Flexion Therapeutics Inc
Form 10-Q
August 08, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED JUNE 30, 2017

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", "smaller reporting company" and "emerging growth 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
Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act

Indicate by check mark whether registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of August 3, 2017 the registrant had 31,905,664 shares of Common Stock ($0.001 par value) outstanding.

FLEXION THERAPEUTICS, INC.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Flexion Therapeutics, Inc.

Condensed Consolidated Balance Sheets

(Unaudited in thousands, except share amounts)

	June 30, 2017	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$197,179	$30,915
Marketable securities	162,680	174,688
Prepaid expenses and other current assets	2,334	3,790
Total current assets	$362,193	$209,393
Property and equipment, net	11,863	11,664
Long-term investments	—	4,725
Restricted cash	600	480
Total assets	$374,656	$226,262
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$2,741	$2,161
Accrued expenses and other current liabilities	7,097	6,245
Current portion of long-term debt	9,967	9,134
Total current liabilities	$19,805	$17,540
Long-term debt, net	17,584	21,399
2024 convertible notes, net	133,484	-
Other long-term liabilities	404	291
Total liabilities	$171,277	$39,230
Commitments and contingencies		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2017 and December 31, 2016 and 0 shares issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 31,904,926 and 31,667,469 shares issued and outstanding, at June 30, 2017 and December 31, 2016, respectively	32	32
Additional paid-in capital	467,874	398,757
Accumulated other comprehensive income	(77)	(71)
Accumulated deficit	(264,450)	(211,686)

Total stockholders' equity	203,379	187,032
Total liabilities and stockholders' equity	$374,656	$226,262

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

Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Operations and Comprehensive Loss

(Unaudited in thousands, except per share amounts)

	Three Months Ended		Six Months Ended	
	June 30, 2017	2016	June 30, 2017	2016
Revenue	$—	$—	$—	$—
Operating expenses:				
Research and development	11,769	8,905	22,524	20,886
General and administrative	15,133	5,215	28,158	9,907
Total operating expenses	26,902	14,120	50,682	30,793
Loss from operations	(26,902)	(14,120)	(50,682)	(30,793)
Other income (expense):				
Interest income	797	295	1,355	631
Interest expense	(2,887)	(202)	(3,520)	(478)
Other income (expense), net	112	(158)	83	(360)
Total other income (expense)	(1,978)	(65)	(2,082)	(207)
Net loss	$(28,880)	$(14,185)	$(52,764)	$(31,000)
Net loss per share basic and diluted	$(0.91)	$(0.63)	$(1.66)	$(1.40)
Weighted average common shares outstanding, basic and diluted	31,826	22,666	31,765	22,115
Other comprehensive (loss) income:				
Unrealized (loss) from available-for-sale securities, net of tax of $0	(17)	(18)	(6)	(108)
Total other comprehensive (loss) income	(17)	(18)	(6)	(108)
Comprehensive loss	$(28,897)	$(14,203)	$(52,770)	$(31,108)

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

Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Changes in Stockholder's Equity (Deficit)

(Unaudited in thousands)

	Common Stock					
	Shares	Par Value	Additional Paid-in-Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholder's Equity (Deficit)
Balance at December 31, 2014	21,440	$ 21	$ 238,402	$ (5)	$ (93,477)	$ 144,941
Exercise of stock options	109	1	592			$ 593
Employee Stock Purchase Plan	21	—	276			276
Stock-based compensation expense			4,583			4,583
Net loss					(46,315)	(46,315)
Other comprehensive loss				(92)		(92)
Balance at December 31, 2015	21,570	$ 22	$ 243,853	$ (97)	$ (139,792)	$ 103,986
Issuance of Common Stock net of issuance costs	10,040	10	147,491			147,501
Exercise of stock options	30	-	167			167
Employee Stock Purchase Plan	27	—	476			476
Stock-based compensation expense			6,770			6,770
Net loss					(71,894)	(71,894)
Other comprehensive loss				26		26
Balance at December 31, 2016	31,667	$ 32	$ 398,757	$ (71)	$ (211,686)	$ 187,032
Exercise of stock options	182	—	1,457			$ 1,457
Employee Stock Purchase Plan	56	—	453			453
Stock-based compensation expense			4,741			4,741
Convertible debt			62,466			62,466
Net loss					(52,764)	(52,764)
Other comprehensive loss				(6)		(6)
Balance at June 30, 2017	31,905	$ 32	$ 467,874	$ (77)	$ (264,450)	$ 203,379

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

Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited in thousands)

	Six Months Ended June 30,	
	2017	2016
Cash flows from operating activities		
Net loss	$(52,764)	$(31,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	927	269
Stock-based compensation expense	4,741	3,260
Amortization of premium (discount) on marketable securities	259	345
Loss on disposal of fixed assets	—	2,278
Amortization of convertible debt discount and debt issuance costs	1,190	18
Premium paid on securities purchased	(580)	(22)
Changes in operating assets and liabilities:		
Accounts receivable	—	(6)
Prepaid expenses, other current and long-term assets	1,456	(353)
Accounts payable	736	412
Accrued expenses and other current and long-term liabilities	1,796	(517)
Net cash used in operating activities	(42,239)	(25,316)
Cash flows from investing activities		
Purchases of property and equipment	(1,682)	(7,678)
Change in restricted cash	(120)	—
Purchases of marketable securities	(118,320)	(10,804)
Sale and redemption of marketable securities	135,363	21,997
Net cash provided by investing activities	15,241	3,515
Cash flows from financing activities		
Proceeds from the issuance of 2024 convertible notes	201,250	—
Payment of debt issuance costs	(6,470)	(42)
Proceeds from the offering of common stock	—	77,644
Payments on notes payable	(3,333)	—
Payments of public offering costs	(95)	(31)
Proceeds from the exercise of stock options	1,457	56
Proceeds from Employee Stock Purchase Plan	453	240
Net cash provided by financing activities	193,262	77,867
Net increase in cash and cash equivalents	166,264	56,066
Cash and cash equivalents at beginning of period	30,915	62,944
Cash and cash equivalents at end of period	$197,179	$119,010
Supplemental disclosures of cash flow information:		
Cash paid for interest	$921	$477
Supplemental disclosures of non-cash financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$66	$154

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

Flexion Therapeutics, Inc.

Notes to Condensed Consolidated Financial Statements (Unaudited)

1. Overview and Nature of the Business

Flexion Therapeutics, Inc. ("Flexion" or the "Company") was incorporated under the laws of the state of Delaware on November 5, 2007. Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis ("OA"), a type of degenerative arthritis. In May 2016, the U.S Food and Drug Administration, or FDA, informed us that the safety and efficacy data from the registration program for Zilretta™ (FX006), our lead investigational product candidate, were acceptable to support the submission of a new drug application, or NDA. In December 2016, we submitted the NDA for Zilretta, and in February 2017, we announced that the FDA accepted the Zilretta NDA for filing and has established a user fee goal date under the Prescription Drug User Fee Act, or PDUFA, of October 6, 2017.

