Flexion Therapeutics Inc
Form 10-Q
May 08, 2018
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
FOR THE QUARTERLY PERIOD ENDED MARCH 31, 2018

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

As of May 1, 2018, the registrant had 37,636,890 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)

	March 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$147,304	$127,789
Marketable securities	224,338	264,589
Accounts receivable, net	2,397	410
Inventories	2,525	1,799
Prepaid expenses and other current assets	4,023	3,403
Total current assets	$380,587	$397,990
Property and equipment, net	10,964	11,189
Long-term investments	4,938	31,538
Restricted cash	600	600
Total assets	$397,089	$441,317
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$3,420	$6,222
Accrued expenses and other current liabilities	11,060	14,383
Current portion of long-term debt	9,967	9,967
Total current liabilities	$24,447	$30,572
Long-term debt, net	10,612	12,936
2024 convertible notes, net	138,983	137,107
Other long-term liabilities	440	428
Total liabilities	$174,482	$181,043
Commitments and contingencies		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2018 and December 31, 2017 and 0 shares issued and outstanding at March 31, 2018 and December 31, 2017	—	—
Stockholders' equity:		
Common stock, $0.001 par value; 100,000,000 shares authorized; 37,632,589 and 37,610,897 shares issued and outstanding, at March 31, 2018 and December 31, 2017, respectively	38	38
Additional paid-in capital	613,881	609,810

Accumulated other comprehensive loss	(576)	(407)
Accumulated deficit	(390,736)	(349,167)
Total stockholders' equity	222,607	260,274
Total liabilities and stockholders' equity	$397,089	$441,317

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 March 31,	
	2018	2017
Revenue		
Product revenue, net	$2,194	$—
Operating expenses:		
Cost of sales	2,698	—
Research and development	11,551	10,756
Selling, general and administrative	26,899	13,026
Total operating expenses	41,148	23,782
Loss from operations	(38,954)	(23,782)
Other income (expense):		
Interest income	1,161	557
Interest expense	(3,919)	(632)
Other income (expense)	143	(22)
Total other income (expense)	(2,615)	(97)
Net loss	$(41,569)	$(23,879)
Net loss per common share, basic and diluted	$(1.10)	$(0.75)
Weighted average common shares outstanding, basic and diluted	37,620	31,704
Other comprehensive (loss) income:		
Unrealized (losses) gains from available-for-sale securities, net of tax of $0	(169)	9
Total other comprehensive (loss) income	(169)	9
Comprehensive loss	$(41,738)	$(23,870)

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

Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(Unaudited in thousands)

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Total Stockholders'
	Shares	Par Value	Paid-in-Capital	Income (Loss)	Deficit	Equity
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
Issuance of common stock for equity awards	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 income				26		26
Balance at December 31, 2016	31,667	$ 32	$ 398,757	$ (71)	$ (211,686)	$ 187,032
Issuance of common stock net of issuance costs	5,520	$ 6	$ 132,171			132,177
Issuance of common stock for equity awards	334		$ 3,858			3,858
Employee Stock Purchase Plan	90	—	1,016			1,016
Stock-based compensation expense	—		11,542			11,542
Portion of convertible debt proceeds allocated to equity component			62,466			62,466
Net loss	—			0	(137,481)	(137,481)
Other comprehensive loss	—			(336)		(336)
Balance at December 31, 2017	37,611	$ 38	$ 609,810	$ (407)	$ (349,167)	$ 260,274
Issuance of common stock for equity awards	22	—	414			$ 414
Stock-based compensation expense			3,657			3,657
Net loss					(41,569)	(41,569)
Other comprehensive loss				(169)		(169)
Balance at March 31, 2018	37,633	$ 38	$ 613,881	$ (576)	$ (390,736)	$ 222,607

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

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Flexion Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited in thousands)

