

Flexion Therapeutics Inc
Form 8-K
September 17, 2014

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): September 17, 2014

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction

of incorporation)

001-36287
(Commission

File Number)

26-1388364
(IRS Employer

Identification No.)

10 Mall Road, Suite 301

01803

Burlington, Massachusetts

(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:

- 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 September 17, 2014, Flexion Therapeutics, Inc. announced that the United States Food and Drug Administration (FDA) informed the company that a clinical hold has been placed on patient enrollment and dosing in the Company's ongoing Phase 2b clinical trial evaluating FX006 in patients with osteoarthritis of the knee. The FDA indicated that the clinical hold is due to a single occurrence of an infection in the injected knee joint of a patient in the Phase 2b clinical trial. The Company intends to work closely with FDA to provide all appropriate information and data required to expedite their review and evaluation of the event.

A press release announcing the clinical hold is attached hereto as Exhibit 99.1.

Forward-Looking Statements

Statements in this press release regarding matters that are not historical facts, including statements relating to the future of Flexion, its ongoing development of its product candidates, Flexion's plans to work with the FDA in relation to the clinical hold and the potential timing and impact of the clinical hold are forward-looking statements. These forward-looking statements are based on management's expectations and assumptions as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, risks associated with the process of discovering, developing and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics, risks associated with investigating and, if applicable, remediating, the cause of the event leading to the clinical hold, the fact that Flexion relies on third parties to manufacture and conduct the clinical trials of its product candidates, which could delay or limit their future development or regulatory approval, the fact that Flexion will require additional capital, including prior to completing Phase 3 development of, filing for regulatory approval for, or commercializing, FX006 or any of its other product candidates and may be unable to obtain such additional capital in sufficient amounts or on terms acceptable to it, the fact that the FDA may change its guidance at any time or impose additional requirements, and other risks and uncertainties described in Flexion's filings with the Securities and Exchange Commission (SEC), including under the heading Risk Factors in Flexion's Annual Report on Form 10-K for the year ended December 31, 2013 and subsequent filings with the SEC. You are encouraged to read Flexion's filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. The forward-looking statements in this report speak only as of the date of this report, and Flexion undertakes no obligation to update or revise any of the statements.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release of Flexion Therapeutics, Inc. dated September 17, 2014.

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: September 17, 2014

By: /s/ Michael D. Clayman, M.D.
Michael D. Clayman, M.D.
President and Chief Executive Officer

EXHIBIT INDEX

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