The Company is subject to risks and uncertainties common to pre-commercial 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. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of June 30, 2017, and for the three and six months ended June 30, 2017 and 2016, 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 10, 2017.

The information presented in the condensed consolidated financial statements and related notes as of June 30, 2017, and for the three and six months ended June 30, 2017 and 2016, is unaudited. The December 31, 2016 consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three and six months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2017, or any future period.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of June 30, 2017 the Company had cash, cash equivalents, marketable securities, and long-term investments of approximately $359,859,000. Management believes that current cash, cash equivalents and marketable securities on hand at June 30, 2017, which includes the net proceeds of its convertible note offering of approximately $194,780,000 described in note ten, should be sufficient to fund operations for at least the next twelve months from the issuance date of these financial statements. 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 May 2014, the FASB issued guidance which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to

customers in an amount that reflects the consideration that the company expects to receive for those goods or services. In August 2015, the FASB issued Accounting Standards Update 2015-14, Revenue from Contracts with Customers: Deferral of the Effective Date. This latest standard defers the effective date of revenue standard ASU 2014-09 by one year and permits early adoption on a limited basis. Since the Company has not generated revenue to date, this guidance will only impact future periods, if any, when revenue is earned. This update will replace existing revenue recognition guidance under GAAP when it becomes effective for the Company beginning January 1, 2018, with early adoption permitted in the first quarter of 2017. The updated standard will permit the use of either the retrospective or cumulative effect transition method. The Company adopted this guidance as of January 1, 2017 and is currently evaluating the potential impact that the adoption of this guidance may have on the Company's future financial statements.

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 became effective for the Company's 2017 fiscal year. Given the Company has a full valuation against its deferred tax assets and liabilities, the impact of adopting this guidance was not material to 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 became effective for annual reporting periods beginning after December 15, 2016, and interim reporting periods within such annual period. The Company adopted this guidance beginning on January 1, 2017 and no longer records stock compensation expense net of forfeitures. The Company adopted this guidance using a modified retrospective approach to reflect forfeitures as they occurred in the total stock based compensation expense recorded in the Company's financial statements. The impact of this adoption was not material to 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 six months ended June 30, 2017 and the year ended December 31, 2016.

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.

3. Fair Value of Financial Assets and Liabilities

The following tables present information about the Company's assets that are measured at fair value on a recurring basis as of June 30, 2017 and December 31, 2016 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of June 30, 2017 Using:			
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$—	$168,473	$ —	$168,473
Marketable securities	—	162,680	—	162,680

	$—	$331,153	$ — $331,153

	Fair Value Measurements as of December 31, 2016 Using:		
(In thousands)	Level 1	Level 2	Level 3 Total
Assets:			
Cash equivalents	$—	$9,830	$ — $9,830
Marketable securities	—	179,414	— 179,414
	$—	$189,244	$ — $189,244

As of June 30, 2017 and December 31, 2016, the Company's cash equivalents that are invested in money market funds and overnight repurchase contracts are valued using Level 2 inputs and primarily rely on quoted prices in active markets for similar securities. 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 six months ended June 30, 2017 and year ended December 31, 2016, 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 June 30, 2017 and December 31, 2016. The result of the calculation yielded a fair value that approximates its carrying value.

The Company issued convertible notes on May 2, 2017 with embedded conversion features. The Company estimated the fair value of the convertible notes using a discounted cash flow approach to derive the value of a debt instrument using the expected cash flows and the estimated yield related to the convertible notes. The significant assumptions used in estimating the expected cash flows were: the estimated market yield based on an implied yield and credit quality analysis of a term loan with similar attributes, and the average implied volatility of the Company's traded and quoted options available as of May 2, 2017. The Company recorded approximately $136.7 million as the fair value of the liability on May 2, 2017, with a corresponding amount recorded as a discount on the initial issuance of the 2024 Convertible Notes of approximately $64.5 million. The debt discount was recorded to equity and is being amortized to the debt liability over the life of the 2024 Convertible Notes using the effective interest method. As of June 30, 2017 the debt liability had a fair value that approximated fair value at issuance.

4. Marketable Securities

As of June 30, 2017 and December 31, 2016 the fair value of available-for-sale marketable securities by type of security was as follows:

	June 30, 2017			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
U.S. government obligations	$46,475	$ —	$ (9)	$ 46,466
Commercial paper	14,445	—	—	14,445
Corporate bonds	101,837	3	(71)	101,769
	$162,757	$ 3	$ (80)	$ 162,680

	December 31, 2016			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$7,769	$ —	$ —	$ 7,769
U.S. government obligations	75,524	5	(12)	75,517
Corporate bonds	96,193	1	(66)	96,128
	$179,486	$ 6	$ (78)	$ 179,414

As of June 30, 2017 and December 31, 2016, marketable securities consisted of approximately $162,680,000 and $174,688,000, respectively, of investments that mature within twelve months and as of December 31, 2016 approximately $4,725,000 of investments that mature within fifteen months. As of June 30, 2017 there were no

marketable securities with maturities beyond twelve months.

5. Property and Equipment, Net

Property and equipment, net, as of June 30, 2017 and December 31, 2016 consisted of the following:

(In thousands)	June 30, 2017	December 31, 2016
Manufacturing equipment	$11,505	$ 10,099
Computer and office equipment	772	573
Software	434	434
Construction—in progress	568	1,254
Furniture and fixtures	426	402
Leasehold improvements	461	278
	14,166	13,040
Less: Accumulated depreciation	(2,303)	(1,376)
Total property and equipment, net	$11,863	$ 11,664

Depreciation expense for the six months ended June 30, 2017 and 2016 was approximately $927,000 and $269,000, respectively. No property and equipment was disposed of during the six months ended June 30, 2017. Approximately $2,265,000 in

manufacturing equipment located at the Evonik facility was disposed of, resulting in a loss of $2,180,000 which was recorded in research and development expenses for the six months ended June 30, 2016. Construction in progress primarily consists of amounts related to equipment purchased for the Company's portfolio expansion efforts.