	Three Months Ended March 31,	
	2018	2017
Cash flows from operating activities		
Net loss	$(41,569)	$(23,879)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	563	453
Stock-based compensation expense	3,657	2,378
Other non-cash charges	—	11
Amortization of (discount) premium on marketable securities	(230)	155
Amortization of debt discount and debt issuance costs	1,884	—
Premium paid on securities purchased	(3)	(264)
Changes in operating assets and liabilities:		
Accounts receivable	(1,987)	—
Inventory	(726)	—
Prepaid expenses, other current and long-term assets	(620)	(517)
Accounts payable	(2,806)	138
Accrued expenses and other current and long-term liabilities	(3,144)	131
Net cash used in operating activities	(44,981)	(21,394)
Cash flows from investing activities		
Purchases of property and equipment	(334)	(1,018)
Purchases of marketable securities	(32,546)	(25,421)
Sale and redemption of marketable securities	99,462	60,328
Net cash provided by investing activities	66,582	33,889
Cash flows from financing activities		
Payments on notes payable	(2,500)	(833)
Payments of public offering costs	—	(95)
Proceeds from the exercise of stock options	414	559
Net cash used in financing activities	(2,086)	(369)
Net increase in cash, cash equivalents, and restricted cash	19,515	12,126
Cash, cash equivalents, and restricted cash at beginning of period	128,389	31,395
Cash, cash equivalents, and restricted cash at end of period	$147,904	$43,521
Supplemental disclosures of cash flow information:		
Cash paid for interest	$326	$469
Supplemental disclosures of non-cash financing activities:		
Purchases of property and equipment in accounts payable and accrued expenses	$13	$234

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

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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 biopharmaceutical company focused on the discovery, development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, or OA, a type of degenerative arthritis. The Company has an approved product, ZILRETTA®, which it markets in the United States. ZILRETTA is the first and only extended-release, intra-articular, or IA (meaning in the joint), injection indicated for the management of OA related knee pain. ZILRETTA is a non-opioid therapy that employs Flexion's proprietary microsphere technology to provide pain relief for over 12 weeks. ZILRETTA is not intended for repeat administration, as the efficacy and safety of repeat administration of ZILRETTA have not been evaluated. The Company also has an additional product candidate (FX201) in development for OA.

The Company is subject to risks and uncertainties common to companies in the biopharmaceutical industry, including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, and the ability to secure additional capital to fund operations. Successfully commercializing ZILRETTA will require significant sales and marketing efforts and the Company's pipeline programs may require significant additional research and development efforts, including extensive preclinical and clinical testing. These activities will in turn require significant amounts of capital, adequate personnel infrastructure and extensive compliance reporting capabilities. There can be no assurance when, if ever, the Company will realize significant revenue from the sales of ZILRETTA or if the development efforts supporting the Company's pipeline, including future clinical trials, will be successful.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying condensed consolidated financial statements as of March 31, 2018, and for the three months ended March 31, 2018 and 2017, 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 8, 2018.

The information presented in the condensed consolidated financial statements and related notes as of March 31, 2018, and for the three months ended March 31, 2018 and 2017, is unaudited. The December 31, 2017 consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2018, or any future period.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that the Company will continue as a going concern and which contemplates the realization of assets and satisfaction of liabilities and commitments in the normal course of business. The Company has incurred recurring losses and negative cash flows from operations. As of March 31, 2018, the Company had cash, cash equivalents, marketable securities, and long-term investments of approximately $376.6 million. Management believes that current cash, cash equivalents and marketable securities on hand at March 31, 2018 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 may be dependent on its ability to raise additional capital to finance its operations, including to support the commercialization of ZILRETTA and fund increased research and development costs in order to seek approval and commercialize its product candidates. The Company may not be able to obtain financing on acceptable terms, or at all. If the Company is unable to obtain funding on a timely basis the Company may need to curtail its operations, including the commercialization of ZILRETTA and research and development activities, which could adversely affect its prospects.

