Flexion Therapeutics Inc
Form 10-Q
November 07, 2016

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 SEPTEMBER 30, 2016

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	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 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

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 October 31, 2016, the registrant had 27,527,419 shares of Common Stock ($0.001 par value) outstanding.

FLEXION THERAPEUTICS, INC.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited in thousands, except share amounts)

	September 30, 2016	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$66,809	$62,944
Marketable securities	92,693	48,303
Accounts receivable	—	95
Prepaid expenses and other current assets	1,584	761
Total current assets	161,086	112,103
Property and equipment, net	11,223	7,442
Long-term investments	2,003	7,357
Other assets	30	157
Restricted cash	80	80
Total assets	$174,422	$127,139
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$2,029	$3,692
Accrued expenses and other current liabilities	3,724	4,367
Current portion of long-term debt	6,634	—
Total current liabilities	12,387	8,059
Long-term debt	23,664	15,002
Other long-term liabilities	339	91
Total liabilities	36,390	23,152
Commitments and contingencies		
Preferred Stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2016 and December 31, 2015 and 0 shares issued and outstanding at September 30, 2016 and December 31, 2015	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 27,527,419 and 21,570,395 shares issued and outstanding, at September 30, 2016 and December 31, 2015, respectively	28	22

Additional paid-in capital	326,605	243,854
Accumulated other comprehensive income	(27)	(97)
Accumulated deficit	(188,574)	(139,792)
Total stockholders' equity	138,032	103,987
Total liabilities and stockholders' equity	$174,422	$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		Nine Months Ended	
	September 30,		September 30,	
	2016	2015	2016	2015
Revenue	$—	$—	$—	$—
Operating expenses:				
Research and development	9,047	7,829	29,933	23,724
General and administrative	8,388	3,197	18,295	8,860
Total operating expenses	17,435	11,026	48,228	32,584
Loss from operations	(17,435)	(11,026)	(48,228)	(32,584)
Other income (expense):				
Interest income	421	274	1,052	882
Interest expense	(561)	(202)	(1,039)	(406)
Other income (expense), net	(207)	(182)	(567)	(639)
Total other income (expense)	(347)	(110)	(554)	(163)
Net loss	$(17,782)	$(11,136)	$(48,782)	$(32,747)
Net loss per share basic and diluted	$(0.65)	$(0.52)	$(2.04)	$(1.52)
Weighted average common shares outstanding, basic and diluted	27,524	21,507	23,938	21,478
Other comprehensive (loss) income:				
Unrealized gains from available-for-sale securities, net of tax of $0	38	9	(70)	8
Total other comprehensive (loss) income	38	9	(70)	8
Comprehensive loss	$(17,744)	$(11,127)	$(48,852)	$(32,739)

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)

	Nine Months Ended September 30,	
	2016	2015
Cash flows from operating activities		
Net loss	$ (48,782)	$ (32,747)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	700	130
Stock-based compensation expense	4,963	3,099
Amortization of premium (discount) on marketable securities	544	637
Other non-cash charges	26	31
Loss on disposal of fixed assets	2,278	—
Premium paid on securities purchased	(273)	—
Changes in operating assets and liabilities:		
Accounts receivable	95	(46)
Prepaid expenses, other current and long-term assets	(697)	(243)
Accounts payable	(1,029)	389
Accrued expenses and other current and long-term liabilities	690	786
Net cash used in operating activities	(41,485)	(27,964)
Cash flows from investing activities		
Purchases of property and equipment	(8,165)	(2,415)
Change in restricted cash	—	24

Purchases of marketable securities	(80,151)	(106,465)
Sale and redemption of marketable securities	40,897	95,704
Discount received on securities purchased	17	—
Net cash used in investing activities	(47,402)	(13,152)
Cash flows from financing activities		
Payment of debt issuance costs	(42)	(108)
Payments on debt	—	(3,500)
Proceeds from the offering of common stock, net of underwriter's commission and fees	77,644	—
Proceeds from the issuance of notes payable	15,000	15,004
Payments of public offering costs	(256)	(225)
Proceeds from the exercise of stock options	166	216
Proceeds from Employee Stock Purchase Plan	240	138
Net cash provided by financing activities	92,752	11,525
Net increase (decrease) in cash and cash equivalents	3,865	(29,591)
Cash and cash equivalents at beginning of period	62,944	103,098
Cash and cash equivalents at end of period	$ 66,809	$ 73,507
Supplemental disclosures of cash flow information:		
Cash paid for interest	$ 823	$ 370
Supplemental disclosures of non-cash financing activities:		
Purchases of property and equipment in	$ —	$ 811

accounts payable and accrued expenses	

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," the "Company," "we," "our," or "us") 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 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, extended-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 the 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 (the "2016 Offering"), 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 their option to purchase additional shares. The Company received aggregate gross proceeds from the 2016 Offering of $77.6 million after deducting underwriting commissions and fees paid by the Company.

The Company's total issued common stock as of September 30, 2016 was 27,527,419.

3. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of September 30, 2016, and for the three and nine months ended September 30, 2016 and September 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 September 30, 2016, and for the three and nine months ended September 30, 2016 and September 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 nine months ended September 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 September 30, 2016 and December 31, 2015, the Company had cash, cash equivalents, marketable securities, and long-term investments of $161,505,000 and $118,604,000, respectively. Management believes that current cash, cash equivalents and marketable securities on

hand at September 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, to fund increased research and development costs in order to seek approval for commercialization of its product candidates, and to successfully commercialize Zilretta, if approved. 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, to establish a commercial infrastructure in order to generate future revenue streams, and to successfully commercialize Zilretta, if approved.

