

**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): June 26, 2020

Chiasma, Inc.
(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction
of incorporation)

001-37500
(Commission
File Number)

76-0722250
(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 8.01 Other Events.

On June 26, 2020, Chiasma, Inc. issued a press release announcing that the United States Food and Drug Administration has approved MYCAPSSA® (octreotide) capsules, an oral somatostatin analog, for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. A copy of the press release is attached hereto as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|--|
| 99.1 | Press Release of Chiasma, Inc. dated June 26, 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: June 26, 2020

Chiasma, Inc.

By: /s/ Mark J. Fitzpatrick

Mark J. Fitzpatrick

President



Chiasma Announces FDA Approval of MYCAPSSA® (Octreotide) Capsules, the First and Only Oral Somatostatin Analog

MYCAPSSA is indicated for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide

Conference call and webcast scheduled today at 2 pm ET

Needham, MA – June 26, 2020 – Chiasma, Inc. (NASDAQ: CHMA), a commercial stage biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) approved MYCAPSSA® (octreotide) capsules for long-term maintenance treatment in acromegaly patients who have responded to and tolerated treatment with octreotide or lanreotide. MYCAPSSA is the first and only oral somatostatin analog (SSA) approved by the FDA and the first product approved by the FDA utilizing Chiasma's Transient Permeability Enhancer (TPE®) technology. Acromegaly is a rare chronic disease often caused by a benign pituitary tumor and characterized by excess production of growth hormone and insulin-like growth factor-1 hormone that is frequently treated with chronic burdensome injections. If left untreated, acromegaly can lead to serious, and sometimes life-threatening medical conditions. The company estimates that approximately 8,000 patients are on injectable SSAs in the U.S.

"The FDA approval of MYCAPSSA represents a major therapeutic advancement for people with acromegaly and validation of our TPE delivery platform," said Raj Kannan, chief executive officer of Chiasma. "We are grateful to patients, healthcare providers, advocates and clinical trial investigators, as well as our employees who have worked diligently to bring MYCAPSSA to people with acromegaly. As we move into this next exciting phase as a commercial company, we are prepared to execute on a successful U.S. launch by working with healthcare providers to bring MYCAPSSA to as many patients who could benefit from it."

"People living with acromegaly experience many challenges associated with injectable therapies and are in need of new treatment options," said Jill Sisco, president of the Acromegaly Community, Inc. "The entire acromegaly community has long awaited oral therapeutic options and it is gratifying to see that the FDA has now approved the first oral SSA therapy with the potential to make a significant impact in the lives of people with acromegaly and their caregivers."

"For patients living with acromegaly and for their physicians and nurses, the FDA approval of oral octreotide capsules ushers in a new era of treatment," said Shlomo Melmed, MB, ChB, MACP, executive vice president of Academic Affairs and dean of the Medical Faculty at Cedars-Sinai. "Over the last 30 years treating physicians have come to trust octreotide in the treatment of acromegaly, and an oral alternative allows patients to avoid many of the documented treatment burdens associated with injections."

"Results from the pivotal Phase 3 CHIASMA OPTIMAL clinical trial are encouraging for patients with acromegaly," said Susan Samson, M.D., Ph.D., FRCPC, FACE, principal investigator of the CHIASMA OPTIMAL clinical trial. "Based on data from the CHIASMA OPTIMAL trial showing patients on therapy being able to maintain mean IGF-1 levels within the normal range at the end of treatment, I believe oral octreotide capsules hold meaningful promise for patients with this disease and will address a long-standing unmet treatment need."



The company expects MYCAPSSA to be commercially available in the fourth quarter of 2020 subject to FDA's timely approval of a planned manufacturing supplement to the approved NDA. Chiasma plans to scale-up its customer facing team in sales, patient services and market access to approximately 45 employees. To help patients switch to MYCAPSSA, Chiasma plans to offer an array of patient support services ranging from assistance with insurance providers and specialty pharmacies to giving patients support to help incorporate MYCAPSSA seamlessly into their daily living. The company believes that patients, physicians, nurses, and payers will appreciate the significant benefits provided by MYCAPSSA. To ensure patients have broad access to this innovation, Chiasma plans to price MYCAPSSA competitively with the fastest growing SSA in the U.S. acromegaly market reflecting the value provided by MYCAPSSA to the health care system.

The FDA approval of MYCAPSSA was based on the positive results of the randomized, double-blind, placebo-controlled, nine-month Phase 3 CHIASMA OPTIMAL clinical trial of octreotide capsules, which met the primary endpoint and all four secondary endpoints, as well as safety data from all of Chiasma's Phase 3 clinical trials of MYCAPSSA. The following important adverse reactions are described in the MYCAPSSA prescribing information: cholelithiasis and complications of cholelithiasis; hyperglycemia and hypoglycemia; thyroid function abnormalities; cardiac function abnormalities; and decreased vitamin B12 levels and abnormal Schilling's tests.

Conference Call and Webcast Information

Chiasma management will host a conference call and webcast to discuss the FDA approval of MYCAPSSA and provide a business update today, June 26, 2020, at 2:00 pm ET. The dial-in number in the U.S. / Canada is 1-877-407-4018; for international participants, the dial-in number is 1-201-689-8471. For all callers, please refer to Conference ID 13705297. To access the live webcast, please use the following link: <http://public.viavid.com/index.php?id=140270>

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 (octreotide or lanreotide) based upon levels of IGF-1, a byproduct of increased growth hormone (GH), levels caused by acromegaly (average IGF-1 $\leq 1.0 \times$ 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 $\geq 1.3 \times$ 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 $\leq 1.0 \times \text{ULN}$ (assessed at weeks 34 and 36). Hierarchical secondary endpoints 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 $> 1.0 \times \text{ULN}$; time to loss of response: IGF-1 of 2 consecutive visits is $\geq 1.3 \times \text{ULN}$; and proportion of patients requiring reversion to prior treatment. As previously announced, CHIASMA OPTIMAL met the primary endpoint and all secondary endpoints.

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 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 the commercial plans for and the commercialization of MYCAPSSA, including its pricing, reimbursement and market adoption, statements concerning the commercial or therapeutic potential of MYCAPSSA and the anticipated market acceptance of MYCAPSSA, statements regarding the company's plan to submit manufacturing supplements 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 concerning the number of customer-facing employees and the timing of their hiring. 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 any manufacturing supplements to the NDA the company plans to 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 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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