Recent Accounting Pronouncements

Accounting Standards Recently Adopted

In January 2016, the Financial Accounting Standards Board, or FASB, issued ASU No. 2016-01, Financial Instruments - Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01"). This new standard amends certain aspects of accounting and disclosure requirements of financial instruments, including the requirement that equity investments with readily determinable fair values be measured at fair value with changes in fair value recognized in the statement of operations. This new standard does not apply to investments accounted for under the equity method of accounting or those that result in consolidation of the investee. Equity investments that do not have readily determinable fair values may be measured at fair value or at cost minus impairment adjusted for changes in observable prices. A financial liability that is measured at fair value in accordance with the fair value option is required to be presented separately in other comprehensive income for the portion of the total change in the fair value resulting from change in the instrument-specific credit risk. In addition, a valuation allowance should be evaluated on deferred tax assets related to available-for-sale debt securities in combination with other deferred tax assets. The Company adopted ASU 2016-01 on January 1, 2018. The adoption of ASU 2016-01 did not have a material impact on the Company's financial position or results of operations.

In August 2016, the FASB issued ASU 2016-15, Statement of cash flows (Topic 230) ("ASU 2016-15"), to increase the consistency of presentation in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted ASU 2016-15 on January 1, 2018. The adoption of ASU 2016-15 did not have a material impact on the Company's financial position or results of operations.

In November 2016, the FASB issued ASU 2016-18, Statement of cash flows (Topic 230): Restricted Cash ("ASU 2016-18"), to provide specific guidance on the cash flow classification and presentation of changes in restricted cash and restricted cash equivalents. The amendments in ASU 2016-18 require that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. The Company adopted ASU 2016-18 on January 1, 2018. As a result of the adoption of ASU 2016-18, $0.6 million and $0.5 million of restricted cash was included in the beginning-of-period cash and cash equivalents amount shown on the statement of cash flows for the three months ended March 31, 2018 and 2017, respectively, and $0.6 million of restricted cash was included in the end-of-period cash and cash equivalents amount shown on the statement of cash flows for the three months ended March 31, 2018 and 2017.

In May 2017, the FASB issued ASU 2017-09, Compensation-Stock Compensation (Topic 718) ("ASU 2017-09") Scope of Modification Accounting. ASU 2017-09 provides clarification on when modification accounting should be used for changes to the terms or conditions of a share-based payment award. This ASU does not change the accounting for modifications but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The Company adopted ASU 2016-18 on January 1, 2018 and it will be applied prospectively to an award modified on or after the adoption date.

Accounting Standards Recently Issued

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 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 currently expects that its operating lease commitments will be subject to the new standard and recognized as operating lease liabilities and right-of-use assets

upon the adoption of ASU 2016-02. The Company is still evaluating whether there are other existing contracts that may become leases under the new lease standard.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments ("ASU 2016-13"). The new standard requires entities to measure all expected credit losses for financial assets held at the reporting date based on historical experience, current conditions and reasonable and supportable forecasts. ASU 2016-13 is effective for fiscal years, and the interim periods within those years, beginning after December 15, 2019 and early adoption is permitted. The Company is currently evaluating the impact of ASU 2016-13 on the Company's consolidated 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 months ended March 31, 2018 and the year ended December 31, 2017.

Revenue Recognition

On October 6, 2017, the FDA approved ZILRETTA. The Company entered into a limited number of arrangements with specialty distributors and a specialty pharmacy in the U.S. to distribute ZILRETTA. These arrangements are the Company's initial contracts with customers and, as a result the Company adopted Accounting Standards Codification ("ASC") Topic 606 - Revenue from Contracts with Customers ("Topic 606") as of January 1, 2017. There is no impact for the transition to Topic 606 because the Company had no historical revenue prior to the launch of ZILRETTA. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance and financial instruments. Under Topic 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to be entitled to in exchange for those goods or services.