In August 2014, the FASB issued ASU No. 2014-15, Presentation of Financial Statements — Going Concern: Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). ASU 2014-15 is intended to define management's responsibility to evaluate whether there is substantial doubt about an organization's ability to continue as a going concern and to provide related footnote disclosures, if required. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, and applies to annual and interim periods thereafter. The Company does not believe that the adoption of ASU 2014-15 will have a significant impact on the Company's financial statement disclosures.

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.

In March 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.

In August 2016, the FASB issued ASU 2016-15, Statement of cash flows (Topic 230), to increase the consistency of presentation in how certain cash receipts and cash payments are presented and classified in the statement of cash

flows. ASU 2016-15 will become effective for fiscal years, and the interim periods within those years, beginning after December 15, 2017. The Company is currently evaluating the potential 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 nine months ended September 30, 2016 and the year ended December 31, 2015, the year Flexion Securities Corporation, Inc. was established.

U.S. Government Grant

The Company previously 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 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 was reimbursed and has offset research and development expenses in the statement of

operations when invoices for allowable costs were 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.

Accounts Receivable

Accounts receivable represents allowable costs under the Company's now terminated U.S. Government agency grant for which the Company has not yet received reimbursement. The Company invoiced 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 September 30, 2016 there were no unbilled accounts receivable, and as of December 31, 2015, there were unbilled accounts receivable of $95,000.

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 denominated 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.

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 September 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 September 30, 2016 Using:		
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$—	$44,540	$ —	$44,540
Marketable securities	—	94,696	—	94,696
	$—	$139,236	$ —	$139,236

	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 September 30, 2016 and December 31, 2015, the Company's cash equivalents that are invested in money market funds are valued based on Level 2 inputs. The Company measures the fair value of marketable securities, which consist of U.S. government obligations, commercial paper, and corporate bonds, using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. During the nine months ended September 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, prepaid expenses, other current assets, accounts payable and accrued expenses approximate their fair value due to the short-term nature of these balances.

The Company has a term loan outstanding under its 2015 credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank (the "2015 term loan"). The amount outstanding on its 2015 term loan 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 September 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 September 30, 2016 and December 31, 2015 the fair value of available-for-sale marketable securities by type of security was as follows:

	September 30, 2016			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. Government obligations	$17,017	$ 7	$ (1)	$ 17,023
Commercial Paper	2,996	—	—	2,996
Corporate bonds	74,710	2	(35)	74,677
	$94,723	$ 9	$ (36)	$ 94,696

	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

As of September 30, 2016 and December 31, 2015, marketable securities consisted of $92,693,000 and $48,303,000, respectively, of investments that mature within twelve months and $2,003,000 and $7,357,000, respectively, of investments that mature within fifteen months.

6. Property and Equipment, Net

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

(In thousands)	September 30, 2016	December 31, 2015
Manufacturing equipment	$ 10,099	$ 2,534
Computers, office equipment, and minor computer software	539	393
Software	436	342
Construction—in progress	429	4,134
Furniture and fixtures	402	290
Leasehold improvements	278	239
	12,183	7,932
Less: Accumulated depreciation	(960)	(490)
Total property and equipment, net	$ 11,223	$ 7,442

Depreciation expense for the nine months ended September 30, 2016 and 2015 was $700,000 and $130,000, respectively. During the nine months ended September 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 nine months ended September 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 Corporation ("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 purchase of a dedicated manufacturing suite for use by the Company's contract manufacturer of Zilretta finished drug product, Patheon UK Limited ("Patheon").

No property and equipment was disposed of during the nine months ended September 30, 2015.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	September 30, 2016	December 31, 2015
Payroll and other employee-related expenses	$ 2,018	$ 1,648

Professional services fees	819	434
Other	258	74
Clinical research	204	552
Interest expense	156	81
Contract manufacturing services	149	1,444
Regulatory services	88	64
Consultant fees and expenses	32	70
Total accrued expenses and other current liabilities	$ 3,724	$ 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 publicly-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 nine months ended September 30, 2016 and 2015 are as follows:

	Nine months ended September 30,	
	2016	2015
Risk-free interest rates	1.05-1.90%	1.49-1.92%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	79.8-81.7%	76.4-81.4%

The following table summarizes stock option activity for the nine months ended September 30, 2016:

(In thousands, except per share amounts)	Shares Issuable Under Options	Weighted Average Exercise Price
Outstanding as of December 31, 2015	1,657	$ 14.28
Granted	948	16.67
Exercised	(30)	5.52
Cancelled	(97)	19.16
Outstanding as of September 30, 2016	2,478	$ 15.11
Options vested and expected to vest at September 30, 2016	2,141	$ 14.72
Options exercisable at September 30, 2016	1,078	$ 11.95

In addition to the approximately 948,000 common stock options granted, approximately 205,000 restricted common stock units ("RSUs") were also granted, of which approximately 10,000 RSUs were cancelled, during the nine months

ended September 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 September 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 30,000 options, with an aggregate intrinsic value of $236,000, were exercised during the nine months ended September 30, 2016.