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets and other assets consisted of the following as of June 30, 2017 and December 31, 2016:

(In thousands)	June 30, 2017	December 31, 2016
Prepaid Expenses	$1,661	$ 1,085
Deposits	61	2,099
Interest receivable on marketable securities	611	605
Employee Advance	1	1
Total prepaid expenses and other current assets	$2,334	$ 3,790

On December 1, 2016, Flexion paid a refundable NDA fee in the amount of $2,038,100 to the FDA. The Company evaluated each of the published criteria to qualify for a waiver and concluded all criteria were met and thus, obtaining a refund of the fee was probable. As of December 31, 2016 the NDA fee was classified as a deposit in other current assets. On May 16, 2017, Flexion received the full refund of this NDA fee.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	June 30, 2017	December 31, 2016
Research and Development	$402	$ 1,606
Payroll and other employee-related expenses	3,154	3,393
Professional services fees	1,957	926
Other	319	159
Interest expense	1,265	161
Total accrued expenses and other current liabilities	$7,097	$ 6,245

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 six months ended June 30, 2017 and 2016 are as follows:

	Six months ended June 30,	
	2017	2016
Risk-free interest rates	1.97-2.29%	1.08-1.90%
Expected dividend yield	0.00%	0.00%
Expected term (in years)	6.0	6.0
Expected volatility	69.9-72.8%	78.8-87.9%

The following table summarizes stock option activity for the six months ended June 30, 2017:

(In thousands, except per share amounts)	Shares Issuable Under Options	Weighted Average Exercise Price
Outstanding as of December 31, 2016	3,268	$ 14.84
Granted	879	22.03
Exercised	(182)	8.01
Cancelled	(89)	17.17
Outstanding as of June 30, 2017	3,876	$ 17.60
Options vested and expected to vest at June 30, 2017	3,876	$ 17.60
Options exercisable at June 30, 2017	1,353	$ 14.15

Approximately 189,300 outstanding restricted stock units (“RSUs”) are included in stock options outstanding at June 30, 2017. The RSUs are performance based awards which will only begin vesting if and when a specified corporate performance based milestone is achieved. No outstanding performance awards were vested as of June 30, 2017.

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 182,000 options, with an aggregate intrinsic value of approximately $2,146,000, were exercised during the six months ended June 30, 2017.

At June 30, 2017 and 2016, there were options for the purchase of approximately 3,876,000 and 2,300,000 shares of the Company’s common stock outstanding, respectively, with a weighted average remaining contractual term of 8.3 years and with a weighted average exercise price of $17.60 and $15.07 per share, respectively.

The weighted average grant date fair value of options granted during the six months ended June 30, 2017 and 2016 was $14.14 and $11.85, respectively.

Stock-based Compensation

The Company recorded stock-based compensation expense related to stock options for the three and six months ended June 30, 2017 and 2016 as follows:

	Three months ended		Six months ended	
	June 30,		June 30,	
(In thousands)	2017	2016	2017	2016
Research and development	$923	$576	$1,802	$1,113
General and administrative	1,440	1,043	2,939	2,147
	$2,363	$1,619	$4,741	$3,260

As of June 30, 2017, unrecognized stock-based compensation expense for stock options outstanding was approximately $27,369,000 which is expected to be recognized over a weighted average period of 3.0 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 FDA of an 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 189,300 with an approximate value of $3,997,000 as of the grant date. The amount of earned shares decreases the longer it takes to achieve the Milestone. If the Milestone is not achieved prior to July 1, 2018, 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 six months ended June 30, 2017 and 2016:

	For the three months ended		For the six months ended	
(In thousands)	June 30, 2017	2016	June 30, 2017	2016
Numerator:				
Net loss	$(28,880)	$(14,185)	$(52,764)	$(31,000)
Net loss:	$(28,880)	$(14,185)	$(52,764)	$(31,000)
Denominator:				
Weighted average common shares outstanding, basic and diluted	31,826	22,666	31,765	22,115
Net loss per share, basic and diluted	$(0.91)	$(0.63)	$(1.66)	$(1.40)

The following common stock equivalents were excluded from the calculation of diluted net loss per share for the periods indicated as including them would have an anti-dilutive effect:

	For the three months ended		For the six months ended	
	June 30, 2017	2016	June 30, 2017	2016
Shares issuable upon conversion of the 2024 convertible notes	4,926,458	—	2,463,229	—
Stock options	3,479,243	2,208,247	3,413,197	2,249,559
Restricted stock units	189,300	189,130	189,300	186,078
Total	8,595,001	2,397,377	6,065,726	2,435,637

10. Debt

Term Loan

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 June 30, 2017, 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 straight line method, which approximates the effective interest method. As of June 30, 2017, the carrying value of the term loan was approximately $27,551,000, of which $9,967,000 was due within 12 months and $17,584,000 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 deducted the debt issuance costs from the carrying amount of the debt as of June 30, 2017 and December 31, 2016.

As of June 30, 2017, annual principal and interest payments due under the 2015 term loan are as follows:

Year	Aggregate Minimum Payments (in thousands)
2017	$ 5,781
2018	11,082
2019	10,448
2020	4,383
Total	$ 31,694
Less interest	(1,443)
Less final payment	(2,700)
Total	$ 27,551

2024 Convertible Notes

On May 2, 2017 the Company issued an aggregate of $201.3 million principal amount of the 2024 Convertible Notes. The 2024 Convertible Notes have a maturity date of May 1, 2024 are unsecured and accrue interest at a rate of 3.375% per annum, payable semi-annually on May 1 and November 1 of each year, beginning November 1, 2017. The Company received $194.8 million for the sale of the 2024 Convertible Notes, after deducting fees and expenses of $6.5 million.

The 2024 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.375% per year, payable semi-annually in arrears on May and November 1st of each year. The 2024 Convertible Notes will mature on May 1, 2024, unless earlier repurchased or converted. Upon conversion of the 2024 Convertible Notes, at the election of each holder of a 2024 Convertible Note (the Holder), will be convertible into cash, shares of the Company’s common stock, or a combination thereof, at the Company’s election (subject to certain limitations in the 2015 term loan), at a conversion rate of approximately 37.3413 shares of common stock per $1,000 principal amount of the 2024 Convertible Notes, which corresponds to an initial conversion price of approximately $26.78 per share of the Company’s common stock.

The Conversion Rate is subject to adjustment from time to time upon the occurrence of certain events, including, but not limited to, fundamental change events and certain corporate events that occur prior to the maturity date of the notes. In addition, if the Company delivers a notice of redemption, the Company will increase, in certain

circumstances, the conversion rate for a Holder who elects to convert its notes in connection with such a corporate event or notice of redemption, as the case may be. At any time prior to the close of business on the business day immediately preceding February 1, 2024, Holders may convert all, or any portion, of the 2024 Convertible Notes at their option only under the following circumstances:

(1) during any calendar quarter commencing after the calendar quarter ending on June 30, 2017 (and only during such calendar quarter), if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day;

(2) during the five business day period after any ten consecutive trading day period (the "measurement period") in which the trading price per $1,000 principal amount of notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the Company's common stock and the conversion rate on each such trading day;

(3) if the Company calls any or all of the notes for redemption, at any time prior to the close of business on the business day immediately preceding the redemption date; and

(4) upon the occurrence of specified corporate events.

