Flexion Therapeutics Inc
Form 10-Q
August 03, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2016

or

o 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	26-1388364
(State or Other Jurisdiction of	(I.R.S. Employer
Incorporation or Organization)	Identification No.)
10 Mall Road, Suite 301	
Burlington, Massachusetts	01803

(Address of Principal Executive Offices) (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 x No o

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 x No o

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 x
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). o Yes x No

As of July 29, 2016, the registrant had 27,521,070 shares of Common Stock ($0.001 par value) outstanding.

FLEXION THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited in thousands, except share amounts)

	June 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$119,010	$62,944
Marketable securities	44,251	48,303
Accounts receivable	101	95
Prepaid expenses and other current assets	1,180	761
Total current assets	164,542	112,103
Property and equipment, net	11,286	7,442
Long-term investments	—	7,357
Other assets	90	157
Restricted cash	80	80
Total assets	$175,998	$127,139
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$3,513	$3,692
Accrued expenses and other current liabilities	3,052	4,367
Current portion of long-term debt	1,634	—
Total current liabilities	8,199	8,059
Long-term debt	13,520	15,002
Other long-term liabilities	253	91
Total liabilities	21,972	23,152
Commitments and contingencies		
Preferred Stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2016 and December 31, 2015 and 0 shares issued and outstanding at June 30, 2016 and December 31, 2015	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 27,521,070 and 21,570,395 shares issued and outstanding, at June 30, 2016 and December 31, 2015, respectively	28	22

Additional paid-in capital	324,780	243,854
Accumulated other comprehensive income	10	(97)
Accumulated deficit	(170,792)	(139,792)
Total stockholders' equity	154,026	103,987
Total liabilities and stockholders' equity	$175,998	$127,139

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

Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited in thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
Revenue	$—	$—	$—	$—
Operating expenses:				
Research and development	8,905	9,640	20,886	15,895
General and administrative	5,215	2,904	9,907	5,664
Total operating expenses	14,120	12,544	30,793	21,559
Loss from operations	(14,120)	(12,544)	(30,793)	(21,559)
Other income (expense):				
Interest income	295	440	631	608
Interest expense	(202)	—	(478)	(204)
Other income (expense), net	(158)	(332)	(360)	(455)
Total other income (expense)	(65)	108	(207)	(51)
Net loss	$(14,185)	$(12,436)	$(31,000)	$(21,610)
Net loss per share basic and diluted	$(0.63)	$(0.58)	$(1.40)	$(1.01)
Weighted average common shares outstanding, basic and diluted	22,666	21,475	22,115	21,463
Other comprehensive (loss) income:				
Unrealized gains from available-for-sale securities, net of tax of $0	(18)	(22)	(108)	(1)
Total other comprehensive (loss) income	(18)	(22)	(108)	(1)
Comprehensive loss	$(14,203)	$(12,458)	$(31,108)	$(21,611)

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

Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited in thousands)

	Six Months Ended June 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (31,000)	$ (21,610)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	269	82
Stock-based compensation expense	3,260	1,978
Amortization of premium (discount) on marketable securities	345	435
Other non-cash charges	18	12
Loss on disposal of fixed assets	2,278	—
Premium paid on securities purchased	(22)	—
Changes in operating assets and liabilities:		
Accounts receivable	(6)	(200)
Prepaid expenses, other current and long-term assets	(353)	(718)
Accounts payable	412	(196)
Accrued expenses and other current and long-term liabilities	(517)	1,180
Net cash used in operating activities	(25,316)	(19,037)
Cash flows from investing activities		
Purchases of property and equipment	(7,678)	(1,427)

Change in restricted cash	—	24
Purchases of marketable securities	(10,811)	(99,477)
Sale and redemption of marketable securities	21,997	48,533
Discount received on securities purchased	7	—
Net cash provided by (used in) investing activities	3,515	(52,347)
Cash flows from financing activities		
Payment of debt issuance costs	(42)	—
Payments on debt	—	(3,500)
Proceeds from the offering of common stock	77,644	—
Payments of public offering costs	(31)	(225)
Proceeds from the exercise of stock options	56	213
Proceeds from Employee Stock Purchase Plan	240	138
Net cash provided by (used in) financing activities	77,867	(3,374)
Net decrease in cash and cash equivalents	56,066	(74,758)
Cash and cash equivalents at beginning of period	62,944	103,098
Cash and cash equivalents at end of period	$ 119,010	$ 28,340
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 477	$ 292
Supplemental disclosures of non-cash financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$ 154	$ 487

Public offering costs included in accounts payable or accrued expenses	$ 236	$ —

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

Flexion Therapeutics, Inc.

