Flexion Therapeutics Inc
Form 8-K
September 03, 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 3, 2014

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36287**	**26-1388364**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer 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:

¨ 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 3, 2014, Flexion Therapeutics, Inc. (the Company) announced that in a meeting with the U.S. Food and Drug Administration (FDA), the agency communicated that it will consider the Company s ongoing placebo-controlled Phase 2b confirmatory trial of FX006 as one of two key efficacy trials required for registration of a single-dose administration for FX006. In addition, the FDA provided guidance that a second placebo-controlled pivotal trial would be sufficient to support the filing of a new drug application (NDA). The FDA also communicated that the approval of FX006 for single-dose administration will not require data from a repeat-dose safety trial. As a result, the Company plans to advance the initiation of a pivotal Phase 3 trial of FX006 to late 2014 and to remove the repeat-dose safety trial from its pre-approval plans. The Company believes this new timing will allow Phase 3 development to be completed by the end of 2015. The Company expects to develop and file repeat-dose safety data in a supplemental NDA after an approval and launch of FX006 for single-dose administration.

The Phase 3 trial for FX006 will be an international, multi-center, randomized, blinded, single-dose study in 462 patients with osteoarthritis of the knee. It will have three arms that include a 40 mg dose of FX006, placebo and a 40 mg dose of immediate-release triamcinolone acetonide (TCA). The primary objective of the trial will be to provide the second pivotal efficacy dataset against placebo at 12 weeks for an NDA submission. In addition, the trial will provide a key comparative dataset against the current standard of care, immediate-release TCA.

A press release announcing the planned initiation of the Phase 3 trial for FX006 is attached hereto as Exhibit 99.1.

Forward-Looking Statements

Statements in this report regarding matters that are not historical facts, including statements relating to the future of Flexion, its ongoing development of its product candidates, the initiation of a Phase 3 trial for FX006, the potential timing for completing Phase 3 development for FX006, the anticipated requirements for filing an NDA and obtaining regulatory approval for FX006, initiation of a repeat-dose safety trial and anticipated clinical and other milestones (including the timing of such milestones) are forward-looking statements. These forward-looking statements are based on management s expectations and assumptions as of the date of this report 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, whether the company s patents will be held valid and enforceable, 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 possibility that future trial results may not be consistent with past results, 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 3, 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 3, 2014

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

EXHIBIT INDEX

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