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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of The Securities Exchange Act of 1934

**Date of Report (Date of Earliest Event Reported): January 8, 2018**

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**Chiasma, Inc.**

(Exact name of registrant as specified in its charter)

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**DELAWARE**  
(State or other jurisdiction  
of incorporation)

**001-37500**  
(Commission  
File Number)

**76-0722250**  
(I.R.S. Employer  
Identification No.)

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

**02451**  
(Zip Code)

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

**275 Wyman Street, Suite 250, Waltham, MA**  
(Former name or former address, if changed since last report)

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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))

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.

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**Item 2.02 Results of Operations and Financial Condition.**

On January 8, 2018, Chiasma, Inc. (the “Company”) issued a press release providing a year-end corporate update and preliminary 2018 outlook, which press release included the Company’s preliminary approximate cash, cash equivalents and marketable securities as of December 31, 2017. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

**Item 7.01 Other Events.**

Reference is made to, and there is hereby incorporated by reference into this Item 7.01, the information set forth above under “Item 2.02. Results of Operations and Financial Condition” relating to preliminary approximate cash, cash equivalents and marketable securities as of December 31, 2017.

The information in this Report on Form 8-K and Exhibit 99.1 attached hereto 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	<a href="#">Press release issued by Chiasma, Inc. dated January 8, 2018, furnished hereto.</a>

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**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: January 8, 2018

**Chiasma, Inc.**

By: /s/ Mark J. Fitzpatrick

Mark J. Fitzpatrick

President, Chief Executive Officer, and Director



## Chiasma Reports on Significant Progress Made During 2017

- *Initiated CHIASMA OPTIMAL Phase 3 Clinical Trial after SPA agreement with FDA*
- *Announces expected year-end 2017 cash and investments balance of approximately \$67 million*
- *Continues to expect existing cash and investments to be sufficient to fund operations through anticipated release of top-line data from CHIASMA OPTIMAL Phase 3 Clinical Trial by the end of 2019*

**WALTHAM, Mass., Jan. 8, 2018** — Chiasma, Inc. (Nasdaq: CHMA), a clinical-stage biopharmaceutical company focused on improving the lives of patients with rare and serious chronic diseases, today provided a review of its achievements in 2017.

“2017 was a critical year for Chiasma, as we achieved three significant milestones in the development of octreotide capsules, conditionally trade-named MYCAPSSA®, our Phase 3 product candidate for the maintenance therapy of adult patients with acromegaly,” said Mark Fitzpatrick, president and CEO of Chiasma. “In August, we announced a Special Protocol Assessment agreement with the FDA, indicating concurrence by the FDA with the adequacy and acceptability of critical elements of the protocol for our new CHIASMA OPTIMAL Phase 3 clinical trial. In September, the first patient was randomized in that trial. Also in September, we announced that we had surpassed 50% patients randomized in our international Phase 3 clinical trial referred to as MPOWERED™.

“As we look ahead to 2018, we are excited about the progress we are making in the development of MYCAPSSA,” Fitzpatrick continued. “If approved, MYCAPSSA would become the first oral somatostatin analog in an injectable-only acromegaly treatment market. We expect to make significant headway this year toward our ultimate goals of completing recruitment of 50 patients in the CHIASMA OPTIMAL trial and randomizing a total of 80 responders to octreotide capsules in the MPOWERED trial. We strongly believe in our mission and the promise of MYCAPSSA as a potential new oral treatment option for adult patients with acromegaly.”

### Cash Position Update

Chiasma ended 2017 with approximately \$67 million in cash, cash equivalents and marketable securities, consistent with the company’s previous expectations. Chiasma projects that, under its current operating plan, this cash will be sufficient to fund its operations through the anticipated release of top-line data from the CHIASMA OPTIMAL Phase 3 trial by the end of 2019 while supporting the MPOWERED trial in parallel.

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#### *About the CHIASMA OPTIMAL Phase 3 Trial*

Chiasma is conducting a Phase 3 clinical trial under a protocol agreed to by the FDA through a Special Protocol Assessment (SPA) for the company's octreotide capsules product candidate for the maintenance therapy of adult patients with acromegaly. The trial, referred to as "CHIASMA OPTIMAL" (Octreotide capsules vs. Placebo Treatment In MultinationAL centers), is 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  $\leq 1.0 \times$  upper limit of normal (ULN)). The patients must also 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 will be randomized on a 1:1 basis to octreotide capsules or placebo. Patients will be dose titrated from 40mg per day to up to a maximum of 80mg per day, equaling two capsules in the morning and two capsules in the evening. Patients meeting predefined withdrawal criteria during the course of the trial will revert to their original treatment of injections and will be monitored for the remainder of the trial.

The primary endpoint of the study 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  $\leq 1.0 \times$  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  $> 1.0 \times$  ULN; time to loss of response of IGF-1  $> 1.3 \times$  ULN; change in mean GH from screening to end of treatment; and change in IGF-1 from baseline to end of treatment. Chiasma anticipates the release of top-line data from this Phase 3 clinical trial by the end of 2019.

#### *About the 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 up to 150 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. Patients are only randomized into the 9-month randomized controlled phase of MPOWERED if they are qualified as responders (IGF-1  $< 1.3 \times$  ULN and GH  $< 2.5$ ng/mL) to octreotide capsules in the study at the end of the six-month run-in phase. 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.

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## **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](http://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 commitment to develop new treatment options for patients with rare and serious chronic diseases, specifically 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 Europe by conducting the ongoing MPOWERED Phase 3 clinical 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 2017 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 and to support 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 September 30, 2017 filed with the Securities and Exchange Commission (SEC) on November 9, 2017, 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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