On or after February 1, 2024, until the close of business on the business day immediately preceding the maturity date, holders may convert their notes at any time, regardless of the foregoing circumstances.

The 2024 Convertible Notes are considered convertible debt with a cash conversion feature. Per ASC 470-20, Debt with Conversion and Other Options, the Company has separated the convertible debt into liability and equity components based on

the fair value of a similar debt instrument excluding the embedded conversion option. The carrying amount of the liability component was calculated by measuring the fair value of a similar liability that does not have an associated convertible feature. The allocation was performed in a manner that reflected our non-convertible debt borrowing rate for similar debt. The equity component of the 2024 Convertible Notes was recognized as a debt discount and represents the difference between the proceeds from the issuance of the 2024 Convertible Notes and the fair value of the liability of the 2024 Convertible Notes on their respective dates of issuance. The excess of the principal amount of the liability component over its carrying amount ("debt discount") is amortized to interest expense using the effective interest method over seven years. The equity component is not re-measured as long as it continues to meet the conditions for equity classification. The liability component of $136.7 million was recorded as long-term debt at May 2, 2017 with the remaining equity component of $64.5 million recorded as additional paid-in capital.

In connection with the issuance of the 2024 Convertible Notes, we incurred approximately $6.5 million of debt issuance costs, which primarily consisted of underwriting, legal and other professional fees, and allocated these costs to the liability and equity components based on the allocation of the proceeds. Of the total debt issuance costs, $4.4 million were allocated to the liability component and are recorded as a reduction of the 2024 Convertible Notes in our consolidated balance sheets. The remaining $2.1 million was allocated to the equity component and is recorded as a reduction to additional paid-in capital.

Debt discount and issuance costs of $68.9 million are being amortized to interest expense over the life of the 2024 Convertible Notes using the effective interest rate method. As of June 30, 2017, the stated interest rate was 3.375%, and the effective interest rate was 9.71%. Interest expense related to the 2024 Convertible Notes for the three months ended June 30, 2017 was $2,302,606, including $1,083,687 related to amortization of the debt discount.

The table below summarizes the carrying value of the 2024 Convertible Notes as of June 30, 2017:

	(in thousands)
Gross proceeds	$ 201,250
Portion allocated to equity (additional paid-in capital)	(64,541)
Debt issuance costs	(6,470)
Portion allocated to equity (additional paid-in capital)	2,075
Amortization of debt discount and debt issuance costs	1,170
Carrying value 2024 Convertible Notes	$ 133,484

11. 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 six months ended June 30, 2017 were $0.2 million and $0.4 million, respectively, compared to zero for the three and six months ended June 30, 2016.

12. Commitments and Contingencies

Operating Leases

In May 2013, the Company entered into a lease for office space in Burlington, Massachusetts. The lease is for a 42-month term with minimum monthly lease payments beginning at $17,588 per month and escalating over the lease term. The Company provided a letter of credit to the lessor in the amount of $98,000 as a security deposit pursuant to the lease agreement to secure its obligations under the lease. During 2015, this letter of credit was reduced to $50,000 pursuant to the original lease agreement.

In July 2015, the Company entered into a first amendment to its existing lease for approximately 4,700 square feet of additional office space (the “Additional Space”) in Burlington, Massachusetts, as well as approximately 6,700 square feet of temporary space to be leased prior to the delivery of the Additional Space (which occurred on May 1, 2016). The amendment extended the term of the original lease through October 31, 2019, contemporaneous with the Additional Space, and also provided the Company with an option to lease an additional 5,400 square feet of office space (the “Option Space”). On September 30, 2015, the Company exercised its option for the Option Space. In addition, the Company has the option to extend the term of a portion or the entire lease space for one additional three-year period. The Company may terminate the amendment for convenience with nine months’ notice upon the occurrence of certain events connected to its clinical stage programs. In addition to the base rent, the Company is also responsible for its share of operating expenses and real estate taxes.

On September 21, 2016, the Company entered into a second amendment to its existing lease for approximately 6,748 additional square feet of rented space located in Burlington, Massachusetts. The lease began October 1, 2016 and expires on October 31, 2017. During October 2016, the Company's lease payment for this additional space was $18,300 per month in incremental rent. Beginning in November 2016, through October 2017, the Company's lease payments for the additional space increased to $19,000 per month.

On April 7, 2017, the Company entered into an amendment to its existing lease for approximately 1,471 additional square feet of rented space located in Burlington, Massachusetts and an extension of the current lease term through October 2023. The amendment also gives the Company the option to lease approximately 6,450 of additional square feet beginning in 2018.

Future minimum lease payments under the Company's lease obligations are as follows:

Year	Aggregate Minimum Payments
2017	$589,554
2018	1,225,490
2019	1,261,051
2020	1,296,776
2021	1,332,670
2022	1,197,370
2023	990,561
Total	$7,893,472

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, 2016 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 10, 2017.

Forward-Looking Statements

This discussion and analysis contains "forward-looking statements" that is statements related to future, not past, events – as defined in Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act that reflect our current expectations regarding future development activities, results of operations, financial condition, cash flows, performance and business prospects, and opportunities, as well as assumptions made by and information currently available to our management. Forward looking statements, include any statement that does not directly related to a current historical fact. The Company has tried to identify forward-looking statements by using words such as "may," "will," "expect," "anticipate," "estimate," "intend," "plan," "predict," "potential," "believe," "should" and similar expressions. believe the expectations reflected in these forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievement. 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, a type of degenerative arthritis, referred to as OA.

In May 2016, the U.S Food and Drug Administration, or FDA, informed us that the safety and efficacy data from the registration program for Zilretta™ (FX006), our lead investigational product candidate, were acceptable to support the submission of a new drug application, or NDA. In December 2016, we submitted the NDA for Zilretta, and in February 2017, we announced that the FDA accepted the Zilretta NDA for filing and has established a user fee goal date under the Prescription Drug User Fee Act, or PDUFA, of October 6, 2017.

