Egalet Corp
Form 10-Q
May 08, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2015

Or

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

For the transition period from to

Commission File Number 001-36295

Egalet Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**46-3575334**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
460 East Swedesford Road Suite 1050 Wayne, PA	
(Address of Principal Executive Offices)	**19087** (Zip Code)

Registrant s telephone number, including area code: **(610) 833-4200**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	NASDAQ Global Market

Securities registered pursuant to Section 12(g) of the Act: **None**

(Title of Class)

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

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

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

Large accelerated filer o	Accelerated filer x	Non-accelerated filer o (Do not check if a	Smaller reporting company o

smaller reporting company)

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

Indicate the number of shares outstanding of each of the issuer s classes of common stock, as of the latest practical date.

Common Stock, $0.001 par value	Shares outstanding as of May 8, 2015: 17,323,663

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On November 26, 2013, Egalet Corporation (the Company) acquired all of the outstanding shares of Egalet Limited (Egalet UK). As a result, Egalet UK became a wholly-owned subsidiary of the Company, and the former shareholders of Egalet UK received shares of the Company (the Share Exchange). Unless the context indicates otherwise, as used in this Quarterly Report on Form 10-Q, the terms Egalet, we, us, our, our company and our business refers to the Company for all periods subsequent to the Share Exchange, and to Egalet UK for all periods prior to the Share Exchange. The Egalet logo is our trademark and Egalet is our registered trademark. All other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this Quarterly Report on Form 10-Q, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Quarterly Report on Form 10-Q without the trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense. Unless otherwise indicated, all statistical information provided about our business in this report is as of March 31, 2015.

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PART I

ITEM 1. FINANCIAL STATEMENTS

Egalet Corporation and Subsidiaries

Consolidated Balance Sheets

(in thousands, except share and per share data)

	December 31, 2014	March 31, 2015 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 52,738	$ 53,887
Related party receivable	679	10,470
Inventory		2,621
Prepaid expenses	698	1,089
Other receivables	1,011	896
Total current assets	55,126	68,963
Intangible assets, net	184	9,536
Property and equipment, net	4,417	4,279
Goodwill		3,367
Deposits and other assets	843	693
Total assets	$ 60,570	$ 86,838
Liabilities and stockholders (deficit) equity		
Current liabilities:		
Debt current portion	$	$ 1,294
Accounts payable	4,209	3,086
Accrued expenses	2,554	4,434
Deferred revenue	588	15,953
Due to Acura Pharmaceuticals		2,500
Other current liabilities	78	53
Total current liabilities	7,429	27,320
Debt non-current portion		13,215
Deferred income tax liability	25	49
Deferred revenue non-current portion	8,855	18,029
Other liabilities		57
Total liabilities	16,309	58,670
Stockholders equity:		
Common stock $0.001 par value at December 31, 2014 and March 31, 2015; 75,000,000 shares authorized at December 31, 2014 and March 31, 2015; 17,283,663 and 17,323,663 shares issued and outstanding at December 31, 2014 and March 31, 2015, respectively	17	17
Additional paid-in capital	121,028	122,471

Accumulated other comprehensive loss		(171)		(986)
Accumulated deficit		(76,613)		(93,334)
Total stockholders equity		44,261		28,168
Total liabilities and stockholders equity	$	60,570	$	86,838

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Operations (Unaudited)

(in thousands, except share and per share data)

	Three months Ended March 31,	
	2014	**2015**
Revenues:		
Net Product Sales	$	$ 162
Related party revenues	256	643
Total revenues	256	805
Cost and Expenses:		
Cost of sales (excluding amortization of product rights)		94
Amortization of product rights		378
General and administrative	3,263	4,861
Sales and marketing	6	1,568
Research and development	2,780	10,251
Total costs and expenses	6,049	17,152
Loss from operations	(5,793)	(16,347)
Other (income) expense:		
Interest expense	7,092	451
Gain on foreign currency exchange	(4)	(103)
	7,088	348
Loss before provision for income taxes	(12,881)	(16,695)
Provision for income taxes	35	26
Net loss	$ (12,916)	$ (16,721)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (1.34)	$ (1.02)
Weighted-average shares outstanding, basic and diluted	9,638,260	16,451,669

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Comprehensive Loss (Unaudited)

(in thousands)

	Three months Ended March 31,	
	2014	**2015**
Net loss	$ (12,916)	$ (16,721)
Other comprehensive income (loss):		
Foreign currency translation adjustment	104	(815)
Comprehensive loss	$ (12,812)	$ (17,536)

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Changes in Stockholders Equity

For the Three months Ended March 31, 2015

(unaudited)

(in thousands, except share data)

	Stockholders Equity					
	Common Stock					
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Income (loss)	Total
Balance, December 31, 2014	17,283,663	$ 17	$ 121,028	$ (76,613)	$ (171)	$ 44,261
Issuance warrants			329			329
Issuance of restricted shares of common stock	40,000					
Stock-based compensation expense			1,114			1,114
Foreign currency translation adjustment					(815)	(815)
Net loss				(16,721)		(16,721)
Balance, March 31, 2015	17,323,663	$ 17	$ 122,471	$ (93,334)	$ (986)	$ 28,168

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

(in thousands)

