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): August 10, 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 August 10, 2020, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 10, 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: August 10, 2020

Chiasma, Inc.

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

Chiasma Reports Second Quarter 2020 Results and Significant Progress on Launch Preparedness

MYCAPSSA® U.S. commercial launch planned for the fourth quarter

On track to announce MPOWERED Phase 3 trial topline data in the fourth quarter

Company to host conference call today, August 10, at 5pm ET

Needham, MA – August 10, 2020 – Chiasma, Inc. (NASDAQ: CHMA), a commercial stage biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2020 and provided a business update.

Recent Business Highlights

- Achieved FDA approval of MYCAPSSA®, the first and only oral somatostatin analog with the potential to become the new standard of pharmacological care in the long-term maintenance treatment of patients with acromegaly.
- Demonstrated longer-term durability of efficacy and safety of MYCAPSSA in the 48-week open-label extension (OLE) of the Phase 3 CHIASMA OPTIMAL study.
- Bolstered a top-tier launch team including the appointment of biopharmaceutical commercial veteran Anand Varadan as EVP, Chief Commercial Officer.
- Secured up to $75 million to support the planned commercial launch of MYCAPSSA through a revenue interest financing agreement with HealthCare Royalty Partners (HCR).
- Raised approximately $75 million of net proceeds through an over-subscribed equity financing.

Anticipated Upcoming 2020 Milestones

- U.S. commercial launch of MYCAPSSA planned to commence in the fourth quarter.
- FDA acceptance and approval of manufacturing supplement to approved MYCAPSSA new drug application (NDA) to include the primary commercial active pharmaceutical ingredient supplier.
- Top-line MPOWERED™ Phase 3 clinical trial results expected to be announced in the fourth quarter.

“We made significant progress since our last quarterly update, most notably our transition to a commercial stage company following the FDA’s approval in June of MYCAPSSA as a novel treatment for acromegaly,” stated Raj Kannan, Chief Executive Officer of Chiasma. “MYCAPSSA is the first and only oral somatostatin analog treatment option in an injectables only market, a key differentiator that we believe is strongly preferred by many patients with acromegaly. We remain optimistic as we prepare for the commercial launch. To that end, we are building a world class customer-facing organization capable of responding to the challenges and opportunities posed by a predominantly remote launch environment.”

“In parallel, we continue to add to the robust dataset for MYCAPSSA. Notably, the data from the 48-week open-label extension of the CHIASMA OPTIMAL trial demonstrated longer-term durability of safety and efficacy of MYCAPSSA and highlights the strong preference of these acromegaly patients for an oral

treatment alternative. We look forward to advancing MYCAPSSA as a preferred treatment option for patients with acromegaly treated with octreotide and lanreotide injectables," Mr. Kannan concluded.

Second Quarter 2020 Financial Results

- **G&A Expenses:** General and administrative expenses were $10.7 million for the second quarter ended June 30, 2020, compared with $2.6 million for the same period of 2019. The current year results include $5.6 million of ongoing pre-commercial activities, an increase in compensation-related expenses, and increased other administrative costs as we prepared for the planned commercialization of octreotide capsules in the U.S. in the fourth quarter of this year.

- **R&D Expenses:** Research and development expenses were $9.7 million for the second quarter ended June 30, 2020, compared with $5.5 million for the same period of 2019. The increase in current period results was primarily driven by the manufacturing of octreotide capsules to support our commercial launch, 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 June 30, 2020, net loss was ($21.1) million, or ($0.50) per basic share, compared with ($7.8) million, or ($0.25) per basic share, in the same period of 2019.

- **Cash Position:** Chiasma ended the second quarter with cash, cash equivalents, marketable securities and restricted cash of $87.1 million, compared with $92.4 million as of December 31, 2019. In April 2020, the company received a $25 million payment, less certain transaction expenses, from Healthcare Royalty Partners under the previously announced revenue interest financing agreement. In July, the company received an additional $25 million from HCR, triggered by FDA approval of MYCAPSSA. Additionally, also in July, Chiasma raised approximately $75 million of net proceeds from an over-subscribed 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 the second quarter results in more detail today, August 10, 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 10010555. To access the live webcast, please use the following link: http://public.viavid.com/index.php?id=141033

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 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 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 fourth quarter of 2020.

About MYCAPSSA

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. MYCAPSSA can cause a serious allergic reaction including anaphylactic shock.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

- Gallbladder abnormalities may occur. Monitor periodically. Discontinue if complications of cholelithiasis are suspected.
- Hypoglycemia or hyperglycemia may occur. Glucose monitoring is recommended and antidiabetic treatment may need adjustment.
- Hypothyroidism may occur. Monitor thyroid levels periodically.
- Bradycardia, arrhythmia or conduction abnormalities may occur. Treatment with drugs that have bradycardia effects may need adjustment.
- Decreased vitamin B12 levels and abnormal Schilling’s tests have been observed in some patients receiving octreotide. Monitor vitamin B12 levels during treatment.

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, oral hypoglycemic agents, beta-blockers, bromocriptine. Counsel women to use an alternative non-hormonal method of contraception or a back-up method when MYCAPSSA is used with combined oral contraceptives.

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 will be made 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. The company estimates that approximately 8,000 adult acromegaly patients are chronically treated with somatostatin analogs in the United States.

About Chiasma

Chiasma is commercial-stage 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 is the first and only oral somatostatin analog approved by the FDA. 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 plans for and the commercialization of MYCAPSSA, statements concerning the commercial or therapeutic potential of MYCAPSSA, including its ability to become a standard of care, and the anticipated market acceptance of MYCAPSSA, statements regarding the data from the open label extension of the CHIASMA OPTIMAL trial, statements regarding the company's expectations relating to the manufacturing supplement it submitted to the FDA 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 and potential for regulatory filings based on those results. 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 supplement to the NDA the company submitted to the FDA, 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

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 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 June 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 six months ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Operating expenses:				
General and administrative	$ 10,665	$ 2,644	$ 18,247	$ 5,094
Research and development	9,672	5,522	17,797	11,993
Total operating expenses	20,337	8,166	36,044	17,087
Loss from operations	(20,337)	(8,166)	(36,044)	(17,087)
Interest and other income, net	128	341	526	525
Interest expense	(907)	—	(907)	—
Loss before income taxes	(21,116)	(7,825)	(36,425)	(16,562)
Provision for income taxes	12	15	89	28
Net loss	$ (21,128)	$ (7,840)	$ (36,514)	$ (16,590)
Earnings per share of common stock:				
Basic	$ (0.50)	$ (0.25)	$ (0.86)	$ (0.59)
Diluted	$ (0.50)	$ (0.25)	$ (0.86)	$ (0.59)
Weighted-average shares outstanding:				
Basic	42,267,507	31,597,698	42,227,601	28,051,856
Diluted	42,267,507	31,597,698	42,227,601	28,051,856

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

	June 30, 2020	December 31, 2019
Cash and cash equivalents	$52,194	$ 27,855
Marketable securities	14,893	64,520
Prepaid expenses and other current assets	3,741	3,881
Property and equipment, net	617	334
Other assets	2,521	2,236
Restricted cash	20,000	—
Total assets	$93,966	$ 98,826
Accounts payable	$ 7,079	$ 3,253
Accrued expenses	8,148	7,576
Other current liabilities	716	546
Deferred royalty obligation	24,601	—
Long-term liabilities	1,444	1,682
Total liabilities	41,988	13,057
Total stockholders' equity	51,978	85,769
Total liabilities and stockholders' equity	$93,966	$ 98,826