

Flexion Therapeutics Inc
Form 10-Q
May 08, 2015
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2015

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE TRANSITION PERIOD FROM _____ TO _____

Commission file number: 001-36287

Flexion Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

26-1388364
(I.R.S. Employer
Identification No.)

10 Mall Road, Suite 301

Burlington, Massachusetts
(Address of Principal Executive Offices)

01803
(Zip Code)

(781) 305-7777

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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Indicate by check mark whether registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer , accelerated filer , smaller reporting company in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company
Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of May 5, 2015, the registrant had 21,461,419 shares of Common Stock (\$0.001 par value) outstanding.

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FLEXION THERAPEUTICS, INC.

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Table of Contents**PART I. FINANCIAL INFORMATION****Item 1. Financial Statements****Flexion Therapeutics, Inc.****Consolidated Balance Sheets****(Unaudited)**

	March 31, 2015	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	\$ 26,963,175	\$ 103,097,522
Marketable securities	105,381,958	48,527,156
Accounts receivable	403,209	
Prepaid expenses and other current assets	1,489,269	502,314
Total current assets	134,237,611	152,126,992
Property and equipment, net	1,663,980	1,109,391
Marketable securities	5,016,200	
Other assets		12,375
Restricted cash	104,000	128,000
Total assets	\$ 141,021,791	\$ 153,376,758
Liabilities, and Stockholders Equity		
Current liabilities:		
Accounts payable	\$ 2,183,842	\$ 1,584,822
Accrued expenses and other current liabilities	1,975,832	3,213,704
Current portion of long-term debt		2,000,000
Total current liabilities	4,159,674	6,798,526
Long-term debt		1,593,333
Other long-term liabilities	28,234	43,008
Total liabilities	4,187,908	8,434,867
Commitments and contingencies		
Preferred Stock, \$.001 par value; 10,000,000 shares authorized at March 31, 2015 and December 31, 2014 and 0 shares issued and outstanding at March 31, 2015 and December 31, 2014		
Stockholders equity:		
	21,461	21,440

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Common stock, \$0.001 par value; 100,000,000 shares authorized; 21,461,419 and 21,440,058 shares issued and outstanding, at March 31, 2015 and December 31, 2014, respectively		
Additional paid-in capital	239,447,573	238,402,514
Accumulated other comprehensive income	15,195	(5,240)
Accumulated deficit	(102,650,346)	(93,476,823)
Total stockholders' equity	136,833,883	144,941,891
Total liabilities and stockholders' equity	\$ 141,021,791	\$ 153,376,758

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**Flexion Therapeutics, Inc.****Consolidated Statements of Operations and Comprehensive Loss****(Unaudited)**

	Three Months Ended March 31,	
	2015	2014
Revenue	\$	\$
Operating expenses:		
Research and development	6,255,111	4,150,847
General and administrative	2,759,832	2,283,913
Total operating expenses	9,014,943	6,434,760
Loss from operations	(9,014,943)	(6,434,760)
Other income (expense):		
Interest income	168,363	30,758
Interest expense	(203,468)	(111,667)
Other income (expense), net	(123,475)	(26,575)
Total other income (expense)	(158,580)	(107,484)
Net loss	\$ (9,173,523)	\$ (6,542,244)
Net loss per share basic and diluted	\$ (0.43)	\$ (0.86)
Weighted average common shares outstanding, basic and diluted	21,451,317	7,632,786
Other comprehensive (loss) income:		
Unrealized gains from available-for-sale securities, net of tax of \$0	20,435	842
Total other comprehensive income	20,435	842
Comprehensive loss	\$ (9,153,088)	\$ (6,541,402)

The accompanying notes are an integral part of these condensed consolidated financial statements.