Notes to Condensed Consolidated 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, local pain therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis (“OA”), a type of degenerative arthritis. The Company’s lead product candidate, Zilretta™ (also known as FX006), is a late-stage, injectable, sustained-release, intra-articular, or IA, meaning “in the joint,” investigational steroid that is being developed as a treatment for patients with moderate to severe knee OA pain.

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. Financing Activities

On June 13, 2016, the Company completed a follow-on public offering of its common stock, which resulted in the sale of 5,500,000 shares of the Company’s common stock at a price to the public of $14.00 per share. On June 21, 2016, the Company completed the sale of an additional 400,000 shares of its common stock at the public offering price pursuant to the underwriters’ exercise of its option to purchase additional shares. The Company received aggregate net proceeds from the follow-on financing of $77.6 million after deducting underwriting discounts, commissions, and offering costs paid by the Company.

The Company’s total issued common stock as of June 30, 2016 was 27,521,070.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of June 30, 2016, and for the three and six months ended June 30, 2016 and June 30, 2015, 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 11, 2016.

The information presented in the condensed consolidated financial statements and related notes as of June 30, 2016, and for the three and six months ended June 30, 2016 and June 30, 2015, is unaudited. The December 31, 2015 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 and six months ended June 30, 2016 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2016, 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 June 30, 2016 and December 31, 2015, the Company had cash, cash equivalents, marketable securities, and long-term investments of $163,261,000 and $118,604,000, respectively. Management believes that current cash, cash equivalents and marketable securities on hand at

June 30, 2016 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 and seek approval for commercialization of the Company's product candidates and to establish a commercial infrastructure in order to generate future revenue streams.

In April 2015, the FASB released Accounting Standards Update ("ASU") 2015-05, Customers Accounting for Fees Paid in a Cloud Computing Arrangement ("CCA"). Previously, there was no specific U.S. GAAP guidance on accounting for such fees from the customer's perspective. Under the new standard, customers apply the same criteria as vendors to determine whether a CCA contains a software license or is solely a service contract. For public companies, the new standard is effective for annual periods, including interim periods, beginning after December 15, 2015 with early adoption allowed. The Company adopted this guidance as of January 1, 2016 and applied it to new internally used software acquired during the quarterly period ended June 30, 2016.

In November 2015, the FASB issued ASU 2015-17, Income Taxes (Topic 740), to simplify the presentation of deferred income taxes. Under the new standard, both deferred tax liabilities and assets are required to be classified as noncurrent in a classified balance sheet. ASU 2015-17 will become effective for fiscal years, and the interim periods within those years, beginning after December 15, 2016, with early adoption allowed. The Company is currently evaluating the potential impact that the adoption of this guidance may have on the Company's financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases ("ASU 2016-02"), to increase transparency and comparability among organizations by recognizing lease assets and liabilities, including for operating leases, on the balance sheet and disclosing key information about leasing arrangements. ASU 2016-02 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018. The Company is currently evaluating the impact that the adoption of this guidance may have on the Company's financial statements.

On March 30, 2016, the FASB released ASU 2016-09, which amends ASC Topic 718, Compensation-Stock Compensation, to require changes to several areas of employee share-based payment accounting in an effort to simplify share-based reporting. The update revises requirements in the following areas: minimum statutory withholding, accounting for income taxes, forfeitures, and intrinsic value accounting for private entities. For public companies, the new rules will become effective for annual reporting periods beginning after December 15, 2016, and interim reporting periods within such annual period. The Company is currently evaluating the impact that the adoption of this guidance may have on the Company's financial statements.

