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): January 3, 2019

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 January 3, 2019, Chiasma, Inc. (the "Company") issued a press release providing a year-end corporate update and preliminary 2019 outlook, which press release included the Company's preliminary approximate cash, cash equivalents and marketable securities as of December 31, 2018. This information is unaudited and does not present all information necessary for an understanding of the Company's financial condition as of December 31, 2018 and its results of operations for the twelve months ended December 31, 2018. A copy of the press release is being furnished as Exhibit 99.1 to this Report on Form 8-K.

Item 7.01 Regulation FD Disclosure.

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, 2018.

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

Exhibit No.	Description
99.1	Press Release of Chiasma, Inc. dated January 3, 2019, furnished hereto.

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 3, 2019

Chiasma, Inc.

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

Exhibit 99.1

Chiasma Previews Important Upcoming Milestones

CHIASMA OPTIMAL Phase 3 topline data expected in Q3 2019

Company anticipates submitting U.S. NDA by year-end 2019, assuming positive CHIASMA OPTIMAL data, and if accepted for filing, further expects a six-month FDA PDUFA review classification

Key U.S. commercial readiness activities planned in 2019

Waltham, MA – January 3, 2019 – Chiasma, Inc. (NASDAQ: CHMA), a clinical-stage biopharmaceutical company focused on improving the lives of patients with rare and serious chronic diseases, today previewed anticipated upcoming corporate milestones and commented on the significant progress made by the company in 2018.

"During 2018, we completed the required enrollment in both of our Phase 3 clinical trials of our investigational octreotide capsules product candidate, which we have conditionally trade-named Mycapssa®, and with those trials progressing as planned, we believe we have set the stage for a catalyst-rich 2019 including the announcement of topline data evaluating Mycapssa's efficacy as potentially the first oral somatostatin analog for the maintenance therapy of adult acromegaly patients," said Mark Fitzpatrick, President and Chief Executive Officer of Chiasma. "As we enter the new year, our plans are firmly in place, assuming positive Phase 3 CHIASMA OPTIMAL data, to submit an NDA by the end of 2019 with an eye toward possible FDA approval of Mycapssa in mid-2020."

"Multiple publications as well as initial screening data from Chiasma's MPOWERED™ clinical trial have highlighted the undesirable treatment burden associated with monthly injectable somatostatin receptor ligands, the current standard of care in the chronic treatment of adults with acromegaly. Based on this data and feedback from physicians and patients, an alternative orally administered therapeutic option could alleviate this burden for some patients. We believe Mycapssa, if approved as the first oral somatostatin analog, has the potential to become a standard of care in acromegaly maintenance treatment. In anticipation of positive clinical trial results in 2019, we intend to meaningfully transition into commercial readiness planning in 2019," Mr. Fitzpatrick concluded.

Anticipated 2019 and 2020 Milestones:

- **CHIASMA OPTIMAL (for U.S. approval).** The Company anticipates reporting topline data in Q3 2019 from its ongoing international CHIASMA OPTIMAL (**O**ctreotide capsules vs. **P**lacebo **T**reatment **I**n **M**ultination**AL** centers) Phase 3 clinical trial of Mycapssa for the maintenance therapy of adult patients with acromegaly. This trial is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) to support potential regulatory approval in the United States. Chiasma announced in October 2018 that it completed enrollment with 56 patients in 17 countries, including 21 from the United States, which exceeded its original SPA-agreed enrollment goal of 50 patients. The enrolled trial has been progressing as planned.

- **U.S. NEW DRUG APPLICATION.** Data from CHIASMA OPTIMAL, if positive, will support the Company's New Drug Application (NDA) in the U.S., which the Company anticipates submitting by year-end 2019. The Company currently expects the FDA to complete its review of the anticipated NDA, if accepted for filing, in six months based on our expectation that the planned NDA filing will be designated a Class 2 resubmission by FDA to address the April 2016 complete response letter to our original NDA.
- **MPOWERED (for EU approval).** Chiasma anticipates completing enrollment in Q2 2019 of up to 150 patients into the run-in phase of MPOWERED (**M**aintenance of acromegaly **P**atients with **O**ctreotide capsules compared **W**ith injections – **E**valuation of **RE**sponse **D**urability). Chiasma anticipates reporting topline data in the second half of 2020 from this global Phase 3 open-label clinical trial of Mycapssa. If data from MPOWERED demonstrates that oral octreotide capsules is non-inferior to standard of care somatostatin analog injections, such data is intended to support submission of a Marketing Authorization Application for potential approval of Mycapssa in the European Union.
- **COMMERCIAL READINESS.** Most diagnosed adult patients with acromegaly and their caregivers are readily identified. During 2019, Chiasma intends to build on its plans and preparations to commercialize Mycapssa in 2020 with a specialty U.S. sales team.
- **CASH.** Chiasma ended 2018 with estimated cash and cash equivalents of approximately $41 million. The Company anticipates that its current cash balance is sufficient to fund its operations as currently planned through CHIASMA OPTIMAL topline data, and into early 2020.