Table of Contents**Flexion Therapeutics, Inc.****Consolidated Statements of Cash Flows****(Unaudited)**

	Three Months Ended March 31,	
	2015	2014
Cash flows from operating activities		
Net loss	\$ (9,173,523)	\$ (6,542,244)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	39,680	27,344
Stock-based compensation expense	1,008,250	436,495
Amortization of premium (discount) on marketable securities	109,330	9,271
Other non-cash charges	12,375	4,125
Changes in operating assets and liabilities:		
Accounts receivable	(403,209)	
Prepaid expenses, other current and long-term assets	(986,955)	(663,202)
Accounts payable	592,786	671,763
Accrued expenses and other current and long-term liabilities	(1,082,972)	(430,366)
Other	(93,333)	
Net cash used in operating activities	(9,977,571)	(6,486,814)
Cash flows from investing activities		
Purchases of property and equipment	(533,060)	(44,875)
Change in restricted cash	24,000	
Purchases of marketable securities	(89,424,898)	(42,731,544)
Redemption of marketable securities	27,465,000	250,000
Net cash used in investing activities	(62,468,958)	(42,526,419)
Cash flows from financing activities		
Payment of public offering costs	(224,648)	(1,096,588)
Payments on debt	(3,500,000)	
Proceeds from the issuance of common stock		69,517,500
Proceeds from the exercise of stock options	36,830	193,312
Net cash (used in) provided by financing activities	(3,687,818)	68,614,224
Net increase (decrease) in cash and cash equivalents	(76,134,347)	19,600,991
Cash and cash equivalents at beginning of period	103,097,522	16,188,254
Cash and cash equivalents at end of period	\$ 26,963,175	\$ 35,789,245

Supplemental disclosures of cash flow information:

Cash paid for interest	\$ 292,037	\$ 100,000
Supplemental disclosures of non-cash financing activities:		
Initial public offering costs included in accounts payable or accrued expenses		\$ 158,029
Conversion of convertible preferred stock into common stock		\$ 74,806,213

The accompanying notes are an integral part of these condensed consolidated financial statements.

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Flexion Therapeutics, Inc.

Notes to Financial Statements (Unaudited)

1. Overview and Nature of the Business

Flexion Therapeutics, Inc. (Flexion or the Company) was incorporated under the laws of the state of Delaware on November 5, 2007. Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, injectable pain therapies. The Company is targeting anti-inflammatory and analgesic therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis (OA) and post-operative pain. Flexion s broad and diversified portfolio of product candidates addresses the OA pain treatment spectrum, from moderate to severe pain, and provides the Company with multiple opportunities to achieve its goal of commercializing novel, patient-focused pain therapies.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities. The Company s product candidates are all in the development stage. There can be no assurance that development efforts, including clinical trials, will be successful. Even if the Company s product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of March 31, 2015, and for the three months ended March 31, 2015 and 2014, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (the SEC) and Generally Accepted Accounting Principles (GAAP) for consolidated financial information including the accounts of the Company and its wholly-owned subsidiary after elimination of all significant intercompany accounts and transactions. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all adjustments which are necessary for a fair statement of the Company s financial position and results of its operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in the Company s Annual Report on Form 10-K filed with the SEC on March 24, 2015.

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2015, and for the three months ended March 31, 2015 and 2014, is unaudited. The December 31, 2014 consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three months ended March 31, 2015 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2015, or any future period.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of March 31, 2015 and December 31, 2014, the Company had cash and cash equivalents and marketable securities of \$137,361,333 and \$151,624,678, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at March 31, 2015 should be sufficient to fund operations for at least the next twelve months. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations and to fund increased research and development costs in order to seek approval for commercialization of its product candidates. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies as this capital is necessary for the Company to perform the research and development activities required to develop the Company's product candidates in order to generate future revenue streams.

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Consolidation

The accompanying condensed consolidated financial statements include the Company and its wholly-owned subsidiary, Flexion Securities Corporation, Inc. The Company has eliminated all intercompany transactions for the three months ended March 31, 2015 and the year ended December 31, 2014, the year Flexion Securities Corporation, Inc. was established.