At September 30, 2016 and 2015, there were options for the purchase of approximately 2,478,000 and 1,578,000 shares of the Company's common stock outstanding, respectively, with a weighted average remaining contractual term of 8.0 and 8.1 years, respectively, and with a weighted average exercise price of $15.11 and $10.32 per share, respectively.

The weighted average grant date fair value of options granted during the nine months ended September 30, 2016 and 2015 was $11.90 and $15.67, respectively.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options for the three and nine months ended September 30, 2016 and 2015 as follows:

	Three months ended		Nine months ended	
	September 30,		September 30,	
(In thousands)	2016	2015	2016	2015
Research and development	$543	$332	$1,656	$941
General and administrative	1,160	789	3,307	2,158
	$1,703	$1,121	$4,963	$3,099

As of September 30, 2016 unrecognized stock-based compensation expense for stock options outstanding was $11,227,000, which was expected to be recognized over a weighted average period of 2.7 years. As of September 30, 2015, unrecognized stock-based compensation expense for stock options outstanding was $11,500,000, which was expected to be recognized over a weighted average period of 2.7 years.

Restricted Stock Units

On January 4, 2016, the Company granted RSUs with performance and time-based vesting conditions to certain executives. These RSUs 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 these awards is 194,400 with an approximate value of $3,538,000 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 these awards, these 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 these awards, beginning on the Milestone achievement date.

9. Net Loss per Share

Basic and diluted net loss per share was calculated as follows for the three and nine months ended September 30, 2016 and 2015:

For the nine months ended

	For the three months ended September 30,		September 30,	
(In thousands)	2016	2015	2016	2015
Numerator:				
Net loss	$(17,782)	$(11,136)	$ (48,782)	$ (32,747)
Net loss:	$(17,782)	$(11,136)	$ (48,782)	$ (32,747)
Denominator:				
Weighted average common shares outstanding, basic and diluted	27,524	21,507	23,938	21,478
Net loss per share, basic and diluted	$(0.65)	$(0.52)	$ (2.04)	$ (1.52)

Stock options and RSUs covering 2,549,000 and 1,716,000 weighted average shares of common stock were excluded from the computation of diluted net loss per share for the three months ended September 30, 2016 and 2015, respectively, and 2,452,000 and 1,658,000 weighted average shares of common stock were excluded from the computation of diluted net loss per share attributable to common shareholders for the nine months ended September 30, 2016 and 2015, respectively. These equity awards were excluded from the computations because the awards 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 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 agreed not to encumber any of its intellectual property without the Lenders' prior written consent. The Company also agreed to maintain a balance in cash or cash equivalents at Silicon Valley Bank equal to the principal balance of the loan plus 5% for so long as the Company maintains any cash or cash equivalents in non-secured bank accounts.

On July 22, 2016, the Company borrowed the remaining $15,000,000 under the credit and security agreement, in the form of a second term loan after receiving positive Phase 3 Zilretta clinical trial data meeting the trial's primary 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.

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 September 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 September 30, 2016, the carrying value of the term loan was $30,298,000, of which $6,634,000 was due within 12 months and $23,664,000 was due in greater than 12 months.

In connection with the credit and security agreement, the Company incurred debt issuance costs totaling approximately $150,000. These costs are being 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 September 30, 2016 and December 31, 2015.

As of September 30, 2016, annual principal and interest payments due under the 2015 term loan are as follows:

Year	Aggregate Minimum Payments (in thousands)
2016 (remaining three months)	$ 474
2017	10,036
2018	11,082
2019	10,448
2020	4,380
Total	$ 36,420
Less interest	(3,422)
Less final payment	(2,700)
Total	$ 30,298

11. Income Taxes

Section 382 of the Internal Revenue Code of 1986, as amended ("Section 382") contains rules that limit the ability of a company that undergoes an ownership change within the meaning of Section 382 to utilize its net operating losses ("NOLs") and existing tax credits as of the date of such ownership change. Under the rules, such an ownership change is generally any change in ownership of more than 50% of a company's stock within a rolling three-year period. The rules generally operate by focusing on changes in ownership among stockholders considered by the rules to own, directly or indirectly, 5% or more of the stock of a company and any change in ownership arising from new issuances of stock by the company. During the quarter ended September 30, 2016, the Company completed a Section 382 study through June 30, 2016. The results of this study showed that one historical ownership change within the meaning of Section 382 had occurred on June 8, 2016 in connection with the Company's 2016 Offering. Although a Section 382 change in ownership has occurred, it is not currently anticipated that a portion of the Company's NOLs will expire unutilized as a result of this Section 382 limitation. Any subsequent ownership changes as defined by Section 382 may potentially limit the amount of our NOL carryforwards that could be utilized annually to offset any future taxable income. The Company has generated losses since inception and therefore has recorded no income tax benefits for those losses due to its uncertainty of realizing a benefit from those losses.

12. Foreign Currency

The Company maintains a bank account denominated 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. Foreign currency losses for the three and nine months ended September 30, 2016 was $0.6 million, compared to zero for the three and nine months ended September 30, 2015.

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 own the exclusive worldwide rights to our lead product candidate, Zilretta, a late-stage, extended-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 developing 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 September 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 September 30, 2016, we have raised $337.0 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 (FX006)—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, extended-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 knee 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 six clinical trials in which a total of over 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, extended-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,
  - 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 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 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. Approximately 33 patients were enrolled in this double-blind randomized, parallel group single dose study, and blood glucose levels were monitored for a total of three weeks (one week prior to injection and two weeks post injection) using a continuous glucose monitoring device. In November 2016, we announced top-line results from this trial that demonstrated a markedly lower post-injection rise in blood glucose levels in patients receiving Zilretta compared to patients receiving immediate-release TCA. The difference was statistically significant ($p<0.05$, 2-sided) and clinically relevant.