	Three months Ended March 31,	
	2014	**2015**
Operating activities:		
Net loss	$ (12,916)	$ (16,721)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	168	631
Stock-based compensation expense	1,683	1,114
Amortization of debt discount	6,987	111
Amortization of deferred financing fees		17
Deferred income taxes	(1)	26
Changes in assets and liabilities, net of business acquisitions:		
Related party receivable	(140)	209
Inventory		(40)
Prepaid expenses	(459)	(422)
Other receivables		(1)
Deposits and other assets		(8)
Accounts payable	240	(1,230)
Accrued expenses	(553)	1,952
Deferred revenue	(115)	14,542
Other current liabilities	25	(17)
Net cash provided by (used in) operating activities	(5,081)	163
Investing activities:		
Payments for purchase of property and equipment	(85)	(163)
Deposits for purchases of property and equipment	(111)	
Purchase of SPRIX		(8,128)
License of OXAYDO		(5,172)
Net cash used in investing activities	(196)	(13,463)
Financing activities:		
Proceeds from debt issuance, net of costs		14,784
Deferred financing costs		(171)
Proceeds from IPO, net of costs	53,124	
Proceeds from issuance of common stock, net of costs	13,950	
Net cash provided by financing activities	67,074	14,613
Effect of foreign currency translation on cash	(47)	(164)
Net increase (decrease) in cash and cash equivalents	61,750	1,149
Cash and cash equivalents beginning of period	15,700	52,738
Cash and cash equivalents end of period	$ 77,450	53,887
Supplemental disclosure of cash flow information:		
Issuance of warrants	$	$ 329

Liability for contractual payment associated with OXAYDO license			$	2,500
Conversion of convertible preferred stock	$	14,957		
Conversion of related party convertible debt	$	24,713		

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Notes to Unaudited Consolidated Financial Statements

1. Organization and Description of the Business

Egalet Corporation (the Company) is a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative medicines for patients with acute and chronic pain while helping to protect physicians, families and communities from the burden of prescription abuse. The Company was incorporated in Delaware in August 2013 and until its initial public offering (IPO) in February 2014, had nominal assets and no operations. Egalet Limited (Egalet UK), incorporated in July 2010 in England and Wales, owned all of the Company s current assets and operations and acquired them in July 2010 pursuant to an agreement to purchase the business and certain assets of Egalet A/S, which was founded under the laws of Denmark. This transaction was accounted for as a business combination. In November 2013, all of the issued and outstanding ordinary shares and preferred shares of Egalet UK were exchanged for an identical number of shares of common stock and preferred stock of the Company, which resulted in Egalet UK becoming a wholly-owned subsidiary of the Company. As Egalet UK and Egalet US Inc. are entities under common control, the consolidated financial statements reflect the historical carrying values of Egalet UK s assets and liabilities and its results of operations as if they were consolidated for all periods presented. As a result of these transactions, the Company has a late-stage portfolio of product candidates that are being developed using the Company s broad-based drug delivery platform specifically designed to resist manipulation, to prevent easy extraction and to deter the abuse of medications via known routes of abuse, including chewing, snorting, and injecting. On January 8, 2015, the Company announced the acquisition and license of two innovative pain products, SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO (oxycodone HCI, USP) tablets for oral use only CII, both approved by the United States (U.S.) Food and Drug Administration (FDA) to treat pain. SPRIX Nasal Spray, a non-steroidal anti-inflammatory drug (NSAID), is indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. OXAYDO is the first and only approved immediate-release (IR) oxycodone product formulated to deter abuse via snorting, for the management of acute and chronic moderate to severe pain where an opioid is appropriate. In addition, using our proprietary Guardian Technology, the Company is developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. The Company s technology platform can be used with a broad range of opioids and non-opioids. The Company has filed patents to protect its inventions covering both the technology and product-specific patents.

Initial Public Offering

On February 11, 2014, 4,200,000 shares of common stock were sold on the Company s behalf at an IPO price of $12.00 per share, for aggregate gross proceeds of $50.4 million. On March 7, 2014, in connection with the exercise by the underwriters of a portion of the over-allotment option granted to them as a part of the Company s IPO, 630,000 additional shares of common stock were sold by the Company at the IPO price of $12.00 per share, for aggregate gross proceeds of approximately $7.6 million. In addition, as part of the IPO, the Company converted all of its convertible preferred stock and related party senior convertible debt into 5,329,451 and 2,585,745 shares of common stock, respectively. Also, Shionogi Limited (Shionogi), a collaboration partner of the Company, purchased 1,250,000 shares of the Company s common stock in a separate private placement concurrent with the completion of the IPO at a price per share equal to $12.00 per share, for aggregate gross proceeds of $15.0 million. The sale of such shares has not been registered under the Securities Act of 1933, as amended. In addition, the 2013 related party senior convertible debt holders automatically exercised 600,000 warrants for shares of common stock at an exercise price of $0.0083 per share.

The Company paid to the underwriters discounts and commissions of approximately $5.1 million in connection with the offering, including discounts and commissions from the exercise of the over-allotment option. In addition, the Company incurred legal, accounting, and other

offering-related expenses of approximately $2.4 million in connection with the offering, which when added to the underwriting discounts and commissions paid by the Company, amounts to total expenses of approximately $7.5 million. Thus, the net proceeds to the Company from the IPO, after deducting underwriting discounts and commissions and offering expenses, were approximately $51.5 million. Additionally, after deducting the expenses related to the private placement with Shionogi, the net proceeds to the Company from the private placement were approximately $14.0 million.

