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 9, 2018

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.)

460 Totten Pond Rd, Suite 530 Waltham, MA	02451
(Address of principal executive offices)	(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 August 9, 2018, Chiasma, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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

Exhibit No.	Description
99.1	Press Release of Chiasma, Inc. dated August 9, 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: August 9, 2018

Chiasma, Inc.

By: /s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
President, Chief Executive Officer, and Director

Exhibit 99.1

Chiasma Reports Second Quarter 2018 Results

Recent Highlights Include Completion of Enrollment of MPOWERED Phase 3 Trial and 50% Randomization in CHIASMA OPTIMAL Phase 3 Trial

WALTHAM, Mass., August 9, 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 second quarter ended June 30, 2018 and provided a business update.

"We have made meaningful progress on our plan to advance the development of octreotide capsules, conditionally trade-named MYCAPSSA®, as an oral maintenance treatment for adult patients with acromegaly," said Mark Fitzpatrick, president and CEO of Chiasma. "We successfully enrolled 135 acromegaly patients into the six-month run-in phase of our MPOWERED Phase 3 trial, and we now expect to complete this trial in Q4 2019, with release of top-line data by early 2020. We also surpassed 50% enrollment in our CHIASMA OPTIMAL Phase 3 trial, an important step toward our goal of submitting a New Drug Application with the FDA. We strongly believe in MYCAPSSA as a potential new treatment option for adults with acromegaly, and we are encouraged by the achievement of these important milestones."

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 in Q4 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 of octreotide capsules which is expected to enroll 50 adult acromegaly patients (at least 20% of whom must be recruited from the United States) under a Special Protocol Assessment with the U.S. Food and Drug Administration (FDA). The trial, referred to as CHIASMA OPTIMAL, is enrolling acromegaly patients 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 $\leq 1.0 \times$ 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 $\geq 1.3 \times$ 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 × ULN. Chiasma continues to anticipate more than 50 clinical sites will be dedicated to CHIASMA OPTIMAL. Chiasma expects the trial to complete randomization by the end of 2018 and anticipates the release of top-line data from this Phase 3 clinical trial in Q4 2019.

MPOWERED™ Phase 3 Trial

Chiasma is also conducting an international Phase 3 clinical trial of octreotide capsules for the maintenance therapy of adult patients with acromegaly under a protocol accepted by the European Medicines Agency (EMA). The trial, referred to as MPOWERED, is a global, randomized, open-label and active-controlled, 15-month trial. Chiasma has completed enrollment in July 2018 with 135 adult acromegaly patients entered into the run-in phase of the trial, 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 trial to be completed in Q4 2019 and expects to release top-line data from this Phase 3 clinical trial by early 2020.

Second Quarter 2018 Financial Results

- **G&A Expenses**: General and administrative expenses were $2.6 million for the second quarter ended June 30, 2018, compared with $2.6 million for the same period of 2017. The current period results include increased legal fees which were primarily offset by a reduction in costs following the November 2017 termination of the Company's office facility lease in Waltham, MA.
- **R&D Expenses**: Research and development expenses were $6.3 million for the quarter ended June 30, 2018, compared with $4.3 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 the MPOWERED trial

which completed enrollment into the six-month run-in phase in July 2018 and were partially offset by reduced personnel costs associated with the transition of the Company's former Chief Development Officer from a full-time employee to member of the board of directors of both Chiasma and its Israeli subsidiary.

- **Net Loss**: For the quarter ended June 30, 2018, net loss was ($8.7) million, or ($0.36) per basic share, compared with ($6.9) million, or ($0.28) per basic share, in the same period of 2017.
- **Cash Position**: Cash, cash equivalents and marketable securities as of June 30, 2018 were $54.6 million, compared with $66.9 million as of December 31, 2017, primarily reflecting the Company's operating expenditures for the first six months 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 in Q4 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. In September 2017, the Company 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 through a special protocol assessment. 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 ability to randomize at least 80 patients who are responders to octreotide capsules in 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 in the fourth quarter of 2019 and the Company's ability to release top-line data from the MPOWERED trial by early 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 in Q4 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 June 30, 2018 filed with the Securities and Exchange Commission (SEC) on August 9, 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.

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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, 2018	June 30, 2017	June 30, 2018	June 30, 2017
Operating expenses:				
General and administrative	$ 2,627	$ 2,641	$ 5,061	$ 5,101
Research and development	6,305	4,279	11,168	8,934
Total operating expenses	8,932	6,920	16,229	14,035
Loss from operations	(8,932)	(6,920)	(16,229)	(14,035)
Other income, net	(280)	(204)	(510)	(364)
Loss before income taxes	(8,652)	(6,716)	(15,719)	(13,671)
Provision (benefit) for income taxes	21	138	(3)	203
Net loss	$ (8,673)	$ (6,854)	$ (15,716)	$ (13,874)
Earnings per share of common stock:				
Basic	$ (0.36)	$ (0.28)	$ (0.64)	$ (0.57)
Diluted	$ (0.36)	$ (0.28)	$ (0.64)	$ (0.57)
Weighted-average shares outstanding:				
Basic	24,384,283	24,359,584	24,383,123	24,359,584
Diluted	24,384,283	24,359,584	24,383,123	24,359,584

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

	June 30, 2018	December 31, 2017
Cash and cash equivalents	$ 13,844	$ 14,603
Marketable securities	40,781	52,336
Prepaid expenses and other current assets	1,175	1,768
Property and equipment, net	153	193
Other assets	982	983
Total assets	$ 56,935	$ 69,883
Accounts payable	$ 2,529	$ 1,017
Accrued expenses	5,648	4,033
Other current liabilities	—	1,695
Long-term liabilities	558	664
Total liabilities	8,735	7,409
Total stockholders' equity	48,200	62,474
Total liabilities and stockholders' equity	$ 56,935	$ 69,883