To determine revenue recognition for arrangements that an entity determines are within the scope of Topic 606, the entity performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The Company only applies the five-step model to arrangements that meet the definition of a contract with a customer under Topic 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of Topic 606, the Company assesses the goods or services promised within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. For a complete discussion of accounting for product revenue, see Product Revenue, Net (below).

Product Revenue, Net— The Company sells ZILRETTA to its customers who then subsequently resell ZILRETTA to physicians, clinics and certain medical centers or hospitals. In addition to distribution agreements with customers, the Company enters into arrangements with government payers that provide for government mandated rebates and chargebacks with respect to the purchase of ZILRETTA.

The Company recognizes revenue on product sales when the customer obtains control of the Company's product, which occurs at a point in time (upon delivery to the customer). The Company has determined that the delivery of ZILRETTA to its customers constitutes a single performance obligation. There are no other promises to deliver goods or services beyond what is specified in each accepted customer order. The Company has assessed the existence of a significant financing component in the agreements with its customers. The trade payment terms with customers do not exceed one year and therefore the Company has elected to apply the practical expedient and no amount of consideration has been allocated as a financing component. Product revenues are recorded net of applicable reserves for variable consideration, including discounts and allowances.

Transaction Price, including Variable Consideration— Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established. Components of variable consideration include trade discounts and allowances, product returns, government chargebacks, discounts and rebates, and other incentives, such as voluntary patient assistance, and other fee for service amounts that are detailed within contracts between the Company and its customers relating to the Company's sale of its products. These reserves, as detailed below, are based on the amounts earned, or to be claimed on the related sales, and are classified as reductions of accounts receivable (if the amount is payable to the customer) or a current liability (if the amount is payable to a party other than a customer). These estimates take into consideration a range of possible outcomes which are probability-weighted in accordance with the expected value method in Topic 606 for relevant factors such as current contractual and statutory requirements, specific known market events and trends, industry data, and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the respective underlying contracts.

The amount of variable consideration which is included in the transaction price may be constrained, and is included in the net sales price only to the extent that it is probable that a significant reversal in the amount of the cumulative revenue recognized under the contract will not occur in a future period. The Company's analyses also contemplated application of the constraint in accordance with the guidance, under which it determined a material reversal of revenue would not occur in a future period for the estimates detailed below as of March 31, 2018 and, therefore, the transaction price was not reduced further during the three months ended March 31, 2018. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's original estimates, the Company will adjust these estimates, which would affect net product revenue and earnings in the period such changes in estimates become known.

Trade Discounts and Allowances—The Company compensates (through trade discounts and allowances) its customers for sales order management, data, and distribution services. However, the Company has determined such services received to date are not distinct from the Company's sale of products to the customer and, therefore, these payments have been recorded as a reduction of revenue within the statement of operations and comprehensive loss through March 31, 2018, as well as a reduction to trade receivables, net on the condensed consolidated balance sheets.

Product Returns— Consistent with industry practice, the Company generally offers customers a limited right of return for product that has been purchased from the Company based on the product's expiration date. The Company estimates the amount of its product sales that may be returned by its customers and records this estimate as a reduction of revenue in the period the related product revenue is recognized, as well as within accrued expenses and other current liabilities, net on the condensed consolidated balance sheets. The Company currently estimates product return liabilities using available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. The Company has not received any returns to date and believes that returns of ZILRETTA will be minimal.

The Company's limited right of return allows for eligible returns of ZILRETTA in the following circumstances:

•Shipment errors that were the result of an error by the Company;

•Quantity delivered that is greater or less than the quantity ordered;

•Product distributed by the Company that is damaged in transit prior to receipt by the customer;

•Expired product, previously purchased directly from the Company, that is returned during the period beginning three months prior to the product's expiration date and ending three months after the product's expiration date;

•Product subject to a recall; and

•Product that the Company, at its sole discretion, has specified to be returned.