Liquidity

The Company has incurred recurring operating losses since inception. As of March 31, 2015, the Company had an accumulated deficit of $93.3 million and will require substantial additional capital to fund its research and development of its proprietary product candidates and commercial plans for SPRIX and OXAYDO. The Company reasonably expects that the net proceeds from the Company s IPO, Hercules term loan (see Note 5), and the 5.50% Senior Convertible Notes (see Note 13), together with its pre-existing cash and cash equivalents, will enable it to fund its operating expenses and capital expenditure requirements through March 31, 2016. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical programs, and the development of its administrative organization. As the Company continues to incur losses, a transition to profitability is dependent upon the successful

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development, approval and commercialization of its product candidates and the achievement of a level of revenue adequate to support the Company s cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through the sale of equity, debt financings or other sources, including potential additional collaborations. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

In January 2015, the Company entered into a Loan and Security Agreement, (the Loan Agreement), with Hercules Technology Growth Capital, Inc., (Hercules) and certain other lenders, pursuant to which the Company borrowed $15.0 million under a term loan. Refer to Note 5 Long term debt for additional information.

During the three months ended March 31, 2015 the Company had significant cash out flows related to the purchase of SPRIX and license of OXAYDO of $8.1 million and $5.2 million, respectively. With regards to OXAYDO, the Company also owes a $2.5 million milestone on the earlier to occur of first commercial sale of OXAYDO or January 1, 2016, but in no event earlier than June 30, 2015. Refer to Note 9 - Acquisitions and License and Collaboration Agreements for additional information.

Forward Stock Split

In connection with preparing for the IPO, the Company s board of directors and stockholders approved a 1.2 to 1 forward stock split of the Company s common stock. The forward stock split became effective on January 21, 2014. All share and per share amounts in the financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to this forward stock split, including reclassifying an amount equal to the increase in par value of common stock to additional paid-in capital.

2. Summary of Significant Accounting Policies and Basis of Accounting

Basis of Presentation

The unaudited consolidated financial statements are prepared in conformity with U.S. generally accepted accounting principles (GAAP) for interim financial information. Certain information and footnotes normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) for quarterly reports on Form 10-Q. The Company s consolidation policy requires the consolidation of entities where a controlling financial interest is held. All intercompany balances and transactions have been eliminated in consolidation.

The accompanying consolidated financial information at March 31, 2015 and for the three months ended March 31, 2014 and 2015 is unaudited. The interim unaudited financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company s financial position as of March 31, 2015 and for the three months ended March 31, 2014 and 2015. The financial data and other information disclosed in these notes related to the three months ended March 31, 2014 and 2015 are not necessarily indicative of the results to be expected

for the year ending December 31, 2015, any other interim periods or any future year or period. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2014 filed on March 16, 2015 with the SEC.

The Company s significant accounting policies are described in Note 2 of the Notes to the Consolidated Financial Statements included in the Company s Annual Report on Form 10-K for the year ended December 31, 2014. Since the date of those financial statements, there have been no changes to the Company s significant accounting policies, except where noted below.

Reclassification

Certain reclassifications were made to prior period amounts to conform to the current period presentation.

Concentration of credit risk

The Company has an exposure to credit risk in trade accounts receivable from sales of product. In the U.S. the Company sells SPRIX to a specialty pharmacy which then distributes to patients. One customer represents 100% of our sales during the three months ended March 31, 2015. We did not have any trade accounts receivable as of March 31, 2015.

Fair Value Measurements

The carrying amounts reported in the Company s consolidated financial statements for cash, accounts receivable, accounts payable, accrued liabilities, and notes payable approximate their respective fair values because of the short-term nature of these accounts. The carrying amount of the Company s debt at March 31, 2015 approximates fair value because the interest rate is reflective of the rate the Company could obtain on debt with similar terms and conditions.

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Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

Fair value should be based on the assumptions that market participants would use when pricing an asset or liability and is based on a fair value hierarchy that prioritizes the information used to develop those assumptions. The fair value hierarchy gives the highest priority to quoted prices in active markets (observable inputs) and the lowest priority to the Company s assumptions (unobservable inputs). Fair value measurements should be disclosed separately by level within the fair value hierarchy. For assets and liabilities recorded at fair value, it is the Company s policy to maximize the use of observable inputs and minimize the use of unobservable inputs when developing fair value measurements, in accordance with established fair value hierarchy.

Fair value measurements for assets and liabilities where there exists limited or no observable market data are based primarily upon estimates, and often are calculated based on the economic and competitive environment, the characteristics of the asset or liability and other factors. Therefore, the results cannot be determined with precision and may not be realized in an actual sale or immediate settlement of the asset or liability. Additionally, there may be inherent weaknesses in any calculation technique, and changes in the underlying assumptions used, including discount rates and estimates of future cash flows, could significantly affect the results of current or future values. From time to time, the Company may be required to record at fair value other assets on a nonrecurring basis, such as assets held for sale and certain other assets. These nonrecurring fair value adjustments typically involve application of lower-of-cost-or-market accounting or write-downs of individual assets.

The Company groups assets and liabilities at fair value in three levels, based on the markets in which the assets and liabilities are traded and the reliability of the assumptions used to determine fair value. These levels are:

Level 1 Valuations for assets and liabilities traded in active exchange markets, such as the New York Stock Exchange.

