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 4, 2021

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 4, 2021, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the fourth quarter and year ended December 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 March 4, 2021
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: March 4, 2021

Chiasma, Inc.

By: /s/ John Doyle
John Doyle
Senior Vice President, Chief Financial Officer

Chiasma Reports Fourth Quarter and Full-Year 2020 Financial Results and Provides Corporate Update

Phased launch of MYCAPSSA® progressing with 2020 net product revenue of $1.1 million

Achieved payor coverage of MYCAPSSA for over 150 million lives

Company to host conference call today, March 4, 2021 at 5:00pm ET

NEEDHAM, Mass., March 4, 2021 – Chiasma, Inc. (NASDAQ: CHMA), a commercial stage biopharmaceutical company utilizing its delivery platform technology to develop and commercialize oral therapies to reduce the burden of chronic injections for people with rare diseases, as evidenced by its recent initiation of a phased U.S. commercial launch of MYCAPSSA® as the first oral therapy for treatment of acromegaly, today announced financial results for the fourth quarter and year ended December 31, 2020 and provided a business update.

Recent Business Highlights

- Commenced U.S. phased launch of MYCAPSSA® in September 2020 with reported 2020 net product revenue of $1.1 million, primarily from the fourth quarter
- Secured payor coverage of MYCAPSSA for over 150 million lives in 2020
- Demonstrated non-inferiority of MYCAPSSA to long-acting injectable somatostatin analogs for maintenance of biochemical response in patients with acromegaly in the top-line results of the MPOWERED Phase 3 study
- Enrolled over 200 acromegaly patients to date, requiring long-term medical therapy into the MACRO disease state registry denoting strong interest in understanding the current state of care
- Complemented the management team with the appointment of John Doyle as Chief Financial Officer
- Exited the fourth quarter with $135.4 million of cash, cash equivalents and marketable securities (exclusive of approximately $20.6 million of restricted cash)

Anticipated Upcoming 2021 Milestones

- Continued growth of MYCAPSSA revenue by building on the U.S. commercial launch progress achieved to date and the planned expansion of the commercial team in 2021 when market conditions warrant
- Presentation of five accepted late-breaker abstracts from the MPOWERED Phase 3 Study planned at the upcoming virtual 2021 Endocrine Society Annual Meeting (ENDO) later this month
- Oral presentation on longer-term efficacy and safety data from the open-label extension of the CHIASMA OPTIMAL Phase 3 trial planned for the upcoming virtual 2021 ENDO Meeting

- Planned submission of the MPOWERED Study results to a peer-reviewed medical journal in 2021
- Submission of a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for MYCAPSSA seeking EU regulatory approval planned for mid-2021

“We continue to gain traction with our phased launch of MYCAPSSA and are encouraged by the positive feedback from physicians and patients,” stated Raj Kannan, Chief Executive Officer of Chiasma. “We made significant progress with payors in covering over 150 million lives, and we have implemented a number of innovative initiatives to both educate our customers and support patients who want to switch to MYCAPSSA.”

“With respect to the COVID-19 pandemic we have continued to experience a challenging environment with reduced patient visits to their physicians and limited access to customers for our commercial team. In anticipation of some of these headwinds, we implemented digital and virtual programs and also phased the hiring of our customer-facing team with the final phase of hiring planned for when market conditions warrant.” concluded Mr. Kannan.

Fourth Quarter and Full-Year 2020 Financial Results

Product Revenue, Net: Net product revenue related to the sales of MYCAPSSA were approximately $1.0 million for the fourth quarter of 2020 marking MYCAPSSA’s first full quarter of sales. Net product revenue related to the sales of MYCAPSSA for the year ended December 31, 2020 were $1.1 million following the September 2020 launch.

SG&A Expenses: Selling, general and administrative expenses were $13.6 million for the fourth quarter of 2020 and $44.9 million for 2020, compared to $5.9 million for the fourth quarter of 2019 and $15.1 million for 2019. The increase of $7.7 million and $29.8 million, respectively, was driven by commercial activities, an increase in personnel-related expenses, and other administrative costs to support the commercialization of MYCAPSSA in the U.S.

R&D Expenses: Research and development expenses were $4.5 million for the fourth quarter of 2020 compared to $6.4 million for the fourth quarter of 2019. The decrease of $1.9 million was primarily driven by a decrease in clinical trial expenses. Research and development expenses for 2020 were $26.8 million compared to $22.5 million for 2019. The increase of $4.3 million was primarily related to the manufacturing of MYCAPSSA to support our U.S. commercial launch, which were expensed prior to FDA approval.