Government Chargebacks, Discounts and Rebates— Chargebacks for fees and discounts to qualified government healthcare providers represent the estimated obligations resulting from contractual commitments to sell products to qualified VA hospitals and 340b entities at prices lower than the list prices charged to customers who directly purchase the product from the Company. The 340b Drug Discount Program is a US federal government program created in 1992 that requires drug manufacturers to provide outpatient drugs to eligible health care organizations and covered entities at significantly reduced prices. Customers charge the Company for the difference between what they pay for the product and the statutory selling price to the qualified government entity. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and trade receivables, net. Chargeback amounts are generally determined at the time of resale to the qualified government healthcare provider by customers, and the Company generally issues credits for such amounts within a few weeks of the Customer's notification to the Company of the resale. Reserves for chargebacks consist of credits that the Company expects to issue for units that remain in the distribution channel inventories at each reporting period-end that the Company expects will be sold to qualified healthcare providers, and chargebacks that customers have claimed, but for which the Company has not yet issued a credit.

Government Rebates— The Company is subject to discount obligations under state Medicaid programs and Medicare. These reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included in accrued expenses and other current liabilities on the condensed consolidated balance sheets. For Medicare, the Company also estimates the number of patients in the prescription drug coverage gap for whom the Company will owe an additional liability under the Medicare Part D program. The Company anticipates its exposure to utilization from the Medicare Part D coverage gap discount program to be immaterial. For Medicaid programs, the Company estimates the portion of sales attributed to Medicaid patients and records a liability for the rebates to be paid to the respective state Medicaid programs. The Company's liability for these rebates consists of invoices received for claims from prior quarters that have not been paid or for which an invoice has not yet been received, estimates of claims for the current quarter, and estimated future claims that will be made for product that has been recognized as revenue, but which remains in the distribution channel inventories at the end of each reporting period.

Other Incentives— Other incentives which the Company offers include voluntary patient assistance programs, such as the co-pay assistance program, which are intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payers. The calculation of the accrual for co-pay assistance is based on an estimate of claims and the cost per claim that the Company expects to receive associated with product that has been recognized as revenue, but remains in the distribution channel inventories at the end of each reporting period. The adjustments are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and the establishment of a current liability which is included as a component of accrued expenses and other current liabilities on the condensed consolidated balance sheets.

To date, the Company's only source of product revenue has been from the U.S. sales of ZILRETTA, which it began shipping to customers in October 2017.

The following table summarizes activity in each of the product revenue allowance and reserve categories for the three months ended March 31, 2018:

(In thousands)	Trade Discounts, Allowances and Government chargebacks	Government rebates and other incentives	Returns	Total
Balance as of December 31, 2017	$ 60	$ 15	$ 2	$77
Provision related to sales in the current year	186	49	12	247
Credit and payments made	(94)	—	—	(94)
Balance as of March 31, 2018	$ 152	$ 64	$ 14	$230

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, revenue and 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 estimates related to revenue, 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 March 31, 2018 and December 31, 2017 and indicate the level of the fair value hierarchy utilized to determine such fair value:

	Fair Value Measurements as of March 31, 2018 Using:			
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$—	$127,468	$ —	$127,468
Marketable securities	—	229,276	—	229,276
	$—	$356,744	$ —	$356,744

	Fair Value Measurements as of December 31, 2017 Using:			
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$—	$109,196	$ —	$109,196
Marketable securities	—	296,127	—	296,127
	$—	$405,323	$ —	$405,323

As of March 31, 2018 and December 31, 2017 the Company's cash equivalents that are invested in money market funds and overnight repurchase contracts are valued based on Level 2 inputs. The Company measures the fair value of marketable securities using Level 2 inputs and primarily relies on quoted prices in active markets for similar marketable securities. During the three months ended March 31, 2018 and year ended December 31, 2017, there were no transfers between Level 1, Level 2, and Level 3. Amortization and accretion of discounts and premiums are recorded in other income.

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 March 31, 2018 and December 31, 2017. The result of the calculation yielded a fair value that approximates its carrying value.

