CHIASMA, INC
Form 8-K
August 18, 2015

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 17, 2015

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.)**

60 Wells Avenue, Suite 102

Newton, MA **02459**
(Address of principal executive offices) **(Zip Code)**
Registrant s telephone number, including area code (866) 637-9703

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))

Item 8.01 Other Events

On August 17, 2015, Chiasma, Inc. (the Company) announced that the U.S. Food and Drug Administration (FDA) had accepted for filing the Company s New Drug Application (NDA) for the marketing and sale of octreotide capsules, an oral drug proposed for the maintenance therapy of adult patients with acromegaly. The FDA is expected to inform the Company of the Prescription Drug User Fee Act (PDUFA) date by the end of August. The PDUFA date is the target date for the FDA to complete its review of the NDA.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements concerning expected regulatory review of the Company s NDA for oral octreotide. Acceptance of the NDA for filing does not represent final evaluation of the adequacy of the data submitted in the NDA and is not a guarantee of approval. There also can be no assurance that the FDA will complete its review by the PDUFA target date, once determined. Any forward-looking statements in this Current Report on Form 8-K 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. These risks and uncertainties include, but are not limited to: risks associated with the regulatory review process generally; the risk that the FDA may determine that that the data included in the NDA are insufficient for approval and that the Company must conduct additional clinical trials, or nonclinical or other studies, before oral octreotide can be approved; the risk that the results of previously conducted studies involving oral octreotide or other product candidates will not be repeated or observed in ongoing or future studies or following commercial launch, if such product candidates are approved; and risks associated with Chiasma s dependence on third parties, including with respect to the manufacture of commercial supply in anticipation of commercial launch, if oral octreotide is approved. For a discussion of 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 the final prospectus related to Chiasma s initial public offering filed with the Securities and Exchange Commission pursuant to Rule 424(b) of the Securities Act of 1933, as amended, as well as discussions of potential risks, uncertainties and other important factors in Chiasma s subsequent filings with the Securities and Exchange Commission. All information in this Current Report on Form 8-K is as of the date of this report, and Chiasma undertakes no duty to update this information unless required by law.

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 18, 2015

Chiasma, Inc.

By: /s/ Mark J. Fitzpatrick
Mark J. Fitzpatrick
Chief Financial Officer, Treasurer and Secretary