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 and six months ended June 30, 2016 and the year ended December 31, 2015, the year Flexion Securities Corporation, Inc. was established.

U.S. Government Grant

The Company has performed research and development for the U.S. Department of Defense under a cost reimbursable grant for a Phase 2 clinical trial investigating Zilretta in active military and medically retired veterans with post-traumatic knee OA. Due to the challenges of enrolling military personnel with post-traumatic knee OA, the Company has discontinued the trial and terminated the grant. The related costs incurred under the grant prior to the

termination have been included in research and development expense in the statement of operations. The Company is reimbursed and has offset research and development expenses in the statement of operations when invoices for allowable costs have been prepared and submitted to the U.S. Department of Defense. 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.

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. As of June 30, 2016 and December 31, 2015, there were unbilled accounts receivable of $47,000 and $95,000, respectively.

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.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation and amortization expense is recognized using the straight-line method over the following estimated useful lives:

	Estimated Useful Life (Years)
Computers, office equipment, and minor computer software	3
Computer software	7
Manufacturing equipment	7-10
Furniture and fixtures	5

Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the related asset. Costs of major additions and improvements are capitalized and depreciated on a straight-line basis over their useful lives. Repairs and maintenance costs are expensed as incurred. Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is credited or charged to income. Property and equipment includes construction-in-progress that is not yet in service.

Foreign Currencies

The Company maintains a bank account designated in British Pounds. All foreign currency payables and cash balances are measured at the applicable exchange rate at the end of the reporting period. All associated gains and losses from foreign currency transactions are reflected in the consolidated statements of operations within other income and expenses, and were not significant in any period.

4. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets that are measured at fair value on a recurring basis as of June 30, 2016 and December 31, 2015 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of June 30, 2016 Using:		
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$—	$94,907	$ —	$94,907
Marketable securities	—	44,251	—	44,251
	$—	$139,158	$ —	$139,158

	Fair Value Measurements as of December 31, 2015 Using:		
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$—	$61,534	$ —	$61,534
Marketable securities	—	55,660	—	55,660
	$—	$117,194	$ —	$117,194

As of June 30, 2016 and December 31, 2015, the Company's cash equivalents and marketable securities that are invested in money market funds are valued based 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 six months ended June 30, 2016 and year ended December 31, 2015, 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.

Under the Company's 2015 credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank (the "2015 term loan"), the amount outstanding is reported at its carrying value in the accompanying balance sheet. The Company determined the fair value of the 2015 term loan using an income approach that utilizes a discounted cash flow analysis based on current market interest rates for debt issuances with similar remaining years to maturity, adjusted for credit risk. The 2015 term loan was valued using Level 2 inputs as of June 30, 2016 and December 31, 2015. The result of the calculation yielded a fair value that approximates its carrying value.

5. Marketable Securities

As of June 30, 2016 and December 31, 2015 the fair value of available-for-sale marketable securities by type of security was as follows:

	June 30, 2016			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Government obligations	$8,009	$ 12	$ —	$ 8,021
Corporate bonds	36,231	5	(6)	36,230
	$44,240	$ 17	$ (6)	$ 44,251

	December 31, 2015			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Corporate Bonds	$55,757	$ 4	$ (101)	$ 55,660
	$55,757	$ 4	$ (101)	$ 55,660

At June 30, 2016, all marketable securities consisted of investments that mature within twelve months. At December 31, 2015, marketable securities consisted of $48,303,000 of investments that mature within twelve months and $7,357,000 of investments that mature within fifteen months.