On May 2, 2017 the Company issued 3.375% convertible senior notes due 2024 (the "2024 Convertible Notes") with embedded conversion features. The Company estimated the fair value of the 2024 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.

The fair value of the 2024 Convertible Notes, which differs from their carrying value, is influenced by interest rates, stock price and stock price volatility and is determined by prices for the 2024 Convertible Notes observed in market trading. The market for trading of the 2024 Convertible Notes is not considered to be an active market and therefore the estimate of fair value is based on Level 2 inputs. The estimated fair value of the 2024 Convertible Notes, face value of $201.3 million, was $226.6 million at March 31, 2018.

4. Marketable Securities

As of March 31, 2018 and December 31, 2017 the fair value of available-for-sale marketable securities by type of security was as follows:

	March 31, 2018			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	22,383	—	—	22,383
U.S. government obligations	$84,254	$ —	$ (156)	$84,098
Corporate bonds	123,218	—	(423)	122,795
	$229,855	$ —	$ (579)	$229,276

	December 31, 2017			
(In thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Commercial paper	$22,436	$ —	$ —	$22,436
U.S. government obligations	121,470	$ —	(136)	121,334
Corporate bonds	152,630	$ —	(273)	152,357
	$296,536	$ —	$ (409)	$296,127

As of March 31, 2018 and December 31, 2017, marketable securities consisted of approximately $224.3 and $264.6 million, respectively, of investments that mature within twelve months and approximately $4.9 million and $31.5 million, respectively of investments that mature after one year but within two years or less from the balance sheet date.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets and other assets consisted of the following as of March 31, 2018 and December 31, 2017:

(In thousands)	March 31, 2018	December 31, 2017
Prepaid expenses	$3,288	$ 2,359
Deposits	66	66
Interest receivable on marketable securities	669	978
Total prepaid expenses and other current assets	$4,023	$ 3,403

6. Inventory

Inventory consisted of the following as of March 31, 2018 and December 31, 2017:

(In thousands)	March 31, 2018	December 31, 2017
Raw materials	$780	$ 928
Work in process	711	746
Finished goods	1,034	125
Total inventories	$2,525	$ 1,799

Inventory acquired prior to receipt of the marketing approval for ZILRETTA, totaling approximately $3.7 million, was expensed as research and development expense as incurred. The Company began to capitalize the costs associated with the production of ZILRETTA upon receipt of FDA approval of ZILRETTA on October 6, 2017.

Finished goods manufactured by the Company have a shelf life of approximately 24 months from the date of manufacture.

The Company reduces its inventory to net realizable value for potentially excess, dated or obsolete inventory based on an analysis of forecasted demand compared to quantities on hand and any firm purchase orders, as well as product shelf life. During the three months ended March 31, 2018, the Company expensed $2.7 million to cost of sales primarily for fixed overhead costs related to the operation of the facility at Patheon. The Company determined that no write-downs to inventory for potentially excess, dated or obsolete inventory were required.

7. Property and Equipment, Net

Property and equipment, net, as of March 31, 2018 and December 31, 2017 consisted of the following:

(In thousands)	March 31, 2018	December 31, 2017
Computer and office equipment	$1,124	$ 1,124
Manufacturing equipment	11,827	11,780
Furniture and fixtures	456	456
Software	434	434
Leasehold improvements	478	474
Construction—in progress	592	305
	14,911	14,573
Less: Accumulated depreciation	(3,947)	(3,384)
Total property and equipment, net	$10,964	$ 11,189

Depreciation expense for the three months ended March 31, 2018 and 2017 was approximately $0.6 million and $0.5 million, respectively. No property and equipment was disposed of during the three months ended March 31, 2018. Construction in progress consists of equipment purchased for the Company's portfolio expansion efforts, as well as leasehold improvements related to the second floor space expansion of the Company's Burlington, Massachusetts headquarters.

8. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consisted of the following:

(In thousands)	March 31, 2018	December 31,