
**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 10, 2018

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.)

460 Totten Pond Rd, Suite 530
Waltham, MA
(Address of principal executive offices)

02451
(Zip Code)

Registrant's telephone number, including area code (617) 928-5300

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))

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 10, 2018, Chiasma, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2018 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Chiasma, Inc. dated May 10, 2018

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 10, 2018

Chiasma, Inc.

By: /s/ Mark J. Fitzpatrick

Mark J. Fitzpatrick

President, Chief Executive Officer, and Director



Chiasma Reports First Quarter 2018 Results

MYCAPSSA Phase 3 trials progressing on track

WALTHAM, Mass., May 10, 2018 — Chiasma, Inc. (NASDAQ: CHMA), a clinical-stage biopharmaceutical company focused on improving the lives of patients with rare and serious chronic diseases, today reported financial results for the first quarter ended March 31, 2018.

“We continue to execute on our plan to advance octreotide capsules, conditionally trade-named MYCAPSSA[®], as a maintenance treatment for adult patients with acromegaly,” said Mark Fitzpatrick, president and CEO of Chiasma. “Our two Phase 3 clinical trials remain on track as we drive toward potential submissions for approval of MYCAPSSA in both the United States and the European Union.”

The Company expects that its existing cash and investments will be sufficient to fund its operations through the anticipated release of top-line data from the CHIASMA OPTIMAL clinical trial by the end of 2019 while supporting the MPOWERED trial in parallel.

CHIASMA OPTIMAL Phase 3 Trial

Chiasma is conducting a randomized, double-blind, placebo-controlled, nine-month clinical trial in 50 adult acromegaly patients (at least 20% of whom must be recruited from the United States) whose disease is biochemically controlled, based upon levels of IGF-1, a byproduct of increased growth hormone (GH) levels caused by acromegaly, on injectable somatostatin analogs at baseline (average IGF-1 ≤ 1.0 x upper limit of normal (ULN)). The patients also must have confirmed active acromegaly following their last surgical intervention based upon an elevated IGF-1 at that time of ≤ 1.3 x ULN. The trial is being randomized on a 1:1 basis to octreotide capsules or placebo. Patients are being dose titrated from 40 mg per day to up to a maximum of 80 mg per day, equaling two capsules in the morning and two capsules in the evening. Patients meeting predefined biochemical failure criteria in either treatment arm during the course of the trial will be considered treatment failures and revert to their original treatment of injections and will be monitored for the remainder of the trial. The primary endpoint of the trial is the proportion of patients who maintain their biochemical response compared to placebo at the end of the nine-month, double-blind, placebo-controlled period as measured using the average of the last two IGF-1 levels ≤ 1.0 x ULN.

Hierarchical secondary endpoints that will be considered by the FDA in evaluating the totality of evidence for octreotide capsules treatment effect include: proportion of

patients who maintain GH response at week 36, compared to screening; time to loss of response of IGF-1 > 1.0 × ULN; time to loss of response of IGF-1 > 1.3 × ULN; change from screening to end of treatment in mean GH; and change in IGF-1 from baseline to end of treatment.

MPOWERED™ Phase 3 Trial

Chiasma is conducting an international Phase 3 clinical trial under a protocol accepted by the European Medicines Agency (EMA) for the Company's octreotide capsules product candidate for the maintenance therapy of adult patients with acromegaly. The trial, referred to as MPOWERED (Maintenance of Acromegaly Patients with Octreotide Capsules Compared With Injections – Evaluation of Response Durability), is a global, randomized, open-label and active-controlled, 15-month trial. It is expected to enroll approximately 130 adult acromegaly patients, of which it expects to randomize at least 80 patients who are responders to octreotide capsules following a six-month run-in to either octreotide capsules or injectable somatostatin receptor ligands (octreotide or lanreotide), and then followed for an additional nine months. The trial was initiated in March 2016 and 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 anticipates the release of top-line data from this Phase 3 clinical trial in 2020.