U.S. Government Grant

The Company performs research and development for a U.S. Government agency under a cost reimbursable grant for clinical development of FX006. The related costs incurred under the grant are included in research and development expense in the statements of operations. The Company is reimbursed and offsets research and development expenses in the statement of operations when invoices for allowable costs are prepared and submitted to the U.S. Government agency. Payments under cost reimbursable grants with agencies of the U.S. Government are provisional payments subject to adjustment upon audit by the U.S. government. When the final determination of the allowable costs for any year has been made, research and development expenses may be adjusted accordingly. The grant also provides the U.S. government agency the ability to terminate the grant for various reasons, including if we fail to meet our obligations as set forth in the grant.

Accounts Receivable

Accounts receivable represents allowable costs under the Company's U.S. Government agency grant for which the Company has not yet received reimbursement. The Company invoices the government on a quarterly basis for reimbursable costs under the grant. Reimbursable costs that have not been invoiced on the last day of the quarter are recorded as unbilled accounts receivable.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities, expenses and related disclosures. The Company bases estimates and judgments on historical experience and on various other factors that it believes to be reasonable under the circumstances. The most significant estimates in these condensed consolidated financial statements include useful lives with respect to long-lived assets, such as property and equipment and leasehold improvements, accounting for stock-based compensation, and accrued expenses, including clinical research costs. The Company's actual results may differ from these estimates under different assumptions or conditions. The Company evaluates its estimates on an ongoing basis. Changes in estimates are reflected in reported results in the period in which they become known by the Company's management.

3. Fair Value of Financial Assets

The following tables present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of March 31, 2015 and December 31, 2014 and indicate the level of the fair value hierarchy utilized to determine such fair value:

Fair Value Measurements as of March 31, 2015 Using:

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	Level 1		Level 2		Level 3		Total
Assets:							
Cash equivalents	\$	\$	24,628,158	\$	\$	24,628,158	
Marketable securities			110,398,158			110,398,158	
	\$	\$	135,026,316	\$	\$	135,026,316	

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	Fair Value Measurements as of December 31, 2014 Using:			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$	\$ 101,687,995	\$	\$ 101,687,995
Marketable securities		48,527,156		48,527,156
	\$	\$ 150,215,151	\$	\$ 150,215,151

As of March 31, 2015 and December 31, 2014, the Company's cash equivalents and marketable securities that were invested primarily in U.S. treasury bills, corporate bonds, money market funds, commercial paper and U.S. Government agency holdings were valued based primarily on Level 2 inputs. The Company measures the fair value of marketable securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. During the three months ended March 31, 2015 and year ended December 31, 2014, there were no transfers between Level 1, Level 2 and Level 3.

The carrying values of accounts receivable, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these balances.

4. Marketable Securities

As of March 31, 2015 and December 31, 2014, the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2015			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 23,719,268	\$ 26,992	\$	\$ 23,746,260
U.S. Government Obligations	13,080,203	644	(198)	13,080,649
Corporate bonds	73,583,492	8,966	(21,209)	73,571,249
	\$ 110,382,963	\$ 36,602	\$ (21,407)	\$ 110,398,158

	December 31, 2014			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	\$ 8,991,820	\$ 7,570	\$	\$ 8,999,390
U.S. Government Obligations	28,300,921	181	(5,101)	28,296,001
Corporate bonds	11,239,655	2	(7,892)	11,231,765
	\$ 48,532,396	\$ 7,753	\$ (12,993)	\$ 48,527,156

At March 31, 2015 and December 31, 2014, marketable securities consisted of investments that mature within 14 months and twelve months, respectively. The estimated fair value and amortized cost of the Company's marketable

debt securities available-for-sale by contractual maturity are summarized as follows:

	As of March 31, 2015		As of December 31, 2014	
	Fair Value	Amortized Cost	Fair Value	Amortized Cost
Due in one year or less	\$ 105,381,958	\$ 105,370,385	\$ 48,527,156	\$ 48,532,396
Due after one year through 5 years	5,016,200	5,012,578		
Total available-for-sale securities	\$ 110,398,158	\$ 110,382,963	\$ 48,527,156	\$ 48,532,396

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5. Property and Equipment

Property and equipment as of March 31, 2015 and December 31, 2014 consisted of the following: