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 5, 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 May 5, 2021, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2021 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 5, 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: May 5, 2021

Chiasma, Inc.

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

Chiasma Reports First Quarter Financial Results and Announced Agreement to Merge with Amryt

Announced agreement to merge with Amryt

Combination to create a global commercial stage rare and orphan disease leader with a diversified portfolio of therapies and a meaningful late-stage development pipeline

Q1 2021 Net Product Revenues of $1.9M, a 100% increase over Q4 2020

Achieved payor coverage for MYCAPSSA in over 185M lives

Submitted an Investigational New Drug (IND) application for the study of MYCAPSSA in patients with carcinoid syndrome associated with Neuroendocrine Tumors (NET)

NEEDHAM, Mass., May 5, 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 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 first quarter ended March 31, 2021 and provided a business update.

Recent Business Highlights

- Announced entry into a definitive merger agreement for the acquisition of the company by Amryt Pharma plc, a biopharmaceutical company focused on acquiring, developing and delivering innovative treatments to help improve the lives of patients with rare and orphan diseases
- Generated MYCAPSSA net product revenue of $1.9 million in Q1 2021
- Increased payor coverage of MYCAPSSA to over 185 million lives
- Submitted an Investigational New Drug (IND) application to the FDA for a Phase 1 relative bioavailability study followed by a single Phase 3 randomized, double-blind, placebo-controlled study of MYCAPSSA in patients with carcinoid syndrome associated with NET. These studies are designed to support a potential modified 505(b)(2) regulatory pathway.
- Exited the first quarter with $115.0 million of cash, cash equivalents and marketable securities

“While we continue to experience customer access challenges related to COVID-19, we are pleased with the launch progress we made in the first quarter and it reiterates our intent of making MYCAPSSA the new standard of pharmacological care,” stated Raj Kannan, Chief Executive Officer of Chiasma. “During the quarter we saw an increased launch momentum as we continued to expand payor coverage for MYCAPSSA. Additionally, we submitted an IND to begin the process of expanding the potential benefits of MYCAPSSA in patients with carcinoid syndrome.”

“Importantly, we believe the merger with Amryt represents a transformational moment in unlocking and accelerating the potential value of Chiasma efficiently for both our patients and for our shareholders,” concluded Mr. Kannan.

First Quarter 2021 Financial Results

Product Revenue, Net: Net product revenue related to the sales of MYCAPSSA were $1.9 million for the first quarter of 2021, as compared to $1.0 million for the fourth quarter of 2020, MYCAPSSA's first full quarter of sales.

SG&A Expenses: Selling, general and administrative expenses were $15.7 million for the first quarter of 2021, as compared with $7.6 million for the first quarter of 2020. The increase was driven by commercial activities, an increase in personnel-related expenses, and other administrative costs to support the launch and commercialization of MYCAPSSA® in the U.S., and diligence costs associated with merger agreement with Amryt.

R&D Expenses: Research and development expenses were $4.2 million for the first quarter of 2021 compared to $8.1 million for the first quarter of 2020. The decrease was primarily related to the costs associated with the manufacturing of octreotide capsules to support the Company's U.S. commercial launch, which were expensed prior to FDA approval of MYCAPSSA in June 2020.

Net Loss: Net loss for the first quarter of 2021 was ($30.5) million, or ($0.49) per basic share, as compared with ($15.4) million, or ($0.36) per basic share for the first quarter of 2020.

Cash Position: Chiasma ended the first quarter 2021 with cash, cash equivalents, and marketable securities of $115.0 million, as compared with $135.4 million as of December 31, 2020.

Conference Call Information

Given the recently announced agreement for Chiasma to be acquired by Amryt, Chiasma will not be hosting a conference call.

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 Neuroendocrine Tumors

NETs arise from neuroendocrine cells throughout the body, most commonly in the gastrointestinal tract, lung, and rarely, the pancreas. While well differentiated neuroendocrine tumors are known to be slow growing, they are often asymptomatic in early stages leading to a substantial number of patients being diagnosed when the tumors have already spread regionally or distantly. Capable of secreting hormones and bioactive amines, approximately 19% of patients have carcinoid syndrome characterized by secretory diarrhea and flushing. With an annual incidence rate of 6.98 per 100,000, it is estimated there are greater than 170,000 individuals living with a diagnosis of NET 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.