Level 2 Valuations for assets and liabilities that can be obtained from readily available pricing sources via independent providers for market transactions involving similar assets or liabilities. The Company s principal markets for these securities are the secondary institutional markets, and valuations are based on observable market data in those markets.

Level 3 Valuations for assets and liabilities that are derived from other valuation methodologies, including option pricing models, discounted cash flow models and similar techniques, and are not based on market exchange or dealer- or broker-traded transactions. Level 3 valuations incorporate certain assumptions and projections in determining the fair value assigned to such assets or liabilities.

Level 3 valuations are for instruments that are not traded in active markets or are subject to transfer restrictions and may be adjusted to reflect illiquidity and/or non-transferability, with such adjustment generally based on available market evidence. In the absence of such evidence, management s best estimate is used.

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1 or Level 2 as of December 31, 2014 and March 31, 2015 and there were no material re-measurements of fair value with respect to financial assets and liabilities, during those years, other than those assets and liabilities that are measured at fair value on a recurring basis. There were no transfers between Level 1 and Level 2 in any of the periods reported.

Net Product Sales

The Company recognizes revenue in accordance with the Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) 605, *Revenue Recognition*, when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller s price to the buyer is fixed or determinable and collectability is reasonably assured. The Company determines that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. Pursuant to the contract terms, the Company determines when title to products and associated risk of loss has passed on to the customer. The Company assesses whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. The Company assesses collectability based primarily on the customer s payment history and creditworthiness.

The Company sells SPRIX in the U.S. to a single specialty pharmaceutical distributor subject to rights of return. The Company has limited SPRIX sales history under the current distribution model and pricing, and the Company has determined that at this time it cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of SPRIX until the right of return no longer exists, which occurs at the earlier of the time SPRIX units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged

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in transit. The Company calculates patient prescriptions dispensed using an analysis of third-party information. As of March 31, 2015, the Company had deferred revenue of $14.7 million related to sales of SPRIX, which is expected to be recognized over the next 12 months.

Related Party Revenue

During 2013, the Company entered into a collaborative research and license agreement with Shionogi. The terms of this agreement contain multiple deliverables which include (i) licenses; (ii) research and development activities and (iii) certain of the Company s core technologies and improvements thereon. The Company has adopted the provisions of Accounting Standards Update (ASU) 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends ASC 605-25, and also adopted ASU 2010-17, *Revenue Recognition Milestone Method*. In accordance with ASU 2009-13, the Company considered whether the deliverables under the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have stand-alone value. See Note 9 Acquisitions and License and Collaboration Agreements for further discussion of the Company s accounting for the collaborative research and license agreement.

Deferred Revenue

The Company records deferred revenue when either: a sale of product has occurred, but revenue recognition criteria has not been met; or when a milestone is achieved under the collaborative research and license agreement with Shionogi as discussed in the Company s Related Party Revenue policy described above. As of March 31, 2015 the deferred revenue balance consisted of $14.7 million for product sales, all of which is classified as current, and $19.2 million related to the collaborative research and license agreement with Shionogi, $1.2 million of which is classified as current.

Product Sales Allowances

The Company recognizes product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of the Company s agreements with customers and third-party payors that may result in future rebates or discounts taken. In certain cases, such as patient discount programs, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company s product sales allowances include:

Specialty Pharmacy Discounts. The Company offers discounts to a certain specialty distributor based on contractually determined rates. The Company accrues the discount on shipment to the respective distributor and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. The Company offers cash discounts to its customers, generally 2% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the prompt pay discount amount and recognizes the

discount as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. The Company offers co-pay discount programs to patients for SPRIX in which patients receive a co-pay discount on their prescriptions. The Company estimates the total amount that will be redeemed based on the quantity of product shipped and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Inventories and Cost of Sales

Inventories are stated at the lower of cost or market net of reserve for excess and obsolete inventory. At March 31, 2015, inventory consisted of raw materials and deferred cost of goods.

Cost of sales includes the cost of inventory sold or reserved; manufacturing, manufacturing overhead and supply chain costs; product shipping and handling costs and product royalties. The cost of sales associated with the deferred product revenues are recorded as deferred costs, which are included in inventory, until such time the deferred revenue is recognized.

Impairment of Goodwill and Intangible Assets

Goodwill represents the excess of the purchase price over the fair value of tangible and identified intangible net assets of businesses acquired. Goodwill is not amortized, but is evaluated for impairment on an annual basis or more often when impairment indicators are present. The Company has one reporting unit. Therefore, the Company s consolidated net assets, including existing goodwill and other intangible assets, are considered to be the carrying value of the reporting unit. If the carrying value of the reporting unit is in excess of its fair value, an impairment may exist, and the Company must perform the second step of the analysis, in

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which the implied fair value of the goodwill is compared to its carrying value to determine the impairment charge, if any. If the estimated fair value of the reporting unit exceeds the carrying value of the reporting unit, goodwill is not impaired and no further analysis is required.

The Company makes judgments about the recoverability of purchased intangible assets with finite lives whenever events or changes in circumstances indicate that impairment may exist. Recoverability of purchased intangible assets with finite lives is measured by comparing the carrying amount of the asset to the future undiscounted cash flows the asset is expected to generate. Impairment, if any, is measured as the amount by which the carrying value exceeds the fair value of the impaired asset.