6. Property and Equipment, Net

Property and equipment as of June 30, 2016 and December 31, 2015 consisted of the following:

(In thousands)	June 30, 2016	December 31, 2015
Manufacturing equipment	$9,796	$ 2,534
Construction—in progress	697	4,134
Computers, office equipment, and minor computer software	549	393
Software	323	342
Furniture and fixtures	258	290
Leasehold improvements	193	239
	11,816	7,932
Less: Accumulated depreciation	(530)	(490)
Total property and equipment, net	$11,286	$ 7,442

Depreciation expense for the six months ended June 30, 2016 and 2015 was $269,000 and $82,000, respectively. During the six months ended June 30, 2016, $2,630,000 of property and equipment was disposed of, resulting in a loss of $2,278,000. Of the $2,630,000 disposed of during the six months ended June 30, 2016, $2,265,000 was related to manufacturing equipment that will no longer be used due to the Company's decision to not utilize Evonik for supplies of clinical or commercial Zilretta finished drug product, resulting in a loss of $2,180,000. Construction-in progress is primarily comprised of amounts related to the construction of new manufacturing equipment for use by the Company's contract manufacturer, Patheon.

No property and equipment was disposed of during the six months ended June 30, 2015.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	June 30, 2016	December 31, 2015
Clinical research	$36	$ 552
Contract manufacturing services	821	1,444
Payroll and other employee-related expenses	1,336	1,648
Regulatory services	61	64
Consultant fees and expenses	76	70
Professional services fees	488	434
Interest expense	78	81
Other	156	74
Total accrued expenses and other current liabilities	$3,052	$ 4,367

8. Stock-Based Compensation

Stock Option Valuation

The fair value of each of the Company's stock option grants is estimated on the date of grant using the Black-Scholes option-pricing model. The Company currently estimates its expected stock volatility based on the historical volatility of its publicly-traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain vanilla" options. The expected term of stock options granted to non-employees is equal to the contractual term of the option award. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future. The relevant data used to determine the value of the stock option grants for the six months ended June 30, 2016 and 2015 are as follows:

	Six months ended June 30,	
	2016	2015
Risk-free interest rates	1.08-1.90%	1.49-1.92%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	79.8-87.7%	77.4-81.4%

The following table summarizes stock option activity for the six months ended June 30, 2016:

(In thousands, except per share amounts and years)	Shares Issuable Under Options	Weighted Average Exercise Price
Outstanding as of December 31, 2015	1,657	$ 14.28
Granted	719	16.73
Exercised	(24)	2.34
Cancelled	(52)	18.55
Outstanding as of June 30, 2016	2,300	$ 15.07
Options vested and expected to vest at June 30, 2016	1,979	$ 14.61
Options exercisable at June 30, 2016	990	$ 11.72

In addition to the approximately 719,000 common stock options granted, approximately 194,000 restricted stock units (RSUs) were also granted, of which approximately 5,000 RSUs were cancelled, during the six months ended June 30, 2016. The RSUs are performance based awards which will begin vesting upon the achievement of a corporate performance based milestone. No outstanding performance awards were vested as of June 30, 2016.

The aggregate intrinsic value of options is calculated as the difference between the exercise price of the options and the fair value of the Company's common stock for those options that had exercise prices lower than the fair value of the Company's common stock. A total of approximately 24,000 options, with an aggregate intrinsic value of $235,000, were exercised during the six months ended June 30, 2016.

At June 30, 2016 and 2015, there were options for the purchase of approximately 2,300,000 and 1,723,000 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 8.1 and 8.3 years, respectively, and with a weighted average exercise price of $15.07 and $14.23 per share, respectively.

The weighted average grant date fair value of options granted during the six months ended June 30, 2016 and 2015 was $11.85 and $15.67, respectively.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options for the three and six months ended June 30, 2016 is as follows:

	Three months ended		Six months ended	
	June 30,		June 30,	
(In thousands)	2016	2015	2016	2015
Research and development	$576	$287	$1,113	$609
General and administrative	1,043	683	2,147	1,369
	$1,619	$970	$3,260	$1,978

As of June 30, 2016 unrecognized stock-based compensation expense for stock options outstanding was $10,836,000, which was expected to be recognized over a weighted average period of 2.7 years. As of June 30, 2015, unrecognized stock-based compensation expense for stock options outstanding was $13,912,000, which was expected to be recognized over a weighted average period of 2.9 years.