Important Additional Information and Where to Find It

In connection with the proposed transaction, Amryt intends to file with the Securities and Exchange Commission (the "SEC") a Registration Statement on Form F-4 that will include a proxy statement of Chiasma and that also constitutes a prospectus of Amryt, and each of Chiasma and Amryt may file with the SEC other documents regarding the proposed transaction. This press release is not a substitute for the proxy statement/prospectus or registration statement or any other document that Amryt or Chiasma may file with the SEC. The definitive proxy statement/prospectus (if and when available) will be mailed to stockholders of Chiasma. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE REGISTRATION STATEMENT ON FORM F-4 AND THE PROXY STATEMENT/PROSPECTUS, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THOSE DOCUMENTS AND ANY OTHER RELEVANT DOCUMENTS TO BE FILED WITH THE SEC IN CONNECTION WITH THE PROPOSED TRANSACTION, IF AND WHEN THEY BECOME AVAILABLE, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT AMRYT, CHIASMA AND THE PROPOSED TRANSACTION.

Investors and security holders may obtain copies of these documents, once such documents are filed with the SEC, free of charge through the website maintained by the SEC at www.sec.gov or from Amryt at its website, https://amrytpharma.com, or from Chiasma at its website, https://chiasma.com. Documents filed with the SEC by Amryt will be available free of charge by accessing Amryt's website under the heading Investors, or, alternatively, by contacting Amryt's Investor Relations department at ir@amrytpharma.com, and documents filed with the SEC by Chiasma will be available free of charge by accessing Chiasma's website at https://chiasma.com under the heading News and Investors or, alternatively, by contacting Chiasma's Investor Relations department at investor.relations@chiasmapharma.com.

No Offer or Solicitation

This press release does not constitute an offer to sell or the solicitation of an offer to buy any securities nor a solicitation of any vote or approval with respect to the proposed transaction or otherwise. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the U.S. Securities Act of 1933, as amended, and otherwise in accordance with applicable law.

Participants in Solicitation

Amryt and Chiasma and certain of their respective directors and executive officers and other members of management and employees may be deemed to be participants in the solicitation of proxies from the stockholders of Chiasma in respect of the proposed transaction under the rules of the SEC.

Information about Chiasma's directors and executive officers is available in Chiasma's definitive proxy statement dated April 26, 2021 for its 2021 Annual Meeting of Stockholders. Information about Amryt's directors and executive officers is available in Amryt's Registration Statement on Form F-1 filed with the SEC on June 23, 2020, as amended. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the proxy statement/prospectus and other relevant materials to be filed with the SEC regarding the proposed transaction when they become available. Investors should read the proxy statement/prospectus carefully when it becomes available before making any voting or investment decisions. You may obtain free copies of these documents from Chiasma or Amryt using the sources indicated above.

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 proposed acquisition of the company by Amryt, the potential development of MYCAPSSA as a treatment for neuroendocrine tumors, 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 and the commercial or therapeutic potential of MYCAPSSA. 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: uncertainties related to the timing and occurrence of the closing of the proposed acquisition of the company by Amryt, the reaction to the proposed acquisition by our business partners as well as our customers and patients, the reaction by competitors to the proposed acquisition, the retention of our employees, Amryt's plans for us, the future growth of our and Amryt's businesses and the possibility that integration following the proposed acquisition may be more difficult than expected; the content and timing of decisions made by the FDA or EMA, 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, 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, 2021	March 31, 2020
Product revenue, net	$ 1,924	$ —
Cost of goods sold	67	—
Gross Profit	1,857	—
Operating expenses:		
Selling, general and administrative	15,698	7,582
Research and development	4,199	8,125
Total operating expenses	19,897	15,707
Loss from operations	(18,040)	(15,707)
Interest and other income (loss), net	(9,583)	398
Interest expense	(2,873)	—
Loss before income taxes	(30,496)	(15,309)
Provision for income taxes	52	77
Net loss	$ (30,548)	$ (15,386)
Earnings per share of common stock:		
Basic	$ (0.49)	$ (0.36)
Diluted	$ (0.49)	$ (0.36)
Weighted-average shares outstanding:		
Basic	62,831,141	42,187,694
Diluted	62,831,141	42,187,694

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

	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 24,576	$ 15,462
Marketable securities	90,457	119,959
Accounts receivable	1,015	538
Inventory	14,381	10,955
Prepaid expenses and other current assets	6,603	6,444
Property and equipment, net	487	534
Other assets	1,744	1,883
Restricted cash	20,272	20,563
Total assets	$159,535	$ 176,338
Accounts payable	$ 6,356	$ 4,240
Accrued expenses	10,338	11,858
Other current liabilities	625	633
Deferred royalty obligation	73,368	63,548
Long-term liabilities	6,160	4,274
Total liabilities	96,847	84,553
Total stockholders' equity	62,688	91,785
Total liabilities and stockholders' equity	$159,535	$ 176,338