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 June 30, 2017, we have funded our operations primarily through the sale of our common stock, convertible preferred stock, convertible debt, and debt financing. From our inception through June 30, 2017, we have raised approximately $624 million from such transactions, including from our initial and follow-on public offerings and the issuance of convertible notes. 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:

Zilretta (FX006) —Late Stage Candidate for Intra-articular Therapy for Patients with Moderate to Severe OA Pain

Zilretta is an injectable, extended-release, intra-articular, or IA, meaning “in the joint,” steroid that we are developing as a treatment for patients with moderate to severe OA pain. Zilretta combines a commonly administered steroid, triamcinolone acetonide, or TA, with poly lactic-co-glycolic acid, referred to as PLGA, with the goal of delivering a 32 mg dose to provide extended therapeutic concentrations in the joint and persistent analgesic effect. Zilretta is intended to address the limitations of current IA therapies by providing extended, local analgesia while avoiding systemic side effects, which are effects that can occur throughout the body as a result of drug that is released from the site of injection into circulating blood. The overall frequency of treatment-related adverse events in these trials has been similar to those observed with placebo and no drug-related serious adverse events have been reported. 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 seen 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, effective and extended pain relief. Zilretta is an injectable, IA, extended-release investigational treatment for patients with moderate to severe OA pain, and we believe it is uniquely distinguished by the following attributes:

- significant improvements in validated OA specific measures compared to the current injectable standard of care;
- significant pain relief against placebo as measured by the weekly mean of the Average Daily Pain, or ADP, score in the Phase 3 trial:
  - demonstrating at week 12, the primary endpoint, at p value of <0.0001, 2 sided
  - at each week beginning at week 1 and continuing through week 16
  - demonstrating, on average, an approximately 50 percent reduction in pain from baseline over weeks 1 through 12
- persistent therapeutic concentrations of drug in the joint and durable efficacy;
- statistically significant ($p<0.05$, 2-sided) reduction in the rise of blood glucose compared to that observed following immediate-release TA injection in Type 2 diabetic patients who also have knee OA;
- reduced rescue medicine consumption compared with placebo and immediate-release TA;
- an acceptable safety profile with limited systemic exposures and the potential for fewer serious side effects compared to oral treatment options for OA pain, and
- amongst the largest analgesic effects seen in OA clinical trials.

In December 2016, we submitted the NDA for Zilretta, and in February 2017, we announced that the FDA accepted the Zilretta NDA for filing and has established a user fee goal date under the Prescription Drug User Fee Act, or PDUFA, of October 6, 2017. Additionally, we have fully enrolled our clinical trial to evaluate the safety of repeat administration of Zilretta in patients with OA of the knee. The data readout is anticipated in 2018. Furthermore, we plan to initiate clinical trials of Zilretta in OA of the hip and shoulder by the end of 2017.

FX101 – Intra-articular Therapy for the Treatment of OA Pain

FX101 (fluticasone extended release) is a pre-clinical drug candidate which aims to provide extended pain relief for patients with OA. FX101 leverages our proprietary microsphere technology, and based on our pre-clinical, in vivo pharmacokinetic studies, we believe it has the potential to provide patients with pain relief for up to six months. We intend to conduct Good Laboratory Practice (GLP) toxicology studies, and pending successful results, we will file an Investigational New Drug to advance FX101 into clinical trials.

Financial Overview

Revenue

We have not generated any revenue since our inception. We do not have any products approved for sale, and we do not expect to generate any revenue from the sale of products in the near future. In the future, if our research and development efforts result in clinical success and regulatory approval, we may generate revenue from the sales of our product candidates, including Zilretta, or we may generate revenue from licensing rights to our product candidates to third parties. If we fail to complete the development of Zilretta or other product candidates, our ability to generate future revenue and our results of operations and financial position will be adversely affected.

Operating Expenses

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

Research and Development Expenses

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

- expenses incurred under agreements with consultants, contract research organizations, or CROs, and investigative sites that conduct our preclinical studies and clinical trials;
- costs of acquiring, developing and manufacturing clinical trial materials;
- 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;
- manufacturing costs in preparation for potential commercialization of Zilretta;
- 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 potential future commercial supplies, and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses to specific research and development programs. These indirect expenses are included within the amounts designated as "Personnel and other costs" in the table below.

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

	Three Months Ended		Six Months Ended	
(In thousands)	June 30, 2017	2016	June 30, 2017	2016
Direct research and development expenses by program:				
Zilretta	$ 4,700	$ 5,322	$9,471	$13,430
FX007	—	47	1	252
Portfolio expansion	646	73	478	170
Other	245	3	974	141
Total direct research and development expenses	5,591	5,445	10,924	13,993
Personnel and other costs	6,178	3,460	11,600	6,893
Total research and development expenses	$ 11,769	$ 8,905	$22,524	$20,886

We 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 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. We were 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. Evonik Corporation, or 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 six months ended June 30, 2016.

We cannot determine with certainty the duration of and completion costs associated with future clinical trials or the regulatory approval process of Zilretta or any additional product candidates we develop. The duration, costs and timing associated with the development and commercialization of Zilretta or other product candidates 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 for any product candidate, when or if we will achieve regulatory approval, generate revenue from sales of any product candidate 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. In

particular, if Zilretta is approved by the FDA in the fourth quarter, we expect to incur material and ongoing increases in general and administrative expenses related to our hiring of a field sales force to market Zilretta in the United States. 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 Securities and Exchange Commission 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 issued approximately $201.3 million in convertible notes, or the 2024 Convertible Notes, which pay semi-annual coupon payments at a rate of 3.375%. We expect to pay coupon payments through the maturity of the 2024 Convertible Notes on May 1, 2024. We have also borrowed $30.0 million under our 2015 term loan facility, 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 other income and expense.

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, 2016 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 six months ended June 30, 2017.

RESULTS OF OPERATIONS

Comparison of the three and six months ended June 30, 2017 and 2016

The following tables summarize our results of operations for the three and six months ended June 30, 2017:

	Three Months Ended June 30,			% Increase/
(In thousands)	2017	2016	Change	(Decrease)
Revenue	$—	$—	$—	—
Operating expenses:				
Research and development	11,769	8,905	2,864	32.2 %
General and administrative	15,133	5,215	9,918	190.2 %
Total operating expenses	26,902	14,120	12,782	90.5 %
Loss from operations	(26,902)	(14,120)	(12,782)	90.5 %
Other income (expense):				
Interest income	797	295	502	170.2 %
Interest expense	(2,887)	(202)	(2,685)	1329.2 %
Other expense	112	(158)	270	(170.9)%
Total other income (expense)	(1,978)	(65)	(1,913)	2943.1 %
Net loss	$(28,880)	$(14,185)	$(14,695)	103.6 %