Chiasma plans to be available for meetings with investors during next week's 37th Annual J.P. Morgan Healthcare Conference.

About the CHIASMA OPTIMAL Trial

The CHIASMA OPTIMAL trial is a randomized, double-blind, placebo-controlled, nine-month clinical trial of octreotide capsules being conducted under a SPA agreement with the FDA. The trial enrolled 56 adult acromegaly patients whose disease was biochemically controlled, based upon levels of IGF-1, a byproduct of increased growth hormone (GH) levels caused by acromegaly, by injectable somatostatin receptor ligands at baseline (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. The trial is randomized on a 1:1 basis, octreotide capsules versus 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 who meet predefined withdrawal 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 $\leq 1.0 \times$ ULN. Chiasma anticipates the release of top-line data from this Phase 3 clinical trial in Q3 2019.

About the Chiasma MPOWERED Trial

Chiasma is conducting an international Phase 3 clinical trial under a protocol accepted by the EMA for the Company's octreotide capsules product candidate for the maintenance therapy of adult patients with acromegaly. The trial, referred to as MPOWERED, is a global, randomized, open-label and active-controlled, 15-month trial intended to support approval in the European Union. Chiasma plans to enroll up to 150 adult acromegaly patients into the trial, of which at least 80 patients who are responders to octreotide capsules following a six-month run-in will be randomized 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, has enrolled 135 patients as of July 2018 (of which the EMA-required minimum of 80 patients have been randomized) 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. In October 2018, Chiasma announced that it had elected to resume enrollment in the trial in an effort to enroll up to 15 additional patients exclusively located in the United States in order to gain further U.S. investigator and patient experience with octreotide capsules. Chiasma now anticipates the trial to complete enrollment into the run-in phase in Q2 2019 and expects to release topline data from this Phase 3 clinical trial during the second half of 2020.

About Acromegaly

Acromegaly typically develops when a benign tumor of the pituitary gland produces too much growth hormone (GH), ultimately leading to significant health problems and early death if untreated. There are an estimated 69,000 individuals with acromegaly worldwide. In 13 studies of acromegaly prevalence since 1980, an average of approximately 75 cases per million was determined, suggesting roughly 24,000 individuals with acromegaly in the United States, of which an estimated 8,000 are treated chronically with somatostatin analog injections. However, previous data suggest that pituitary tumors may be more prevalent than previously thought, and that the global prevalence of acromegaly may be higher, between 85 and 118 cases per million people. National Institutes of Health (NIH) also cites an annual incidence of three to four new cases per million each year. Because symptoms often develop slowly, diagnosis may be delayed by years or decades, making it difficult to determine the total number of people with the disease.

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.

Current treatment options include surgery to remove the pituitary tumor, radiation therapy, which destroys any lingering tumor cells, and/or medical treatment in cases where these approaches are not possible or fully effective. Today's medical treatments include dopamine agonists, GH antagonists, and injectable somatostatin analogs, which are the current standard of care.

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 October 2018, the Company completed enrollment in 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. Prior to trial initiation, The Company reached 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 ongoing 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 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 Q3 2019, the Company's ability to file an NDA by the end of 2019 and to obtain a 6-month review of the NDA from FDA if accepted for filing, the Company's ability to release top-line data from the MPOWERED trial during the second half of 2020, and the Company's cash forecasts, including its expected cash and investment balances as of the end of 2018 and that it has sufficient existing cash and investments on hand to fund its operations through at least its anticipated release of top-line data from the Phase 3 CHIASMA OPTIMAL clinical trial in Q3 2019 and that its cash and investments balance is sufficient to fund operations as currently planned into early 2020. 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 Annual Report on Form 10-K for the year ended December 31, 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:
Ashley R. Robinson
LifeSci Advisors, LLC
617-535-7742
arr@lifesciadvisors.com