Restricted Stock Units

On January 4, 2016, the Company granted restricted common stock units with performance and time-based vesting conditions to certain executives. The restricted stock units vest, and the underlying shares of common stock become deliverable, in the event the Company receives approval from the U.S. Food and Drug Administration ("FDA") of a new drug application ("NDA") for Zilretta (the "Milestone"). Depending on when and if the Milestone is achieved, the maximum aggregate number of shares of the Company's common stock available to be earned under the awards is 189,300 with an approximate value of $3,445,000 as of the grant date. The amount of earned shares decreases the closer that the Milestone date is to the termination date of the award. If the Milestone is not achieved prior to July 1, 2018, the termination date of the awards, the awards will not vest, will be forfeited in their entirety and no shares of common stock will be delivered. Since it is not possible for the Company to determine the probability of the performance condition being achieved, no compensation costs will be recorded until the Milestone is achieved. If the Milestone is achieved prior to the termination date, compensation costs will be recognized over the remaining requisite service period of the awards.

9. Net Loss per Share

Basic and diluted net loss per share was calculated as follows for the three and six months ended June 30, 2016:

	For the three months ended		For the six months ended	
(In thousands)	June 30, 2016	2015	June 30, 2016	2015
Numerator:				
Net loss	$ (14,185)	$ (12,436)	$ (31,000)	$ (21,610)
Net loss:	$ (14,185)	$ (12,436)	$ (31,000)	$ (21,610)
Denominator:				
Weighted average common shares outstanding, basic and diluted	22,666	21,475	22,115	21,463
Net loss per share, basic and diluted	$ (0.63)	$ (0.58)	$ (1.40)	$ (1.01)

Stock options and restricted stock units for the purchase of 2,436,000 and 1,670,000 weighted average shares of common stock were excluded from the computation of diluted net loss per share for the three months ended June 30, 2016 and 2015, respectively, and 2,397,000 and 1,629,000 weighted average shares of common stock were excluded from the computation of diluted net loss per share attributable to common shareholders for the six months ended June 30, 2016 and 2015, respectively. These options were excluded from the computations because the options had an anti-dilutive impact due to the net loss incurred for those periods.

10. Long-term Debt

On August 4, 2015, the Company entered into a credit and security agreement with MidCap Financial Trust, as agent, and MidCap Financial Funding XIII Trust and Silicon Valley Bank, as lenders, (the "Lenders"), to borrow up to $30,000,000 in term loans, (the "2015 term loan"). The Company concurrently borrowed an initial term loan of $15,000,000 under the facility. The Company 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. The Company also agreed not to encumber any of its intellectual property without the Lenders' prior written consent. The Company must maintain a balance in cash or cash equivalents at Silicon Valley Bank equal to the principal balance of the loan plus 5 percent for so long as the Company maintains any cash or cash equivalents in non-secured bank accounts. The credit and security agreement also contains certain representations, warranties, and covenants of the Company as well as a material adverse event clause. As of June 30, 2016, the Company was compliant with all covenants.

Borrowings under the credit facility accrue interest monthly at a fixed interest rate of 6.25 % per annum. Following an interest-only period of 19 months, 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, the Company will be obligated to pay a final payment equal to 9% of the total principal amounts borrowed under the facility. The final payment amount is being accreted to the carrying value of the debt using the effective interest rate method. As of June 30, 2016, the carrying value of the term loan was $15,154,000, of which $1,634,000 was due within 12 months and $13,520,000 was due in greater than 12 months.

In connection with the credit and security agreement, the Company incurred debt issuance costs totaling $150,000. These costs will be amortized over the estimated term of the debt using the straight-line method which approximates the effective interest method. The Company elected the early adoption of ASU 2015-03, Interest – Imputation of Interest, and accordingly deducted the debt issuance costs from the carrying amount of the debt as of June 30, 2016 and December 31, 2015.