	Six Months Ended June 30,			% Increase/
(In thousands)	2017	2016	Change	(Decrease)
Revenue	$—	$—	$—	—
Operating expenses:				
Research and development	22,524	20,886	1,638	7.8 %
General and administrative	28,158	9,907	18,251	184.2 %
Total operating expenses	50,682	30,793	19,889	64.6 %
Loss from operations	(50,682)	(30,793)	(19,889)	64.6 %
Other income (expense):				
Interest income	1,355	631	724	114.7 %
Interest expense	(3,520)	(478)	(3,042)	636.4 %
Other expense	83	(360)	443	(123.1)%
Total other income (expense)	(2,082)	(207)	(1,875)	905.8 %
Net loss	$(52,764)	$(31,000)	$(21,764)	70.2 %

Research and Development Expenses

	Three Months Ended June 30,			
(In thousands)	2017	2016	Change	% Increase/(Decrease)
Direct research and development expenses by program:				
Zilretta	$4,700	$5,322	$(622)	(11.7)%
FX007	—	47	(47)	(100.0)%
Portfolio expansion	646	73	573	784.9 %
Other	245	3	242	8066.7 %
Total direct research and development expenses	5,591	5,445	146	2.7 %
Personnel and other costs	6,178	3,460	2,718	78.6 %
Total research and development expenses	$11,769	$8,905	$2,864	32.2 %

	Six Months Ended June 30,			
(In thousands)	2017	2016	Change	% Increase/(Decrease)
Direct research and development expenses by program:				
Zilretta	$9,471	$13,430	$(3,959)	(29.5)%
FX007	1	252	(251)	(99.6)%
Portfolio expansion	478	170	308	181.2 %
Other	974	141	833	590.8 %
Total direct research and development expenses	10,924	13,993	(3,069)	(21.9)%
Personnel and other costs	11,600	6,893	4,707	68.3 %
Total research and development expenses	$22,524	$20,886	$1,638	7.8 %

Research and development expenses were $11.8 million and $8.9 million for the three months ended June 30, 2017 and 2016, respectively. The increase in research and development expenses of $2.9 million was primarily due to a $0.8 million increase in preclinical expenses related to our portfolio expansion and other program costs and an increase of $2.7 million in personnel and other employee-related costs for additional headcount and stock compensation expense, partially offset by a $0.6 decrease in development expenses for Zilretta, including CMC and clinical trial costs.

Research and development expenses were $22.5 million and $20.9 million for the six months ended June 30, 2017 and 2016, respectively. The increase in research and development expenses of $1.6 million was primarily due to an increase of $1.1 million in preclinical expenses related to our portfolio expansion and other program costs, and a $4.7 million increase in personnel and other employee-related costs for additional headcount and stock compensation expense, partially offset by a decrease of $4.0 million in development expenses for Zilretta, including CMC and clinical trial costs.

General and Administrative Expenses

General and administrative expenses were $15.1 million and $5.2 million for the three months ended June 30, 2017 and 2016, respectively. The increase in general and administrative expenses of $9.9 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 cost related to the creation of commercial marketing and sales capabilities, and stock compensation expense.

General and administrative expenses were $28.2 million and $9.9 million for the six months ended June 30, 2017 and 2016, respectively. The increase in general and administrative expenses of $18.3 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 cost related to the creation of commercial marketing and sales capabilities, and stock compensation expense.

Other Income (Expense)

Interest income was $0.8 million and $0.3 million for the three months ended June 30, 2017 and 2016, respectively. Interest income was $1.4 million and $0.6 million for the six months ended June 30, 2017 and 2016, respectively. The increase in interest income was primarily due to an increase in average investment balance yield during 2017.

Interest expense was $2.9 million and $0.2 million for the three months ended June 30, 2017 and 2016, and $3.5 million and $0.5 million for the six months ended June 30, 2017 and 2016, respectively. The increase in interest expense for the three and six months ended June 30, 2017 was primarily due to interest incurred on the 2024 Convertible Notes and 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 June 30, 2017, we had an accumulated deficit of $264.5 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 and convertible debt financings, government or other third-party funding, and licensing or collaboration arrangements.

Since our inception through June 30, 2017, we have funded our operations primarily through the sale of our common stock and convertible preferred stock, convertible debt, and venture debt financing. From our inception through June 30, 2017, we have raised approximately $624 million from such transactions, including amounts from our initial and follow-on public offerings during 2014 and 2016 as well as our 2024 Convertible Notes issuance in 2017. As of June 30, 2017, we had cash and cash equivalents of $197.2 million and marketable securities of $162.7 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 from the date of issuance of the financial statements included in this report. 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 six months ended June 30, 2017 and 2016:

	Six Months Ended June 30,	
(In thousands)	2017	2016
Cash flows used in operating activities	$(42,239)	$(25,316)
Cash flows provided by investing activities	15,241	3,515
Cash flows provided by financing activities	193,262	77,867
Net increase in cash and cash equivalents	$166,264	$56,066

Net Cash Used in Operating Activities

Operating activities used $42.2 million of cash in the six months ended June 30, 2017. The cash flow used in operating activities resulted primarily from our net loss of $52.8 million for the period, partially offset by changes in our operating assets and liabilities of $4.0 million and non-cash charges of $6.5 million. Our non-cash charges consisted primarily of $4.7 million of stock-based compensation expense and $1.2 million of depreciation and amortization offset by $0.6 million of premium paid on marketable securities. Net cash provided by changes in our operating assets and liabilities consisted primarily of a $1.5 million decrease in our prepaid expenses and other current assets due primarily to the receipt of the refund of the NDA fee and an increase of $2.5 million in accounts payable and accrued expenses.

Operating activities used $25.3 million of cash in the six months ended June 30, 2016. The cash flow used in operating activities resulted primarily from our net loss of $31.0 million for the period and cash used for changes in our operating assets and liabilities of $0.5 million, partially offset by non-cash charges of $6.1 million. Our non-cash

charges consisted primarily of $3.3 million of stock-based compensation expense and $2.3 million of loss related to the disposal of our fixed assets, and $0.6 million of depreciation and amortization. Net cash used for changes in our operating assets and liabilities consisted primarily of a $0.4 million increase in prepaid expenses and other current assets due primarily to insurance costs and a decrease of $0.1 million in accounts payable and accrued expenses.

Net Cash Provided by Investing Activities

Net cash provided by investing activities was $15.2 million in the six months ended June 30, 2017. Net cash provided by investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $135.4 million, partially offset by cash used to purchase marketable securities of $118.3 million. In addition, $1.7 million of cash was used to purchase manufacturing equipment.

Net cash provided by investing activities was $3.5 million in the six months ended June 30, 2016. Net cash provided by investing activities consisted primarily of cash received for the redemption and sale of marketable securities of $22.0 million, partially

offset by cash used for the of purchase marketable securities of $10.8 million. In addition, $7.7 million of cash was used to purchase manufacturing equipment.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $193.3 million for the six months ended June 30, 2017. Net cash provided by financing activities in the six months ended June 30, 2017 consisted primarily of net cash received from the issuance of the 2024 Convertible Notes of $194.8 million and $1.9 million received from the exercise of stock options and employee stock purchases through our employee stock purchase plan. These cash inflows were partially offset by $3.3 million related to the payment of principal on our 2015 term loan and $0.1 million in public offering expenses incurred as part of our November 2016 equity offering.