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 in December 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 obtain regulatory approval for 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.

16

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 ("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		Nine Months Ended	
	September 30,		September 30,	
(In thousands)	2016	2015	2016	2015
Direct research and development expenses by program:				
Zilretta	$ 5,023	$ 5,455	$ 18,453	$ 15,718
FX007	12	103	264	383
Portfolio expansion	52	—	222	—
Other	62	79	203	242
Total direct research and development expenses	5,149	5,637	19,142	16,343
Personnel and other costs	3,898	2,192	10,791	7,381
Total research and development expenses	$ 9,047	$ 7,829	$ 29,933	$ 23,724

Related costs incurred under our prior grant from the U.S. Department of Defense for the Phase 2 clinical trial that investigated Zilretta in active military and medically retired veterans with post-traumatic knee OA were included in research and development expenses. Reimbursements were recorded as an offset to research and development expenses when invoices for allowable costs were prepared and submitted to the U.S. Department of Defense. Due to the challenges of enrolling military personnel with post-traumatic knee OA, we discontinued this Phase 2 trial and terminated the grant. Payments under cost reimbursable grants with agencies of the U.S. government were provisional payments subject to adjustment upon audit by the U.S. government. To date we have been reimbursed for approximately $757,000 under the grant.

Our research and development expenses are expected to increase in the foreseeable future. Specifically, our costs associated with Zilretta will increase as we conduct additional clinical trials, make initial investments for commercial product supply, and further the manufacturing process in anticipation of validation and commercialization, including the costs for the build-out of the portion of the dedicated manufacturing facility with our contract manufacturer, Patheon. Evonik, our supplier of PLGA for Zilretta, had previously manufactured finished drug product for our Zilretta clinical trial materials; however, in early 2016 we decided to use Patheon as our sole supplier of Zilretta finished drug product for clinical trials and commercial supply. We impaired approximately $2,265,000 in manufacturing equipment located at the Evonik facility, resulting in a loss of $2,180,000 which was recorded in research and development expenses for the nine months ended September 30, 2016.

We cannot determine with certainty the duration of and completion costs associated with future clinical trials of Zilretta or the regulatory approval process. The duration, costs and timing associated with the development and commercialization of Zilretta will depend on a variety of factors, including uncertainties associated with the results of our clinical trials and our ability to obtain regulatory approval. As a result of these uncertainties, we are currently unable to estimate with any precision our future research and

development expenses, when or if we will achieve regulatory approval, generate revenue from sales or achieve a positive cash flow position.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel costs, including salaries, related benefits, travel expenses and stock-based compensation of our executive, finance, business development, commercial, information technology, legal and human resources functions. Other general and administrative expenses include an allocation of facility-related costs, patent filing expenses, and professional fees for legal, consulting, auditing and tax services.

We anticipate that our general and administrative expenses will increase in the future as we continue to build our corporate and commercial infrastructure to support the continued development and potential launch of Zilretta or any other product candidates. Additionally, we anticipate increased expenses related to the audit, legal and compliance, regulatory, investor relations and tax-related services associated with maintaining compliance with the SEC and Nasdaq requirements and healthcare laws and compliance requirements, director and officer insurance premiums and other costs associated with operating as a publicly-traded company.

Other Income (Expense)

Interest income. Interest income consists of interest earned on our cash and cash equivalents balances and our marketable securities. The primary objective of our investment policy is capital preservation.

Interest expense. We have borrowed $30.0 million under our 2015 term, and we incur interest related to this borrowing at a fixed rate of 6.25% per annum. We expect to incur future interest expense related to this borrowing until February 1, 2020.

Foreign currency gain (loss). We maintain a bank account denominated 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 general and administrative expenses.

Other expense. Other expense consists of the net amortization of premiums and discounts related to our marketable securities, and our realized gains (losses) on redemptions of our marketable securities. We will continue to incur expenses related to net amortization of premiums on marketable securities for as long as we hold these investments.

Critical Accounting Policies and Significant Judgments and Estimates

Our management’s discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, and the reported revenue and expenses during the reported periods. We evaluate these estimates and judgments, including those described below, on an ongoing basis. We base our estimates on historical experience, known trends and events, contractual milestones and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe that the estimates, assumptions and judgments involved in the accounting policies described in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2015 have the greatest potential impact on our financial statements, so we consider them to be our critical accounting policies and estimates. There were no material changes to our critical accounting policies and estimates during the nine months ended September 30, 2016.