Net Loss: Net loss for the fourth quarter of 2020 was ($19.8) million, or ($0.32) per basic share, as compared with ($12.0) million, or ($0.29) per basic share for the fourth quarter of 2019. Net loss for 2020 was ($74.8) million, or ($1.43) per basic share, as compared with ($36.3) million, or ($1.06) per basic share, for 2019.

Cash Position: Chiasma ended 2020 with cash, cash equivalents, and marketable securities of $135.4 million (excluding $20.6 million of restricted cash), as compared with $92.4 million for the year ended December 31, 2019.

2021 Financial Guidance: As previously stated, operating expenses for the full year 2021 are expected to be in a range of $80 million to $90 million, including estimated stock-based compensation expense in a range of $5 million to $6 million. This guidance is based on the company’s current U.S. commercial plans and excludes expenditures related to potential EU launch preparations of MYCAPSSA or additional new development programs.

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 4, 2021, at 5:00 pm ET. The dial-in number in the U.S. / Canada is 877-407-4018; for international participants, the dial-in number is 201-689-8471. For all callers, please refer to Conference ID 13715763. To access the live webcast, please use the following link: http://public.viavid.com/index.php?id=143291

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 the webcast will be available on the company's website approximately two hours after the event. The archived webcast will be available for one year.

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. In June 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, the commercialization of MYCAPSSA, including potential market adoption and commercial success, the commercial or therapeutic potential of MYCAPSSA, including its ability to become a standard of care and the anticipated market acceptance and third-party reimbursement of and access to MYCAPSSA, the expansion of the customer-facing team, the data from the MPOWERED trial and whether the data will support the submission of a marketing authorization application (MAA) to the European Medicines Agency (EMA) for MYCAPSSA in the European Union and ultimately regulatory approval, the presentation and publication plans for the data from the MPOWERED trial, and the company's financial guidance, including operating expense and cash runway guidance. 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 or EMA, the sufficiency of the data collected from the company's clinical trials to obtain regulatory approval in the European Union or elsewhere, the company's ability to retain requisite regulatory approvals for the continued commercial sale of MYCAPSSA in the United States, the timing and costs involved in establishing and maintaining 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 Annual Report on Form 10-K for the year ended December 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		For the twelve months ended	
	December 31, 2020	December 31, 2019	December 31, 2020	December 31, 2019
Product revenue, net	$ 964	$ —	$ 1,106	$ —
Cost of goods sold	58	—	61	—
Gross Profit	906	—	1,045	—
Operating expenses:				
Selling, general and administrative	13,597	5,912	44,892	15,122
Research and development	4,482	6,354	26,802	22,457
Total operating expenses	18,079	12,266	71,694	37,579
Loss from operations	(17,173)	(12,266)	(70,649)	(37,579)
Interest and other income, net	178	469	1,826	1,543
Interest expense	(2,839)	—	(5,872)	—
Loss before income taxes	(19,834)	(11,797)	(74,695)	(36,036)
Provision (benefit) for income taxes	(26)	250	84	284
Net loss	$ (19,808)	$ (12,047)	$ (74,779)	$ (36,320)
Earnings per share of common stock:				
Basic	$ (0.32)	$ (0.29)	$ (1.43)	$ (1.06)
Diluted	$ (0.32)	$ (0.29)	$ (1.43)	$ (1.06)
Weighted-average shares outstanding:				
Basic	62,807,536	42,022,030	52,234,945	34,204,284
Diluted	62,807,536	42,022,030	52,234,945	34,204,284

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

	December 31, 2020	December 31, 2019
Cash and cash equivalents	$ 15,462	$ 27,855
Marketable securities	119,959	64,520
Accounts receivable	538	—
Inventory	10,955	—
Prepaid expenses and other current assets	6,444	3,881
Property and equipment, net	534	334
Other assets	1,883	2,236
Restricted cash	20,563	—
Total assets	$ 176,338	$ 98,826
Accounts payable	$ 4,240	$ 3,253
Accrued expenses	11,858	7,576
Other current liabilities	633	546
Deferred royalty obligation	63,548	—
Long-term liabilities	4,274	1,682
Total liabilities	84,553	13,057
Total stockholders' equity	91,785	85,769
Total liabilities and stockholders' equity	$ 176,338	$ 98,826