Net cash provided by financing activities provided in the six months ended June 30, 2016 was $77.9 million and consisted of $77.4 million in net proceeds from a follow-on public offering and $0.3 million related to the exercises of stock options and employee stock purchases through our employee stock purchase plan.

Contractual Obligations

In February 2017, we entered into a five year lease for laboratory space located in Woburn, Massachusetts with a total cash obligation of approximately $0.9 million.

On April 7, 2017, we entered into an amendment to our existing lease for approximately 1,471 additional square feet of rented space located in Burlington, Massachusetts and an extension of our current lease term through October 2023. The amendment also gives us the option to lease approximately 6,450 of additional square feet beginning in 2018.

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 exposures to market risk are interest income sensitivity and equity price risk. Interest income 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.

Investments

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.

Convertible Notes

On May 2, 2017, we issued $201.3 million aggregate principal amount of 2024 Convertible Notes. The 2024 Convertible Notes are senior unsecured obligations and bear interest at a rate of 3.375% per year, payable semi-annually in arrears on May and November 1st of each year. The 2024 Convertible Notes will mature on May 1, 2024, unless repurchased or converted earlier. The 2024 Convertible Notes will be convertible into cash, shares of our common stock, or a combination thereof, at our election (subject to certain limitations in the 2015 term loan), at a conversion rate of approximately 37.3413 shares of common stock per $1,000 principal amount of the 2024 Convertible Notes, which corresponds to a conversion price of approximately $26.78 per share of our common stock and represents a conversion premium of approximately 35% based on the last reported sale price of our common stock of $19.72 on May 2, 2017, the date the 2024 Convertible Notes offering was priced. As of May 2, 2017, the fair value of the 2024 Convertible Notes was $136.7 million. Our 2024 Convertible Notes include conversion and settlement provisions that are based on the price of our common stock at conversion or at maturity of the 2024 Convertible Notes. The amount of cash we may be required to pay is determined by the price of our common stock. The fair values of our 2024 Convertible Notes are dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes. As of June 30, 2017, the debt liability had a fair value that approximated fair value at issuance.

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 June 30, 2017 we had no payables to vendors denominated in currencies other than the U.S. dollar, therefore a hypothetical 10% change in foreign exchange rates would have no effect on the value of our liabilities. As of June 30, 2017, we had approximately $5.7 million in cash denominated in British Pounds. A hypothetical 10% change in foreign exchange rates would result in either a $0.5 million increase, in the event the U.S. dollar strengthens relative to the British Pound, or a $0.4 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 and financial officer, as appropriate to allow timely decisions regarding required disclosure.

Based on our management's evaluation (with the participation of our principal executive and financial officer) of our disclosure controls and procedures as required by Rule 13a-15 under the Exchange Act, our principal executive and financial officer has concluded that our disclosure controls and procedures were effective to achieve their stated purpose as of June 30, 2017, 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 June 30, 2017 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. 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.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

We have a limited operating history. To date, we have focused primarily on developing our lead product candidate, Zilretta. Any additional product candidates we develop will require substantial development time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have incurred significant net losses in each year since our inception, including net losses of $71.90 million, $46.3 million, and $27.3 million for fiscal years 2016, 2015, and 2014, respectively, and $52.8 million for the six months ended June 30, 2017. As of June 30, 2017 we had an accumulated deficit of $264.5 million.

We have devoted most of our financial resources to product development, including our non-clinical development activities and clinical trials. To date, we have financed our operations exclusively through the sale of equity securities and debt. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, none of our product candidates have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market our product candidates in the United States, our revenue is also dependent upon the size of the markets outside of the United States, as well as our ability to obtain marketing approval and achieve commercial success.

We expect to continue to incur substantial and increased expenses as we continue our development activities with respect to Zilretta and FX101 and as we scale up manufacturing for and prepare to commercialize Zilretta. We also expect a continued increase in our expenses associated with our operations as a publicly-traded company. As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future.

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 ongoing and planned clinical trials for Zilretta, continue our manufacturing scale-up activities and build a sales and marketing organization to commercialize Zilretta.

As of June 30, 2017 we had cash, cash equivalents and marketable securities of $359.9 million and working capital of $342.4 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 from the issuance date of these financial statements, including through the Prescription Drug User Fee Act, or PDUFA, action goal date of our 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 approving 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 existing indebtedness contains restrictions that limit our flexibility in operating our business. We may be required to make a prepayment or repay our outstanding indebtedness earlier than we expect, which could have a materially adverse effect on our business, or may otherwise be unable to repay our indebtedness as it becomes due.

On August 4, 2015, we entered into a credit and security agreement with MidCap Financial SBIC, LP, or MidCap, as administrative agent, MidCap Funding XIII Trust and Silicon Valley Bank, as agent lenders, to borrow up to $30.0 million and contemporaneously drew down $15.0 million under the credit facility. The credit 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 credit 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 credit agreement. 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 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 credit agreement occurs. In the case of a continuing event of default under the credit 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 credit agreement, or otherwise exercise the rights of a secured creditor. Amounts outstanding under the credit agreement are secured by all of our existing and future assets, excluding intellectual property, which is subject to a negative pledge arrangement.

In April 2017, we also issued $201.3 million principal amount of our 3.375% Convertible Senior Notes due 2024, or the 2024 Convertible Notes. The 2024 Convertible Notes will mature on May 1, 2024, unless earlier redeemed, repurchased or converted in

accordance with the terms of the indenture governing the notes. If specified bankruptcy, insolvency or reorganization-related events of default occur, or if certain other events of default occur and the trustee or certain holders of the 2024 Convertible Notes elect, the principal of, and accrued and unpaid interest on, all of the then-outstanding 2024 Convertible Notes will automatically become due and payable. In addition, if we undergo certain fundamental change transactions specified in the indenture governing the 2024 Convertible notes, the holders of the notes may require us to repurchase their notes at a price equal to 100% of the principal amount of the notes, plus any accrued and unpaid interest.

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 or refinance our indebtedness at the time any such repayment or repurchase 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.

Risks Related to Clinical Development and Regulatory Approval

Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical failure can occur at any stage of clinical development.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of subsequent clinical trials. In particular, the results generated in our completed Zilretta pivotal Phase 3 clinical trial do not ensure that any ongoing or future Zilretta clinical trial will be successful or consistent with the results generated in the Phase 3 trial.