As of June 30, 2016, annual principal and interest payments due under the Company's 2015 term loan are as follows (in thousands):

Year	Aggregate Minimum Payments

2016 (remaining six months)	$ 477
2017	5,018
2018	5,541
2019	5,224
2020	2,190
Total	$ 18,450
Less interest	(1,946)
Less final payment	(1,350)
Total	$ 15,154

11. Subsequent Events

On July 22, 2016, the Company drew down the remaining $15,000,000 under the credit and security agreement with MidCap Financial Trust, as agent, MidCap Financial Funding XIII Trust and Silicon Valley Bank, as lenders, in the form of a second term loan after receiving positive Phase 3 Zilretta clinical trial data meeting the trial's preliminary endpoint and which is sufficient to file an NDA for Zilretta. The second term loan is subject to the same credit terms as the initial term loan under the facility.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with our financial statements and accompanying notes included in this Quarterly Report on Form 10-Q and the financial statements and accompanying notes thereto for the fiscal year ended December 31, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed by us with the Securities and Exchange Commission, or SEC, on March 11, 2016.

Forward-Looking Statements

This discussion contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Such forward looking statements, which represent our intent, belief, or current expectations, involve risks and uncertainties. We use words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "po "believe," "should" and similar expressions to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this Quarterly Report on Form 10-Q. As a result of many factors, including without limitation those set forth under "Risk Factors" in our Annual Report on Form 10-K and subsequent Quarterly Reports on Form 10-Q, and elsewhere in this Quarterly Report on Form 10-Q, our actual results may differ materially from those anticipated in these forward-looking statements. We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a specialty pharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis or OA, a type of degenerative arthritis. We retain the exclusive worldwide rights to our lead product candidate, Zilretta, a late-stage, sustained-release, intra-articular investigational steroid that we are developing for the treatment of OA knee pain.

We were incorporated in Delaware in November 2007, and to date we have devoted substantially all of our resources to our development efforts relating to our product candidates, including conducting clinical trials with our product candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from product sales. From our inception through June 30, 2016, we have funded our operations primarily through the sale of our common stock and convertible preferred stock and, to a lesser extent, debt financing. From our inception through June 30, 2016, we have raised $336.8 million from such transactions, including from our initial and follow-on public offerings. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, government or third-party funding, and licensing or collaboration arrangements.

Product Candidates and Recent Developments

Zilretta—Late Stage Candidate for Intra-articular Therapy for Patients with Moderate to Severe OA Pain

Our lead product candidate, Zilretta, is a late-stage, injectable, sustained-release, intra-articular, or IA, meaning "in the joint," investigational steroid that we are developing as a treatment for patients with moderate to severe OA pain. We

specifically designed Zilretta to combine a commonly administered steroid, triamcinolone acetonide, or TCA, with poly lactic-co-glycolic acid, referred to as PLGA, with the goal of providing sustained therapeutic concentrations in the joint and persistent analgesic effect. Zilretta is intended to address the limitations of current IA therapies by providing long-lasting, local analgesia while avoiding systemic side effects, which are effects that occur throughout the body as a result of drug that is released from the site of injection into circulating blood. To date, we have completed five clinical trials in which a total of approximately 600 patients with OA of the knee were treated with Zilretta. The overall frequency of treatment-related adverse events in these trials has been similar to those observed with placebo and no serious adverse events have been assessed as related to Zilretta in those trials. Both the magnitude and duration of pain relief provided by Zilretta in clinical trials have been shown to be clinically meaningful with the magnitude of pain relief amongst the largest reported to date in OA clinical trials.

Based on the strength of our pivotal and other clinical trials, we believe that Zilretta has the potential to address a significant unmet medical need for OA pain management by providing safe, more effective and sustained pain relief. We believe the following attributes uniquely distinguish Zilretta:

- An injectable, IA, non-opioid, sustained-release investigational treatment for patients with moderate to severe OA pain that has demonstrated the following in clinical trials to date:
- statistically significant, durable and clinically meaningful improvements in validated OA specific measures compared to the current injectable standard of care,
- statistically significant, durable and clinically meaningful pain relief compared to placebo,
- persistent therapeutic concentrations of drug in the joint and durable efficacy, and
- limited systemic exposures and the potential for fewer serious side effects compared to oral treatment options for OA pain.
- Amongst the largest analgesic effects reported in OA clinical trials.
- Strong proprietary position through a combination of patents, trade secrets and proprietary know-how, as well as eligibility for marketing exclusivity.
- Well-defined Section 505(b)(2) of the Federal Food Drug and Cosmetic Act, regulatory pathway seeking approval for a novel formulation of the same dose and administration route of the already approved immediate-release steroid used by orthopedists and rheumatologists.
- Familiarity of orthopedists and rheumatologists with IA injections utilizing the same steroid at the same dose.
- Fast Track designation from the FDA.