RESULTS OF OPERATIONS

Comparison of the three and nine months ended September 30, 2016 and 2015

The following tables summarize our results of operations for the three and nine months ended September 30, 2016 (certain items may not sum correctly due to rounding):

	Three Months Ended September 30,			% Increase/
(In thousands)	2016	2015	Change	(Decrease)
Revenue	$—	$—	$—	—
Operating expenses:				
Research and development	9,047	7,829	1,218	15.6 %
General and administrative	8,388	3,197	5,191	162.4 %
Total operating expenses	17,435	11,026	6,409	58.1 %
Loss from operations	(17,435)	(11,026)	(6,409)	58.1 %
Other income (expense):				
Interest income	421	274	147	53.6 %
Interest expense	(561)	(202)	(359)	177.7 %
Other expense	(207)	(182)	(25)	13.7 %
Total other income (expense)	(347)	(110)	(237)	215.5 %
Net loss	$(17,782)	$(11,136)	$(6,646)	59.7 %

	Nine Months Ended September 30,			% Increase/
(In thousands)	2016	2015	Change	(Decrease)
Revenue	$—	$—	$—	—
Operating expenses:				
Research and development	29,933	23,724	6,209	26.2 %
General and administrative	18,295	8,860	9,435	106.5 %
Total operating expenses	48,228	32,584	15,644	48.0 %
Loss from operations	(48,228)	(32,584)	(15,644)	48.0 %
Other income (expense):				
Interest income	1,052	882	170	19.3 %
Interest expense	(1,039)	(406)	(633)	155.9 %
Other expense	(567)	(639)	72	(11.3)%
Total other income (expense)	(554)	(163)	(391)	239.9 %
Net loss	$(48,782)	$(32,747)	$(16,035)	49.0 %

Research and Development Expenses

	Three Months Ended September 30,			% Increase/ (Decrease)
(In thousands)	2016	2015	Change	
Direct research and development expenses by program:				
Zilretta	$5,023	$5,455	$(432)	(7.9)%
FX007	12	103	(91)	(88.3)%
Portfolio expansion	52	—	52	100.0 %
Other	62	79	(17)	(21.5)%
Total direct research and development expenses	5,149	5,637	(488)	(8.7)%
Personnel and other costs	3,898	2,192	1,706	77.8 %
Total research and development expenses	$9,047	$7,829	$1,218	15.6 %

	Nine Months Ended September 30,			% Increase/ (Decrease)
(In thousands)	2016	2015	Change	
Direct research and development expenses by program:				
Zilretta	$18,453	$15,718	$2,735	17.4 %
FX007	264	383	(119)	(31.1)%
Portfolio expansion	222	—	222	100.0 %
Other	203	242	(39)	(16.1)%
Total direct research and development expenses	19,142	16,343	2,799	17.1 %
Personnel and other costs	10,791	7,381	3,410	46.2 %
Total research and development expenses	$29,933	$23,724	$6,209	26.2 %

Research and development expenses were $9.0 million and $7.8 million for the three months ended September 30, 2016 and 2015, respectively. The increase in research and development expenses year over year of $1.2 million was primarily due to a $1.7 million increase in personnel and other employee-related costs for additional headcount and stock compensation expense offset by a $0.4 million decrease in CMC costs due to the change in our Zilretta finished drug product manufacturer, from Evonik to Patheon.

Research and development expenses were $29.9 million and $23.7 million for the nine months ended September 30, 2016 and 2015, respectively. The increase in research and development expenses year over year of $6.2 million was primarily due to a $3.4 million increase in personnel and other employee-related costs for additional headcount and stock compensation expense and a $2.7 million increase in investments in the commercial product supply and the advancement of our manufacturing process in anticipation of validation and commercialization.

General and Administrative Expenses

General and administrative expenses were $8.4 million and $3.2 million for the three months ended September 30, 2016 and 2015, respectively. The increase in general and administrative expenses of $5.2 million was primarily due to additional costs associated with building a commercial infrastructure to effectively support the potential commercialization of Zilretta, including increases in public relations and promotional expenses, market research

expenses, and salary and related costs associated with additional headcount and stock compensation expense.

General and administrative expenses were $18.3 million and $8.9 million for the nine months ended September 30, 2016 and 2015, respectively. The increase in general and administrative expenses of $9.4 million was primarily due to additional costs associated with building a commercial infrastructure to effectively support the potential commercialization of Zilretta, including increases in public relations and promotional expenses, market research expenses, and salary and related costs associated with additional headcount and stock compensation expense.

Other Income (Expense)

Interest income was $0.4 million and $0.3 million for the three months ended September 30, 2016 and 2015, respectively. Interest income was $1.1 million and $0.9 million for the nine months ended September 30, 2016 and 2015. The increase in interest income was primarily due to an increase in average investment balance yield during 2016.

Interest expense was $0.6 million and $0.2 million for the three months ended September 30, 2016 and 2015, respectively, and $1.0 million and $0.4 million for the nine months ended September 30, 2016 and 2015, respectively. The increase in interest expense

for the three and nine months ended September 30, 2016 was primarily due to interest incurred on the $30 million borrowed under our 2015 term loan.

Liquidity and Capital Resources

To date, we have not generated any revenue and have incurred losses since our inception in 2007. As of September 30, 2016, we had an accumulated deficit of $188.6 million. We anticipate that we will continue to incur losses for the foreseeable future. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may seek to obtain through one or more equity offerings, debt financings, government or other third-party funding, and licensing or collaboration arrangements.

Since our inception through September 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 September 30, 2016, we have raised $337 million from such transactions, including amounts from our initial and follow-on public offerings during 2014 and 2016. As of September 30, 2016, we had cash and cash equivalents of $66.8 million and marketable securities of $94.7 million. Based on our current operating plan we anticipate that our existing cash, cash equivalents and marketable securities will fund our operations for at least the next twelve months. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to capital preservation.