Stock-Based Compensation Expense

The Company accounts for stock-based compensation in accordance with the provisions of ASC Topic 718, *Compensation Stock Compensation* (ASC 718), which requires the recognition of expense related to the fair value of stock-based compensation awards in the Statements of Operations and Comprehensive Loss.

For stock options issued to employees and members of the Board of Directors, the Company estimates the grant date fair value of each option using the Black-Scholes option-pricing model. The use of the Black-Scholes option pricing model requires management to make assumptions with respect to the expected term of the option, the expected volatility of the common stock consistent with the expected life of the option, risk-free interest rates, the value of the common stock and expected dividend yields of the common stock. For awards subject to service-based vesting conditions, the Company recognizes stock-based compensation expense, net of estimated forfeitures, equal to the grant date fair value of stock options on a straight-line basis over the requisite service period, which is generally the vesting term.

Share-based payments issued to non-employees are recorded at their fair values, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period in accordance with the provisions of ASC 718 and ASC Topic 505, *Equity*. See Note 7 Stock-based compensation for a discussion of the assumptions used by the Company in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the stock option activity under the Company s stock-based compensation plan for the three months ended March 31, 2015.

The stock-based compensation expense for restricted stock awards is determined based on the closing market price of the Company s common stock on the grant date of the awards applied to the total number of awards that are anticipated to vest.

Long Term Debt

Long term debt consists of the Loan Agreement with Hercules and certain other lenders, pursuant to which the Company borrowed $15.0 million in January 2015 under a term loan (see Note 5). The term loan bears an interest rate per annum equal to the greater of either (i) 9.40% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (ii) 9.40%.

Common Stock Warrants

The Company issued warrants to Hercules in connection with the Loan Agreement with Hercules and certain other lenders. The Company evaluated the warrants under *ASC 480 - Distinguishing Liabilities from Equity* and determined the warrants are classified as equity. The fair value of the warrants was recorded as a debt discount.

Income Taxes

Income taxes are recorded in accordance with ASC Topic 740, *Income Taxes* (ASC 740), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are provided, if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2014 and March 31, 2015, the Company does not have any significant uncertain tax positions.

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Foreign Currency Translation

The financial statements of the Company s foreign operations are measured using the local currency as the functional currency. The local currency assets and liabilities are translated at the rate of exchange to the U.S. dollar on the Company s balance sheet date and the local currency revenues and expenses are translated at average rates of exchange to the U.S. dollar during the reporting periods. Foreign currency transaction gains (losses) have been reflected as a component of other income (expense), net, within the Company s consolidated statements of operations and foreign currency translation gains (losses) have been included as a component of the Company s consolidated statements of comprehensive loss and accumulated other comprehensive income within the Company s consolidated balance sheets.

Intercompany payables and receivables are considered to be long-term in nature and any change in balance due to foreign currency fluctuation is included as a component of the Company s consolidated statements of comprehensive loss and accumulated other comprehensive income within the Company s consolidated balance sheets.

Recent Accounting Pronouncements

In May 2014, a new accounting standard was issued that amends the guidance for the recognition of revenue from contracts with customers to transfer goods and services. This new standard will be effective for interim and annual periods beginning January 1, 2017, and is required to be adopted using either a full retrospective or a modified retrospective approach, and early adoption is not permitted. We are currently evaluating the impact that this new standard will have on our financial statements.

In April 2015, a new accounting standard was issued that amends the presentation for debt issuance costs. Upon adoption, such costs shall be presented on our consolidated balance sheets as a direct deduction from the carrying amount of the related debt liability and not as a deferred charge presented in other assets on our consolidated balance sheets. This new standard will be effective for interim and annual periods beginning on January 1, 2016, and is required to be retrospectively adopted. Adoption of this new standard is not expected to have a material impact on our consolidated balance sheets or related disclosures.

3. Inventory

Inventory is stated at the lower of cost or market using actual cost net of reserve for excess and obsolete inventory. The following represents the components of inventory at March 31, 2015. There was no inventory at December 31, 2014.

(in thousands)	**March 31, 2015**
Raw materials	$ 520
Work in process	
Finished goods	
Deferred cost of goods sold	2,101

Total	$	2,621

Deferred costs of goods sold represents inventory sold to our specialty pharmacy partner, but not yet sold to patients.

4. Intangible Assets and Goodwill

The following represents the balance of the intangible assets at March 31, 2015:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	$ 7,671	$ 274	$ 7,397	4.75
SPRIX product rights	2,080	104	1,976	6.75
IP R&D	163		163	Indefinite
Total	$ 9,914	$ 378	$ 9,536	

The following represents the balance of the intangible assets at December 31, 2014:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets
IP R&D	$ 184		$ 184
Total	$ 184	$	$ 184

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There was no impairment to intangible assets or goodwill recognized in the three months ended March 31, 2014 and 2015.

Collaboration and License Agreement with Acura

In January 2015, the Company entered into a License Agreement with Acura Pharmaceuticals, Inc. (Acura) to commercialize OXAYDO (oxycodone hydrochloride) tablets containing Acura s Aversion® Technology. The Company paid Acura an upfront payment of $5.0 million in January 2015 and will pay a $2.5 million milestone on the earlier to occur of first commercial sale of OXAYDO or January 1, 2016, but in no event earlier than June 30, 2015. The Company also incurred transaction costs of $172,000 associated with the deal. Refer to Note 9 Acquisitions and license and collaboration agreements for additional details.