First Quarter 2018 Financial Results

- **G&A Expenses:** General and administrative expenses were \$2.4 million for the first quarter ended March 31, 2018, compared with \$2.5 million for the same period of 2017. The decrease was primarily due to the reduction in costs following the November 2017 termination of our office facility lease in Waltham, MA and was partially offset by increased legal fees.
- **R&D Expenses:** Research and development expenses were \$4.9 million for the quarter ended March 31, 2018, compared with \$4.7 million for the same period of 2017. The increase was primarily due to costs related to the CHIASMA OPTIMAL clinical trial which was initiated in September 2017 and was partially offset by reduced personnel costs associated with the transition of the Company's former Chief Development Officer from a full-time employee to board of director member of both Chiasma and its Israeli subsidiary.
- **Net Loss:** For the quarter ended March 31, 2018, net loss was (\$7.0) million, or (\$0.29) per basic share, unchanged from the same period of 2017.

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- **Cash Position:** Cash, cash equivalents and marketable securities as of March 31, 2018 were \$60.5 million, compared with \$66.9 million as of December 31, 2017, primarily reflecting the Company's operating expenditures for the first quarter of 2018. The Company continues to expect to have a cash and investment balance of at least \$35.0 million at the end of 2018 and its existing cash, cash equivalents and marketable securities to fund operations through the anticipated release of top-line CHIASMA OPTIMAL data by the end of 2019 while supporting its MPOWERED trial in parallel.

About Chiasma

Chiasma is focused on improving 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. The Company recently initiated CHIASMA OPTIMAL, its third Phase 3 clinical trial for its octreotide capsules product candidate, conditionally trade-named MYCAPSSA®, for the maintenance therapy of adult patients with acromegaly in whom prior treatment with somatostatin analogs has been shown to be effective and tolerated following agreement with the FDA on the design of the trial. Chiasma is headquartered in Waltham, 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 development of octreotide capsules, conditionally named MYCAPSSA, for the treatment of acromegaly, the Company's efforts to potentially obtain regulatory approval in the United States by conducting the Phase 3 CHIASMA OPTIMAL clinical trial under a Special Protocol Assessment, the Company's efforts to potentially obtain regulatory approval in the European Union by conducting the ongoing MPOWERED Phase 3 clinical trial, the Company's estimate that 130 patients will be required for the MPOWERED trial, the timing of receipt and announcement of top-line and other clinical data and submission of regulatory filings, including the Company's ability to release top-line data from the CHIASMA OPTIMAL trial by the end of 2019 and the Company's ability to release top-line data from the MPOWERED trial in 2020, and the Company's cash forecasts, including its expected cash and investment balances as of the end of 2018 and the expectation that it has sufficient existing cash and investments on hand to fund its operations through its anticipated release of top-line

data from the Phase 3 CHIASMA OPTIMAL clinical trial by the end of 2019 while supporting the MPOWERED trial in parallel. Any forward-looking statements in this press release are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. For a discussion of these and other risks and uncertainties, and other important factors, any of which could cause our 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, 2018 filed with the Securities and Exchange Commission (SEC) on May 10, 2018, 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.

Contact:

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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, 2018	March 31, 2017
Operating expenses:		
General and administrative	\$ 2,434	\$ 2,460
Research and development	4,863	4,655
Total operating expenses	<u>7,297</u>	<u>7,115</u>
Loss from operations	(7,297)	(7,115)
Other income, net	(230)	(160)
Loss before income taxes	(7,067)	(6,955)
Provision (benefit) for income taxes	(24)	65
Net loss	<u>\$ (7,043)</u>	<u>\$ (7,020)</u>
Earnings per share of common stock:		
Basic	<u>\$ (0.29)</u>	<u>\$ (0.29)</u>
Diluted	<u>\$ (0.29)</u>	<u>\$ (0.29)</u>
Weighted-average shares outstanding:		
Basic	<u>24,381,924</u>	<u>24,359,584</u>
Diluted	<u>24,381,924</u>	<u>24,359,584</u>

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

	<u>March 31, 2018</u>	<u>December 31, 2017</u>
Cash and cash equivalents	\$ 15,248	\$ 14,603
Marketable securities	45,250	52,336
Prepaid expenses and other current assets	1,688	1,768
Property and equipment, net	175	193
Other assets	986	983
Total assets	<u>\$ 63,347</u>	<u>\$ 69,883</u>
Accounts payable	\$ 2,295	\$ 1,017
Accrued expenses	4,409	4,033
Other current liabilities	—	1,695
Long-term liabilities	586	664
Total liabilities	7,290	7,409
Total stockholders' equity	56,057	62,474
Total liabilities and stockholders' equity	<u>\$ 63,347</u>	<u>\$ 69,883</u>