The following table shows a summary of our cash flows for each of the nine months ended September 30, 2016 and 2015:

	Nine Months Ended September 30,	
(In thousands)	2016	2015
Cash flows used in operating activities	$ (41,485)	$ (27,964)
Cash flows used in investing activities	(47,402)	(13,152)
Cash flows provided by financing activities	92,752	11,525
Net increase (decrease) in cash and cash equivalents	$ 3,865	$ (29,591)

Net Cash Used in Operating Activities

Operating activities used $41.5 million of cash in the nine months ended September 30, 2016. The cash flow used in operating activities resulted primarily from our net loss of $48.8 million for the period and cash used for changes in our operating assets and liabilities of $0.9 million, partially offset by non-cash charges of $8.2 million. Our non-cash charges consisted primarily of $5.0 million of stock-based compensation expense, $2.3 million of loss related to the disposal of our fixed assets, and $1.2 million of depreciation and amortization. Net cash used for changes in our operating assets and liabilities consisted primarily of a $0.7 million increase in our prepaid expenses and other current assets due to insurance costs and a decrease of $0.3 million in accounts payable and accrued expenses.

Operating activities used $28.0 million of cash in the nine months ended September 30, 2015. The cash flow used in operating activities resulted primarily from our net loss of $32.7 million for the period partially offset by cash provided by changes in our operating assets and liabilities of $0.9 million, and non-cash charges of $3.9 million. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $0.4 million increase in our accounts payable, and an increase of $0.8 million in accrued expenses. The increase in accounts payable, accrued

expenses and other current liabilities was primarily attributable to increased expenses related to clinical research and contract manufacturing services. These changes were partially offset by an increase in accounts receivable and other current assets of $0.3 million. Our non-cash charges consisted primarily of $3.1 million of stock-based compensation expense and $0.8 million in depreciation expense and amortization and accretion related to our investments.

Net Cash Used in Investing Activities

Net cash used in investing activities was $47.4 million in the nine months ended September 30, 2016. Net cash used in investing activities consisted primarily of cash used for the purchase of marketable securities of $80.2 million, partially offset by cash received for the redemption of marketable securities of $40.9 million. In addition, $8.2 million of cash was used to purchase manufacturing equipment.

Net cash used in investing activities was $13.2 million in the nine months ended September 30, 2015. Net cash used in investing activities consisted primarily of cash used for the purchase of marketable securities of $106.5 million, partially offset by cash received from the redemption and sale of marketable securities of $95.7 million. In addition, $2.4 million of cash was used to purchase property and equipment.

Net Cash Provided by Financing Activities

Financing activities provided $92.8 million for the nine months ended September 30, 2016. Net cash provided by financing activities in the nine months ended September 30, 2016 consisted of $77.6 million in gross proceeds from a follow-on public offering, $15.0 million from borrowing the remaining amount under our credit facility with MidCap Financial Funding XIII Trust and Silicon Valley, and $0.4 million related to the exercises of stock options and employee stock purchases through our employee stock purchase plan.

Net cash provided by financing activities in the nine months ended September 30, 2015 was $11.5 million and consisted of $15.0 borrowed under our credit facility with MidCap Financial Funding XIII Trust and Silicon Valley Bank in August 2015, partially offset by $3.5 million paid to satisfy our 2013 term loan obligation. In addition, we received $0.4 million in proceeds from the exercise of stock options and the issuance of common stock related to our employee stock purchase plan that was partially offset by $0.2 million in financing costs associated with our follow-on financing in late 2014 and $0.1 million in issuance costs associated with our long-term loan obligation.

Contractual Obligations

The total cash obligation for the base rent from inception through the lease termination date for the office space committed to under the lease, as amended, is approximately $3.1 million.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of a majority of our investment portfolio and the low risk profile of our investments, an immediate 10.0% change in interest rates would not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by a sudden change in market interest rates on our investment portfolio.

Our 2015 term loan carries a fixed interest rate and, thus, we are subject to limited interest rate risk.

We do not believe that our cash, cash equivalents and marketable securities have significant risk of default or illiquidity. While we believe our cash and cash equivalents and marketable securities are invested with the goal of capital preservation, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Most of our transactions are conducted in the U.S. dollar. We do have certain agreements with vendors located outside the United States, which have transactions conducted primarily in British Pounds and Euros. As of September 30, 2016 we had approximately $0.1 million in payables to vendors denominated in currencies other than the U.S. dollar. A hypothetical 10% change in foreign exchange rates would not have a material effect on the value of our liability. As of September 30, 2016, we also had approximately $11.6 million in cash denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in either a $1.0 million increase, in the event the U.S. dollar strengthens relative to the British Pound, or a $0.8 million decrease, in the event the U.S. dollar weakens relative to the British Pound, of cash denominated in British Pounds.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

We are responsible for maintaining disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Disclosure controls and procedures are controls and other procedures designed to ensure that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive officer and our principal financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive officer and our principal financial officer have concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of September 30, 2016, the end of the period covered by this report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any material legal proceedings.

