

Edgar Filing: Flexion Therapeutics Inc - Form 8-K

Flexion Therapeutics Inc
Form 8-K
May 26, 2016
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 25, 2016

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

| | | |
|------------------------------|--------------|---------------------|
| Delaware | 001-36287 | 26-1388364 |
| (State or other jurisdiction | (Commission | (IRS Employer |
| of incorporation) | File Number) | Identification No.) |

10 Mall Road, Suite 301

| | |
|--|------------|
| Burlington, Massachusetts | 01803 |
| (Address of principal executive offices) | (Zip Code) |

Registrant's telephone number, including area code: (781) 305-7777

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

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- o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events.

On May 26, 2016, Flexion Therapeutics, Inc. (“Flexion”) reported that on May 25, 2016 it had received written responses from the U.S. Food & Drug Administration (“FDA”) to questions Flexion had submitted in advance of a pre-New Drug Application (“NDA”) meeting regarding its lead product candidate, Zilretta™ (also known as FX006). The FDA indicated in its responses that the safety and efficacy data from the registration program for Zilretta are acceptable to support filing of an NDA submission. Based on this positive FDA feedback, Flexion has determined to forgo the in-person pre-NDA meeting and the FDA’s written responses will serve as the official meeting minutes.

On May 26, 2016, Flexion issued a press release related to the written responses from the FDA. A copy of the press release is attached as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit

No. Description

99.1 Press Release dated May 26, 2016.

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.

Flexion Therapeutics, Inc.

Dated: May 26, 2016

By: /s/ Frederick W. Driscoll
Frederick W. Driscoll
Chief Financial Officer

INDEX TO EXHIBITS

Exhibit

No. Description

99.1 Press Release dated May 26, 2016.