In April 2016, we initiated a double-blind, randomized, parallel group, single dose Phase 2 clinical trial of Zilretta in patients with OA of the knee who also have type 2 (adult) diabetes. Approximately 36 patients will be randomized, and blood glucose levels will be monitored for a total of three weeks (one week prior to injection and two weeks post injection) using a continuous glucose monitoring device. Approximately 20% of patients with knee OA have diabetes and clinical trial data demonstrate that these patients, when treated with IA injections of immediate-release TCA (as well as other corticosteroids) can experience substantial elevations in blood glucose levels in the days post injection. These increases in blood glucose coincide with peak plasma concentrations of the injected steroid and are thought to reflect the anti-insulin effects of such drugs. Since Zilretta has demonstrated in clinical trials lower post-injection plasma concentrations than those seen with immediate-release TCA, we believe that administration of Zilretta may avoid elevated blood glucose levels. The primary endpoint of this trial is the average blood glucose levels over time from baseline through 72 hours post injection for patients receiving Zilretta compared to patients receiving immediate-release TCA.

In April 2015, we announced that the U.S. Department of Defense awarded us a grant worth approximately $2.0 million to conduct a Phase 2 clinical trial investigating Zilretta for the management of OA pain in active military and medically retired veterans with post-traumatic OA of the knee. In April 2016, due to the challenges of enrolling military personnel with post-traumatic knee OA, we discontinued the Phase 2 trial and terminated the grant.

Based upon the results of our pivotal clinical trials and the written responses from the FDA to questions we submitted in advance of a pre-NDA meeting with the FDA regarding Zilretta, we anticipate submitting our Zilretta NDA for single-dose administration to the FDA during the fourth quarter of 2016.

Financial Overview

Revenue

We have not generated any revenue since our inception. We do not have any products approved for sale, and we do not expect to generate any revenue from the sale of products in the near future. In the future, if our research and development efforts result in clinical success and regulatory approval, we may generate revenue from the sales of our

product candidates, including Zilretta, or we may generate revenue from licensing rights to our product candidates to third parties. If we fail to complete the development of Zilretta or other product candidates, our ability to generate future revenue, and our results of operations and financial position will be adversely affected.

Operating Expenses

The majority of our operating expenses to date have been related to the development activities of Zilretta.

Research and Development Expenses

Since our inception, we have focused our resources on our development activities, including: preclinical studies, clinical trials, and chemistry, manufacturing, and controls, or CMC. Our development expenses consist primarily of:

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical studies and clinical trials;
- costs of acquiring, developing and manufacturing clinical trial materials, as well as scale-up for potential commercial supply;
- personnel costs, including salaries, benefits, stock-based compensation and travel expenses for employees engaged in scientific research and development functions;
- costs related to compliance with regulatory requirements;
- expenses related to the in-license of certain technologies from pharmaceutical companies; and
- allocated expenses for rent and maintenance of facilities, insurance and other general overhead.

We expense research and development costs as incurred. Our direct research and development expenses consist primarily of external-based costs, such as fees paid to investigators, consultants, investigative sites, CROs and companies that manufacture our clinical trial materials and anticipated future commercial supplies, and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses to specific research and development programs. These indirect expenses are included within the amounts designated as “Personnel and other costs” in the table below.

The following table summarizes our research and development expenses for the periods presented:

	Three Months Ended		Six Months Ended	
(In thousands)	June 30, 2016	2015	June 30, 2016	2015
Direct research and development expenses by program:				
Zilretta	$ 5,322	$ 6,750	$ 13,430	$ 10,263
FX007	47	164	252	280
Portfolio expansion	73	—	170	—
Other	3	20	141	163
Total direct research and development expenses	5,445	6,934	13,993	10,706
Personnel and other costs				