During the three months ended March 31, 2015 the Company recognized amortization expense of $274,000 related to the OXAYDO product right intangible.

SPRIX Acquisition

In January 2015, the Company entered into and consummated the transactions contemplated by the Purchase Agreement with Luitpold Pharmaceuticals, Inc..(Luitpold). Pursuant to the Purchase Agreement, the Company acquired specified assets and liabilities associated with SPRIX® (ketorolac tromethamine) Nasal Spray for a purchase price of $7.0 million. The Company recorded an intangible asset of $2.1 million and goodwill of $3.4 million related to this transaction. Refer to Note 9 for additional details.

During the three months ended March 31, 2015 the Company recognized amortization expense of $104,000 related to the SPRIX product rights intangible.

In-Process Research and Development (IP R&D)

In connection with the acquisition of Egalet A/S, the Company recognized an IP R&D asset related to the drug delivery platform specifically designed to help deter physical abuse of pain medications. The IP R&D is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. As of December 31, 2014 and March 31, 2015, the carrying value of IPR&D was $184,000, and $163,000, respectively. The change in value was entirely due to fluctuation in foreign currency exchange rates.

5. Long-term Debt

Hercules Loan and Security Agreement

In January 2015, the Company entered into the Loan Agreement with Hercules and certain other lenders, pursuant to which the Company borrowed $15.0 million under a term loan. The term loan bears an interest rate per annum equal to the greater of either (i) 9.40% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (ii) 9.40%. Pursuant to the terms of the Loan Agreement, the Company will make interest-only payments for 12 months beginning on February 1, 2015, and then repay the principal balance of the loan in 30 equal monthly payments of principal and interest through the scheduled maturity date of July 1, 2018. In connection with the Loan Agreement, the Company granted a security interest in substantially all of its assets, excluding intellectual property and certain new drug applications and related approvals, as collateral for the obligations under the Loan Agreement.

The Loan Agreement also contains representations and warranties, and indemnification in favor of Hercules. The Company is required to comply with various customary covenants, including, among others, restrictions on indebtedness, investments, distributions, transfers of assets and acquisitions. The Loan Agreement contains several events of default, including, among others, payment defaults, breaches of covenants or representations, material impairment in the perfection of Hercules security interest or in the collateral and events related to bankruptcy or insolvency. Upon an event of default, Hercules may declare all outstanding obligations immediately due and payable, and Hercules may take such further actions as set forth in the Loan Agreement, including collecting or taking such other action with respect to the collateral pledged in connection with the Loan Agreement.

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In connection with the Loan Agreement, the Company issued Hercules a warrant (the Warrant) to purchase $600,000 in shares of the Company s common stock at an exercise price of $5.29 per share (or, approximately 113,421 shares of common stock). The Warrant is considered a standalone instrument since it may be exercised separately from the Loan Agreement. .The Warrant is exercisable for a period of five years beginning on the date of issuance and has an expected fair value of $328,610 that is included in stockholders equity. The fair value of the Warrant was determined through the use of a Black Scholes calculation using the below assumptions:

Risk-free interest rate	1.50%
Expected term (in years)	5.00
Expected volatility	71.68%
Dividend yield	

6. Net Loss Per Common Share

The following table sets forth the computation of basic and diluted net loss per share for the periods indicated:

	Three months Ended March 31,	
(in thousands, except share and per share data)	**2014**	**2015**
Basic and diluted net loss per common share calculation:		
Net loss attributable to common stockholders	$ (12,916)	$ (16,721)
Weighted-average common shares outstanding	9,638,260	16,451,669
Net loss per share of common stock basic and diluted	$ (1.34)	$ (1.02)

The following outstanding securities for the three months ended March 31, 2014 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Three months Ended March 31,	
	2014	**2015**
Options outstanding	81,696	866,048
Unvested restricted stock awards	1,113,360	872,535
Warrants outstanding		113,421
Total	1,195,056	1,852,004

7. Stock-based Compensation

2013 Stock-Based Incentive Plan

In November 2013, the Company adopted its 2013 Stock-Based Incentive Plan (the Plan). Pursuant to the Plan, the Company s compensation committee is authorized to grant equity-based incentive awards to its board of directors, executive officers and other employees and service providers, including officers, employees and service providers of its subsidiaries and affiliates. The number of shares of common stock initially

reserved for issuance under the Plan was 1,680,000, in the form of restricted stock and stock options. A 2,000,000 share increase to shares reserved for issuance under the plan was authorized by the Company s stockholders in June 2014. The amount, terms of grants and exercisability provisions are determined by the board of directors or our chief executive officer. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors. All options vest over time as stipulated in the individual award agreements.

Shares Reserved for Future Issuance

As of March 31, 2015, the Company has reserved the following shares of common stock for issuance:

Shares initially reserved under the Plan	1,680,000
Authorized increase to the Plan	2,000,000
Common stock options outstanding	(866,048)
Restricted stock awards granted	(1,436,160)
Remaining shares available for future issuance	1,377,792

The estimated grant-date fair value of the Company s share-based awards is amortized ratably over the awards service periods. Stock-based compensation expense recognized was as follows:

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(in thousands)	Three months Ended March 31, 2014	2015
General and administrative	$ 1,156	$ 831
Sales and marketing		20
Research and development	527	263
Total stock-based compensation expense	$ 1,683	$ 1,114

Stock Options Granted under the 2013 Stock-Based Incentive Plan

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted-average Remaining Contractual Term (in years)
Balance, December 31, 2014	638,548	$ 7.38	9.43
Granted	232,500	$ 9.43	
Exercised			
Expired	(5,000)	11.50	
Balance, March 31, 2015	866,048	$ 7.97	9.60
Vested or expected to vest at March 31, 2015	866,048	$ 7.97	9.60
Exercisable at March 31, 2015	24,706	$ 11.63	9.05

The intrinsic value of our 841,343 unvested options as of March 31, 2015 was $4.4 million, based on a per share price of $12.93, the Company s closing stock price on that date, and a weighted-average exercise price of $7.87 per share.