We have conducted preclinical toxicology studies in healthy dogs with single and repeat doses of Zilretta, blank microspheres and immediate-release TA. The immediate-release TA and Zilretta groups produced similar findings in these studies. In the single-dose study, local cartilage findings of reduced extracellular matrix were completely reversed by the end of the nine-month recovery period in both the Zilretta and immediate-release TA study arms. With repeat administrations of Zilretta and immediate-release TA, a larger reduction in extracellular matrix in cartilage partially recovered by six months following the last dose; however, structural changes in cartilage were observed with repeat administrations of both Zilretta and immediate-release TA. Repeat administration of immediate-release TA has a long history of safe clinical use in patients with OA, and in a randomized, double-blind clinical trial conducted in 2003 by Raynauld et al, administration of immediate-release TA or saline every three months for up to two years in 68 OA patients was well-tolerated and demonstrated no deleterious effects in the knee joint when assessed by clinical exam and X-ray evaluation. Using a more sensitive MRI imaging technology in 2015, Driban et al again demonstrated that cartilage structure changes between OA patients treated with immediate-release TA and saline in patients were similar. In 2017, the same authors reporting on the same data set concluded that there was a relative loss of cartilage in the immediate-release TA group. We are studying Zilretta in a repeat dose safety clinical trial and if Zilretta is approved and the data from the repeat dose trial are supportive, we intend to seek inclusion of these data in the label. It is possible that we could observe detrimental effects on joint structure with repeated doses of Zilretta, similar to those outcomes observed in our preclinical studies and third party trials, which would limit Zilretta's commercial potential and could harm our ability to maintain regulatory approval.

Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. In addition to the safety and efficacy trials of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, placebo effect and patient enrollment criteria. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we or our

collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We cannot guarantee that we won't be required to conduct an additional pivotal trial which would delay our approval timeline and result in additional development costs. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. In any event, our future clinical trials may not be successful.

If Zilretta or any other product candidate is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it and our business would be materially harmed. If the results of any of our ongoing or future clinical trials for Zilretta demonstrate unexpected safety findings or do not achieve the primary efficacy endpoint, the prospects for approval of Zilretta, or the commercial potential for Zilretta, if approved, as well our stock price and our ability to create stockholder value would be materially and adversely affected.

Risks Related to Commercialization of Our Product Candidates

Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among physicians, healthcare payors, patients and the medical community.

Even if we obtain regulatory approval for Zilretta or any of our other potential future product candidates, the product may not gain market acceptance among physicians, healthcare payors, patients and the medical community, which is critical to commercial success. Market acceptance of any product candidate for which we receive approval depends on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- acceptance by physicians, the medical community and patients of the product candidate as a safe and effective treatment;
- the ability to distinguish safety and efficacy from existing, less expensive generic alternative therapies;
- the convenience of prescribing, administrating and initiating patients on the product candidate;
- the potential and perceived advantages of such product candidate over alternative treatments;
- the potential and perceived value of such products over alternative treatments;
- the cost of treatment in relation to alternative treatments, including any similar generic treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse side effects; and
- the effectiveness of sales and marketing efforts.

If our product candidates, including Zilretta, are approved but fail to achieve an adequate level of acceptance by physicians, healthcare payors, patients and the medical community, we will not be able to generate significant revenue, and we may not become or remain profitable.

If we are unable to achieve and maintain adequate levels of third-party payor coverage and reimbursement for Zilretta or any other product candidates, if approved, on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of any approved product candidates depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high.

Payors may require documented proof that patients meet certain eligibility criteria in order to be reimbursed for Zilretta, requiring that a patient first try and fail treatment with an injection of generic corticosteroid. Payors may even require that pre-approval, or prior-authorization, be obtained from the payor for reimbursement of Zilretta. Patients are unlikely to use our products, including Zilretta, if approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. In addition, if approved, Zilretta may be sold to physicians on a “buy and bill” basis and they may be reluctant to purchase Zilretta in advance if there are issues with reimbursement.

In addition, the market for Zilretta and any of our other product candidates may depend significantly on access to third-party payors' medical policies, drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies, and we will be required to offer discounted rates to state Medicaid programs to ensure Medicaid coverage of our drugs. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third party coverage and reimbursement for Zilretta or any of our other product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, or may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. If coverage and reimbursement are not available or only available at limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection, confidentiality agreements and proprietary know how, and intend to seek marketing exclusivity for any approved product, in order to protect the intellectual property related to product candidates, and to date we have only three issued patents covering Zilretta in the United States. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. If this were to occur, early generic competition could be expected against Zilretta and potentially our other product candidates in development. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Also, a third party may challenge our ownership of patents and patent applications assigned to us, or may challenge our exclusive rights to patents and patent applications that we license from third parties. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the additional patent applications we hold with respect to Zilretta or our other product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop them and threaten our ability to commercialize any resulting products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will not be found invalid and unenforceable or will go unthreatened by third parties. Further, if we encounter delays in regulatory approvals, the period of time during which we could market Zilretta or any other product candidate under patent protection could be reduced. Furthermore, patent applications by third parties can result in an interference proceeding in the United States being provoked by a third party or instituted by us to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. See “Business—Patents and Patent Applications” for additional information regarding our material patents and patent applications.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development process that involve proprietary know-how, information or technology that is not covered by patents. For example, we maintain trade secrets with respect to certain of the formulation and manufacturing techniques related to the TA-formulated PLGA microspheres in Zilretta, including those that relate to precise pharmaceutical release. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

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[(3)]	Indenture, dated May 2, 2017, by and between the Registrant and Wells Fargo Bank, National Association, as trustee.
4.3[(3)]	Form of Note representing the Registrant's 3.375% Convertible Senior Notes due 2024 (included as Exhibit A to the Indenture filed as Exhibit 4.4).
10.1	Seventh Amendment of Lease, dated April 7, 2017, between the Registrant and CIP II/RJK 10-20 BMR Owner, LLC.
10.2[(3)]	Consent and Second Amendment to Credit and Security Agreement, dated April 24, 2017, between the Registrant and MidCap Financial Trust, as administrative agent.
10.3[(4)]	Change in Control Severance Benefit Plan and Form of Participation Agreement.
10.4	Offer Letter, dated February 15, 2017 and as amended July 19, 2017, between the Registrant and Yamo Deniz, M.D.
31.1	Certification of the Principal Executive Officer and 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.
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.
(3) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on May 2, 2017.
(4) Incorporated by reference to the Registrant's Current Report on Form 8-K, filed with the SEC on June 23, 2017.

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: August 8, 2017 By: /s/ Michael D. Clayman
Michael D. Clayman
Chief Executive Officer
(Principal Financial Officer)