ITEM 1A. RISK FACTORS

You should carefully consider the risk factors included in Item 1A of our Annual Report on Form 10-K, as updated by the risk factors included in Exhibit 99.1 to our Current Report on Form 8-K filed on June 7, 2016, which are incorporated herein by reference and are further updated by the risk factors included in Item 1A of our Quarterly Report on Form 10-Q filed on August 3, 2016, which are incorporated herein by reference, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of these risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. In these circumstances, the market price of our common stock would likely decline. You should consider all of the factors described in Item 1A of our Annual Report on Form 10-K, the risk factors included in Exhibit 99.1 to our Current Report on Form 8-K filed on June 7, 2016, and the risk factors included in Item 1A of our Quarterly Report on Form 10-Q filed on August 3, 2016, when evaluating our business. Other than the changes to the risk factors included in Exhibit 99.1 to our Current Report on Form 8-K filed on June 7, 2016 and in the risk factors included in Item 1A of our Quarterly Report on Form 10-Q filed on August 3, 2016, there have been no material changes to the risk factors included in Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015.

If we fail to obtain additional financing, we would be forced to delay, reduce or eliminate our product development programs and planned commercialization activities.

Developing and commercializing pharmaceutical products, including conducting preclinical studies and clinical trials, and building and maintaining sales and marketing capabilities, is expensive. We expect our expenses to substantially increase in connection with our ongoing activities, particularly as we advance our clinical programs, including our on-going and planned clinical trials for Zilretta, continue our manufacturing scale-up activities and build a sales and marketing organization to commercialize Zilretta.

As of September 30, 2016, we had cash, cash equivalents and marketable securities of $161.5 million and working capital of $148.7 million. Based upon our current operating plan, we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital requirements for at least the next twelve months, including through the submission of an NDA for Zilretta. Regardless of our expectations as to how long our cash, cash equivalents and marketable securities will fund our operations, changing circumstances beyond our control may cause us to consume capital more rapidly than we currently anticipate. For example, our clinical trials may encounter technical, enrollment or other difficulties that could increase our development costs more than we expect or the FDA could impose additional or different clinical development requirements on us prior to or following our submission of an NDA for Zilretta. In any event, we may require additional capital prior to commercializing Zilretta or any of our other product candidates.

Attempting to secure additional financing may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of our product candidates;
- seek corporate partners for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available;
- relinquish or license on unfavorable terms, our rights to technologies or product candidates that we otherwise would seek to develop or commercialize ourselves; or
- significantly curtail, or cease, operations.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Our credit and security agreement with MidCap Financial Trust, or MidCap, and Silicon Valley Bank contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay the outstanding indebtedness earlier than we expect under our credit and security agreement if a prepayment event or an event of default occurs, including a material adverse change with respect to us, which could have a materially adverse effect on our business.

On August 4, 2015, we entered into a credit and security agreement with MidCap, as administrative agent, and MidCap Funding XIII Trust and Silicon Valley Bank, as lenders, to borrow up to $30.0 million. We have since drawn down the full $30.0 million under the credit facility. The agreement contains various covenants that limit our ability to engage in specified types of transactions. These covenants limit our ability to, among other things:

- incur or assume certain debt;
- merge or consolidate or acquire all or substantially all of the capital stock or property of another entity;
    - enter into any transaction or series of related transactions that would be deemed to result in a change in control of us under the terms of the agreement;
- change the nature of our business;
- change our organizational structure or type;
- amend, modify or waive any of our organizational documents;
- license, transfer or dispose of certain assets;
- grant certain types of liens on our assets;
- make certain investments;
- pay cash dividends;
- enter into material transactions with affiliates; and
- amend or waive provisions of material agreements in certain manners.

The restrictive covenants of the agreement could cause us to be unable to pursue business opportunities that we or our stockholders may consider beneficial.

A breach of any of these covenants could result in an event of default under the agreement. As of September 30, 2016 we were in compliance with these covenants. An event of default will also occur if, among other things, a material adverse change in our business, operations or condition occurs, which could potentially include negative results in our future clinical trials or unfavorable determinations by the FDA with respect to the potential approval of Zilretta, or a material impairment of the prospect of our repayment of any portion of the amounts we owe under the agreement occurs. In the case of a continuing event of default under the agreement, the lenders could elect to declare all amounts outstanding to be immediately due and payable, proceed against the collateral in which we granted the lenders a security interest under the agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

We may not have enough available cash or be able to raise additional funds on satisfactory terms, if at all, through equity or debt financings to repay our indebtedness at the time any such repayment is required. In such an event, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Our business, financial condition and results of operations could be materially adversely affected as a result.

We rely completely on third parties to manufacture our preclinical and clinical drug supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate.

If we were to experience an unexpected loss of supply of our product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat clinical trials and could also face delays with respect to any NDA submission or approval. We do not currently have nor do we plan to acquire the infrastructure or capability internally to manufacture our preclinical and clinical drug supplies and we lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. The facilities used by our contract manufacturers or other third party manufacturers to manufacture our product candidates, including Patheon with respect to

supplies of Zilretta, must be approved by the FDA. While we work closely with our third party manufacturers on the manufacturing process for our product candidates, including quality audits, we generally do not control the implementation of the manufacturing process of, and are completely dependent on, our contract manufacturers or other third party manufacturers for compliance with cGMP regulatory requirements and for manufacture of both active drug substances and finished drug products. If our contract manufacturers or other third party manufacturers cannot successfully manufacture material that conforms to applicable specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities.

In addition, we have no control over the ability of our contract manufacturers or other third party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved.