The Company uses the Black-Scholes option-pricing model to estimate the fair value of stock options at the grant date. The Black-Scholes model requires the Company to make certain estimates and assumptions, including estimating the fair value of the Company s common stock, assumptions related to the expected price volatility of the Company s stock, the period during which the options will be outstanding, the rate of return on risk-free investments and the expected dividend yield for the Company s stock.

The per-share weighted-average grant date fair value of the options granted to employees during the three months ended March 31, 2015 was estimated at $6.49 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.77%
Expected term of options (in years)	6.25
Expected volatility	78.04%
Dividend yield	

The weighted-average valuation assumptions were determined as follows:

- Risk-free interest rate: The Company based the risk-free interest rate on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected option term.

- Expected term of options: The Company estimated the expected life of its employee stock options using the simplified method, as prescribed in Staff Accounting Bulletin (SAB) No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to its lack of sufficient historical data.

- Expected stock price volatility: The Company estimated the expected volatility based on actual historical volatility of the stock price of similar companies with publicly-traded equity securities. The Company calculated the historical volatility of the selected companies by using daily closing prices over a period of the expected term of the associated award. The companies were selected based on their enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the associated award. A decrease in the selected volatility would have decreased the fair value of the underlying instrument.

- Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0.0%.

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As of March 31, 2015, there was $4.4 million of total unrecognized compensation expense, related to unvested options granted under the Plan, which will be recognized over the weighted-average remaining period of 2.07 years.

Restricted stock

Upon consummation of the IPO, the Company granted an aggregate of 862,800 shares of restricted stock to its chief executive officer, chief financial officer, chief business officer and senior vice president of research and development. On March 3, 2014, the Company granted an aggregate of 250,560 shares of restricted stock to three individuals who were providing research and development consulting services to the Company. On May 1, 2014, the Company granted an aggregate of 257,800 shares of restricted stock to certain employees at a grant date fair value of $11.15 per share. On August 5, 2014, the Company granted 25,000 shares of restricted stock to its chief medical officer. On January 2, 2015 the Company granted 40,000 shares of restricted stock to its chief commercial officer.

A summary of the status of the Company s restricted stock awards at March 31, 2015 and of changes in restricted stock awards outstanding under the Plan for the three months ended March 31, 2015 is as follows:

	Shares		Weighted-average Grant Date Fair Value per Share
Outstanding balance at December 31, 2014	832,535	$	
Granted	40,000	$	5.18
Vested restricted stock awards	(54,955)	$	12.01
Outstanding balance at March 31, 2015	817,580	$	11.41

For stock awards that vest subject to the satisfaction of service requirements, compensation expense is measured based on the fair value of the award on the date of grant and is recognized as expense on a straight-line basis (net of estimated forfeitures) over the requisite service period. All restricted stock awards issued above vest over time as stipulated in the individual award agreements. In the event of a change in control, the unvested awards will be accelerated and fully vested immediately prior to the change in control. There are no performance based features or market conditions.

As of March 31, 2015, there was $7.8 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.56 years.

8. Commitments and Contingencies

Employment Agreements

The Company has entered into employment agreements with its president and chief executive officer, chief financial officer, chief business officer, chief medical officer, chief commercial officer and senior vice president of research and development, that provide for, among other things, salary, bonus and severance payments.

Legal Proceedings

As a result of the Company s acquisition of SPRIX from Luitpold and in-license of OXAYDO from Acura in January 2015, the Company has been substituted or otherwise become subject to certain legal proceedings involving SPRIX and OXAYDO, which are further described below.

On August 10, 2012, Luitpold, the prior exclusive licensee of U.S. Patent No. 6,333,044 (the 044 patent), filed a complaint for infringement of the 044 patent against Amneal Pharmaceuticals, LLC et al. in response to Amneal s certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that the 044 Patent covering SPRIX is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Luitpold s generic ketorolac tromethamine nasal spray, filed under ANDA No. 23-382 with the FDA. On November 19, 2013, Luitpold and Amneal entered into a settlement and license agreement permitting Amneal to launch its generic product on or after March 25, 2018 subject to royalty payments.

On January 26, 2015, the Company was substituted for Luitpold as plaintiff in a patent litigation against Apotex Corp. and Apotex, Inc. (collectively, Apotex), involving the SPRIX Nasal Spray. Apotex submitted an ANDA to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval for the commercial manufacture, use, offer for sale, sale, and/or importation of generic ketorolac tromethamine nasal spray 15.75 mg/spray (ANDA Product). In so doing, Apotex made a certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that the 044 Patent covering SPRIX is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Apotex s ANDA Product. On July 11, 2014, Luitpold filed a complaint for infringement of the 044 patent against Apotex, prompting a 30-month stay on the approval of Apotex s ANDA application by the FDA. This litigation is currently ongoing. The Company is aggressively defending its legal position to preserve the exclusivity of SPRIX in the market. As is the case with patent litigation, there is a risk that the 044 patent may be invalidated, unenforceable, not infringed or limited or narrowed in scope. The 044 Patent expires on December 25, 2018.

