Flexion Therapeutics Inc
Form 8-K
August 04, 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): July 31, 2015

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 1.01. Entry Into a Material Definitive Agreement.

Manufacturing and Supply Agreement with Patheon U.K. Limited

On July 31, 2015, Flexion Therapeutics, Inc. (Flexion) and Patheon U.K. Limited (Patheon) entered into a Manufacturing and Supply Agreement (the Manufacturing Agreement) and Technical Transfer and Service Agreement (the Technical Transfer Agreement) for the manufacture of FX006, Flexion s lead program, which is an intra-articular (IA) sustained-release steroid for the treatment of osteoarthritis.

Patheon has agreed in the Technical Transfer Agreement to undertake certain technical transfer activities and construction services needed to prepare Patheon s Swindon, United Kingdom facility for the commercial manufacture of FX006 in dedicated manufacturing suites. Flexion will provide Patheon with certain equipment and materials necessary to manufacture FX006 and it will pay Patheon a monthly base fee for such activities and reimburse Patheon for certain material, equipment and miscellaneous expenses and additional services.

The Technical Transfer Agreement expires upon completion of the build out and FDA approval of the dedicated manufacturing suites. Flexion may terminate the Technical Transfer Agreement if Patheon does not meet certain construction and manufacturing milestones, or at any time for convenience upon 90 days notice prior to FDA approval of the Patheon dedicated suite for the manufacture of FX006 (the FDA Approval Date). Either party may terminate the Technical Transfer Agreement in the event of an unremedied material breach by or bankruptcy of the other party or if a material force majeure event remains uncured for a period of more than 90 days. If the Technical Transfer Agreement is terminated before the FDA Approval Date, the Manufacturing Agreement will concurrently and automatically terminate. Upon termination of the Technical Transfer Agreement by Flexion for convenience prior to the FDA Approval Date, Flexion will be obligated to pay a termination fee and pay for the costs associated with removing its manufacturing equipment and for Patheon s termination costs up to a specified maximum amount.

Pursuant to the Manufacturing Agreement, Flexion will submit rolling 18-month forecasts to Patheon for FX006 supply, the first four months of which will constitute binding orders. There are no minimum order requirements. Flexion will pay a monthly base fee to Patheon for the operation of the manufacturing suites and a per product fee for each vial of FX006 produced by Patheon. The per product fee is subject to adjustment from time to time, including due to changes in price indices and actual annual product orders following a certain number of years after the FDA Approval Date. Flexion will also reimburse Patheon for purchases of materials and equipment made on its behalf, certain nominal expenses and additional services.

The initial term of the Manufacturing Agreement is 10 years from the FDA Approval Date. Flexion may terminate the Manufacturing Agreement upon one month s notice if a regulatory authority causes the withdrawal from, or halts development of, FX006 (in either case for reasons outside the reasonable control of Flexion) in the United States or any other market that represents 80% of Flexion s overall sales. Flexion may also terminate the agreement at any time for convenience by providing (i) prior to the FDA Approval Date, three months notice and, (ii) after the FDA Approval Date, 24 months notice. Either party may terminate the Manufacturing Agreement in the event of (a) an unremedied material breach or bankruptcy of the other party, (b) if a material force majeure event remains uncured for a period of more than 90 days and (c) the granting of a permanent injunction to a third party claiming intellectual property infringement of FX006 in the United States or UK. Upon termination of the Manufacturing Agreement, Flexion will pay for the costs associated with the removal of its manufacturing equipment and for Patheon s termination costs up to a specified maximum amount.

The agreements with Patheon contain certain representations, warranties, limitations of liabilities and confidentiality and indemnity obligations.

Credit Facility with MidCap Funding XIII Trust and Silicon Valley Bank

On August 4, 2015, Flexion entered into a credit and security agreement with MidCap Financial Trust, as agent, and MidCap Funding XIII Trust and Silicon Valley Bank, as agent (the Lenders), to borrow up to $30 million in term loans. Flexion concurrently borrowed $15.0 million under an initial term loan. The remaining $15.0 million under the facility may be drawn down in the form of a second term loan at Flexion s option through September 2016, subject to Flexion s receipt of positive Phase 3 data meeting primary endpoints and sufficient to file an NDA for FX006, as well as other customary conditions for funding.

Borrowings under the credit facility accrue interest monthly at a fixed interest rate of 6.25 % per annum. Following an interest-only period, principal will be due in 36 equal monthly installments commencing March 1, 2017 and ending February 1, 2020 (the maturity date). Upon the maturity date, Flexion will be obligated to pay a final payment equal to 9% of the total principal amounts borrowed under the facility. Flexion may elect to prepay all amounts under the facility prior to the maturity date, subject to a prepayment fee equal to 3% of the amount prepaid if the prepayment occurs on or prior to the first anniversary of the closing date, 2% if the prepayment occurs after the first anniversary and on or prior to the second anniversary of the closing date, 1% if the prepayment occurs after the second anniversary and on or prior the third anniversary of the closing date, and 0% thereafter. No equity or warrants were issued in connection with the entering into of the credit and security agreement.

Flexion granted the Lenders a security interest in substantially all of its personal property, rights and assets, other than intellectual property, to secure the payment of all amounts owed under the credit facility. Flexion also agreed not to encumber any of its intellectual property without the Lenders prior written consent.

The credit and security agreement contains certain representations, warranties and affirmative and negative covenants customary for agreements of this type.

The foregoing description of the agreements with Patheon and the Lenders does not purport to be complete and is qualified in its entirety by the terms of the agreements. Flexion will file copies of such agreements as exhibits to its Quarterly Report on Form 10-Q for the quarter ending September 30, 2015.

Item 2.03 Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant

The disclosure set forth under Item 1.01 of this Current Report on Form 8-K with respect to Flexion s credit facility and borrowings thereunder is incorporated into this Item 2.03 by reference.

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: August 4, 2015

By: */s/ Michael Clayman*
Michael Clayman
Chief Executive Officer