We are particularly reliant on Patheon with respect to maintaining the Zilretta manufacturing suites and validating the Zilretta manufacturing process in those suites. These Patheon facilities will need to be approved by the FDA as a condition to any NDA approval for Zilretta, as we intend to rely exclusively on Patheon for initial commercial supply of Zilretta. In addition, because Patheon will be manufacturing Zilretta in the United Kingdom, or U.K., it will need to maintain and update its facility license with the applicable U.K. regulatory agencies and any delay or inability to do so would delay or prevent Patheon from being able to produce commercial supplies of Zilretta. Furthermore, the manufacturing process for Zilretta is unique and involves specialized equipment and proprietary processes, and Patheon has not previously manufactured Zilretta, which subjects us to heighted risks that Patheon will experience delays in validating the manufacturing process. If Patheon experiences such delays, particularly delays in producing Zilretta in compliance with cGMP regulations, our ability to submit an NDA for Zilretta would be impaired or the FDA may refuse to file or approve the NDA. In addition, due to the fact that most cGMP batches of Zilretta have been produced by Evonik, and any cGMP batches produced at Patheon's facilities will not have been subject to longer-term stability testing by the time we anticipate submitting an NDA for Zilretta, we will need to demonstrate that Zilretta produced at Patheon's facilities is comparable to Zilretta previously produced by Evonik. If we are unable to demonstrate such comparability to the satisfaction of the FDA, it may result in a deficiency in the NDA during the review and delay approval until such time that batches of Zilretta produced by Patheon have demonstrated sufficient stability.

We also rely on our manufacturers to purchase from third party suppliers the materials necessary to produce our product candidates for our clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our product candidates for our clinical trials, and if approved, for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a contract manufacturer or other third party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates. If our manufacturers or we are unable to purchase these raw materials after regulatory approval has been obtained for our product candidates, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenue from the sale of our product candidates.

We expect to continue to depend on contract manufacturers or other third party manufacturers for the foreseeable future. Other than our commercial supply agreement with Patheon, we have not entered into long-term commercial supply agreements with our current contract manufacturers. Although we intend to do so prior to any commercial launch in order to ensure that we maintain adequate supplies to manufacture finished drug product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business.

We rely on certain sole sources of supply for our product candidates and any disruption in the chain of supply may cause delay in developing, obtaining approval for and commercializing our product candidates.

Currently, we use the following sole sources of supply for manufacturing Zilretta: Farmabios SpA for TCA, Evonik Corporation for PLGA, and Patheon for finished microspheres drug product. Because of the unique equipment and process for loading TCA onto PLGA microspheres, transferring finished drug product manufacturing activities for Zilretta to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching Zilretta finished drug suppliers may involve substantial cost and could result in a delay in our desired clinical, regulatory and commercial timelines. For Zilretta, we expect that for the foreseeable future we will only seek to qualify Patheon as a commercial supplier with the FDA. As a result, if supply from Patheon is interrupted, there could be a significant

disruption in commercial supply. Any alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new Zilretta supplier is relied upon for commercial production.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of Zilretta or any of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredient on a timely basis and at commercially reasonable prices and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue in the event of a product stockout if Zilretta or any other product candidate is approved and launched.

Our agreements with Patheon may expose us to unanticipated expenses and we may never realize an adequate return on our investment.

We and Patheon have entered into Manufacturing and Technical Transfer Agreements for the manufacture of Zilretta. Under the terms of the Technical Transfer Agreement, Patheon has agreed to undertake certain technical transfer activities and construction services needed to prepare its United Kingdom facility for the manufacture of Zilretta in dedicated manufacturing suites. We have agreed with Patheon, among other things, to provide the equipment necessary to manufacture Zilretta in these suites, to pay for construction of the suites, and to make payments related to their establishment and validation of manufacturing processes in the suites, and we expect these costs to be substantial.

Due to the complexity of the Zilretta manufacturing process and the fact that Patheon had never previously manufactured Zilretta, the validation of the Zilretta manufacturing process in the Patheon suits may be subject to heighted risk of cost overruns and delays. If Patheon experiences unanticipated cost overruns, if Patheon experiences delays in validating the Zilretta manufacturing process, or if the Patheon suites do not receive regulatory approvals in the timeframe anticipated, if at all, this could have a material adverse effect on our business, financial position and results of operations. In particular, if we are unable to obtain regulatory approval for Zilretta or subsequent commercial supply of Zilretta from Patheon, we may not realize an appropriate return, or any return, on our significant investment in establishing and validating the Patheon manufacturing suites.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit number	Description of document
3.1[(1)]	Amended and Restated Certificate of Incorporation of the Registrant.
3.2[(1)]	Amended and Restated Bylaws of the Registrant.
4.1[(2)]	Form of Common Stock Certificate of the Registrant.
4.2[(2)]	Amended and Restated Investor Rights Agreement, dated December 3, 2012, by and among the Registrant and certain of its stockholders.
4.3[(2)]	Conversion, Amendment and Waiver Agreement, dated January 27, 2014, by and among the Registrant and certain of its stockholders.
10.1	Sixth Amendment of Lease, dated September 21, 2016, between the Registrant and CIP II/RJK 10-20 BMR Owner, LLC.
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on February 19, 2014.

(2) Incorporated by reference to the Registrant's Registration Statement on Form S-1 (File No. 333-193233), as amended.

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 thereunto duly authorized.

Flexion Therapeutics, Inc.

Date: November 7, 2016 By: /s/ Frederick W. Driscoll
Frederick W. Driscoll
Chief Financial Officer
(Principal Financial Officer)