analog indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide.

CONTRAINDICATIONS

Hypersensitivity to octreotide or any of the components of MYCAPSSA. Anaphylactoid reactions, including anaphylactic shock, have been reported in patients receiving octreotide.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

MYCAPSSA can cause problems with the gallbladder. Monitor patients periodically. Discontinue if complications of cholelithiasis are suspected.

Blood sugar, thyroid levels, and vitamin B_{12} levels should be monitored and treated accordingly.

Bradycardia, arrhythmia, or conduction abnormalities may occur. Treatment with drugs that have bradycardia effects may need to be adjusted.

ADVERSE REACTIONS

The most common adverse reactions (incidence >10%) are nausea, diarrhea, headache, arthralgia, asthenia, hyperhidrosis, peripheral swelling, blood glucose increased, vomiting, abdominal discomfort, dyspepsia, sinusitis, and osteoarthritis.

DRUG INTERACTIONS

The following drugs require monitoring and possible dose adjustment when used with MYCAPSSA: cyclosporine, insulin, antidiabetic drugs, calcium channel blockers, beta blockers, lisinopril, digoxin, bromocriptine, and drugs mainly metabolized by CYP3A4. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when MYCAPSSA is used with combined oral contraceptives.

Patients taking proton pump inhibitors, H2-receptor antagonists, or antacids concomitantly with MYCAPSSA may require increased dosages of MYCAPSSA.

PREGNANCY

Advise premenopausal females of the potential for an unintended pregnancy.

To report SUSPECTED ADVERSE REACTIONS, contact the product information department at 1-844-312-2462 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*

The full Prescribing Information for MYCAPSSA is available at www.MYCAPSSA.com.

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. Chiasma estimates that approximately 8,000 adult acromegaly patients are chronically treated with somatostatin analog injections in the United States.

About Chiasma

Chiasma is a commercial-stage biopharmaceutical company focused on developing and commercializing oral therapies to improve 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. On June 26, 2020, Chiasma received FDA approval of MYCAPSSA for long-term maintenance therapy in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. MYCAPSSA, the first and only oral somatostatin analog approved by the FDA, is available for commercial sale. 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 expectations relating to MYCAPSSA for the long-term maintenance therapy in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide, statements regarding the commercialization of MYCAPSSA, including its reimbursement and market adoption, statements concerning the commercial or therapeutic potential of MYCAPSSA, including its ability to become a standard of care and the anticipated market acceptance of and access to MYCAPSSA, statements concerning the success of a commercial launch of MYCAPSSA in the United States, statements regarding the company's expectations regarding formulary coverage for MYCAPSSA, statements regarding the release of top-line results from the MPOWERED Phase 3 trial and potential for regulatory filings based on those results, and statements regarding the company's commercial organization and efforts and potential sales and revenue growth. 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 manufacturing supplements to the company's approved new drug

application, the results of any inspections of the company's third-party manufacturers, the company's reliance on third parties to manufacture active pharmaceutical ingredient and commercial octreotide capsules, the company's ability to retain requisite regulatory approvals for the commercial sale of octreotide capsules in the United States, and the timing and costs involved in establishing a commercial organization and launching the sale of MYCAPSSA, and the impact the ongoing COVID-19 pandemic 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 September 30, 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		For the nine months ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Product revenue, net	$ 142	$ —	$ 142	$ —
Cost of goods sold	3	—	3	—
Gross Profit	139	—	139	—
Operating expenses:				
Selling, general and administrative	13,048	4,116	31,295	9,210
Research and development	4,523	4,110	22,320	16,103
Total operating expenses	17,571	8,226	53,615	25,313
Loss from operations	(17,432)	(8,226)	(53,476)	(25,313)
Interest and other income, net	1,122	549	1,648	1,074
Interest expense	(2,126)	—	(3,033)	—
Loss before income taxes	(18,436)	(7,677)	(54,861)	(24,239)
Provision for income taxes	21	6	110	34
Net loss	$ (18,457)	$ (7,683)	$ (54,971)	$ (24,273)
Earnings per share of common stock:				
Basic	$ (0.30)	$ (0.20)	$ (1.13)	$ (0.77)
Diluted	$ (0.30)	$ (0.20)	$ (1.13)	$ (0.77)
Weighted-average shares outstanding:				
Basic	61,459,491	38,490,768	48,685,024	31,569,731
Diluted	61,459,491	38,490,768	48,685,024	31,569,731

Chiasma, Inc.

Condensed Consolidated Balance Sheets Information

(amounts in thousands)

(unaudited)

	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 72,840	$ 27,855
Marketable securities	83,917	64,520
Accounts receivable	179	—
Inventory	8,942	—
Prepaid expenses and other current assets	5,383	3,881
Property and equipment, net	581	334
Other assets	2,419	2,236
Restricted cash	20,300	—
Total assets	$ 194,561	$ 98,826
Accounts payable	$ 7,149	$ 3,253
Accrued expenses	10,275	7,576
Other current liabilities	722	546
Deferred royalty obligation	63,529	—
Long-term liabilities	2,548	1,682
Total liabilities	84,223	13,057
Total stockholders' equity	110,338	85,769
Total liabilities and stockholders' equity	$ 194,561	$ 98,826