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There were a number of generic challengers to OXAYDO (formerly Oxecta) during 2012 and 2013, including Watson Laboratories, Inc., Par Pharmaceuticals, Inc., Impax Laboratories, Inc., Sandoz, Inc., and Ranbaxy Laboratories, Ltd. Along with their ANDA submissions, each generic challenger made a certification under 21 U.S.C. §355(j)(2)(B)(iv)(II) that U.S. Patent Nos. 7,201,920; 7,510,726; 7,981,439; 8,409,616; and/or 8,637,540 are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of their generic oxycodone HCl product. In response, Acura filed a complaint for infringement of U.S. Patent No.7,510,726 (the 726 Patent) against each generic challenger. As of November 2013, Acura resolved all claims at issue in each of the litigations: Watson amended its ANDA to a Paragraph III certification (i.e., launch at expiry of the patents) and the lawsuit was dismissed; Acura entered into a settlement agreement and consent judgment with Ranbaxy that its generic oxycodone HCl product does not infringe Acura s patents; and Acura entered into settlement and license agreements with the remaining generic challengers allowing entry of a generic oxycodone HCl product on or after January 1, 2022.

On April 3, 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P., and The P.F. Laboratories, Inc. (collectively, Purdue) sued Acura Pharmaceuticals, Inc. (Acura) and Egalet Corporation and Egalet US, Inc. (collectively, Egalet) in the U.S. District Court for the District of Delaware for patent infringement of U.S. Patent No. 8,389,007 (the 007 patent) alleging that Acura s and Egalet s commercialization of OXAYDO will infringe the 007 patent. Purdue contends that the court should declare that such commercialization will infringe the 007 patent, and that Acura and Egalet should be enjoined from making, using, selling and offering for sale OXAYDO. The Company s review of Purdue s allegations is ongoing and the due date to answer or otherwise respond to Purdue s allegations has been extended until May 29, 2015. The Company will avail itself of all legal positions, actions and remedies to preserve its right to market and sell OXAYDO. As is the case with patent litigation, there is a risk that the Court may enjoin the making, using, selling and offering for sale OXAYDO and/or may find that OXAYDO infringes the 007 patent.

In addition, Purdue has requested the U.S. Patent and Trademark Office (USPTO) to declare an interference between Purdue s U.S. Patent Application Ser. Nos. 14/243,580 and 14/605,034 and Acura s U.S. Patent Nos. 8,409,616, 8,637,540, 7,981,439, 7,510,726, and 7,201,920. These patents, which have been exclusively licensed to the Company, cover OXAYDO. The USPTO denied Purdue s request for interference as premature . However, Purdue may request an interference in the future. The Company is reviewing Purdue s assertions, but no response is due or requested at this time.

9. Acquisitions and License and Collaboration Agreements

License and Collaboration Agreement with Shionogi

In November 2013, the Company entered into a license and collaboration agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using certain of the Company s core technologies. The collaboration allows Shionogi to develop and commercialize an abuse-deterrent single-agent hydrocodone-based product and up to 20 different abuse-deterrent combination product candidates containing hydrocodone.

Under the terms of the agreement, the Company received an upfront payment of $10.0 million in 2013 and payment of $10.0 million in April 2015 upon submission of an investigational new drug (IND) application by Shionogi. The Company is eligible to receive regulatory milestone payments under the agreement as follows: (i) an additional $50.0 million upon successful achievement of specified regulatory milestones for the first licensed product candidate; (ii) up to $42.5 million upon successful achievement of specified regulatory milestones for a defined combination product candidate; (iii) up to $25.0 million upon successful achievement of specified regulatory milestones for a second product candidate (other than the defined combination product candidate); and (iv) up to $12.5 million upon successful achievement of specified regulatory milestones for further product candidates. In addition, the Company is eligible to receive up to an aggregate of $185.0 million based

on successful achievement of specified net sales thresholds of licensed products.

The Company determined that the deliverables under the Shionogi agreement were the exclusive, royalty-bearing, worldwide license to its abuse-deterrent hydrocodone-based product candidates using certain of the Company s core technologies, the research and development services to be completed by the Company and the Company s obligation to serve on a joint committee. The license did not have standalone value to Shionogi and was not separable from the research and development services, because of the uncertainty of Shionogi s ability to develop the product candidates without the research and development services of the Company during the transfer period and over the term of the agreement.

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Due to the lack of standalone value for the license and research and development services, the upfront and IND payment are being recognized ratably using the straight line method through November 2030, the expected term of the agreement. The Company recorded the $10.0 million upfront payment and subsequent $10.0 million IND milestone as deferred revenue within its consolidated balance sheet as of March 31, 2015. For the three months ended March 31, 2014 and 2015, the Company recognized revenue of $115,000 and $173,000, respectively, related to the milestones the Company has received.

Additionally, during the three months ended March 31, 2014 and 2015, the Company recognized revenue of $141,000 and $470,000, respectively, related to certain development costs incurred under the Company s collaborative research and license agreement. In accordance with the accounting guidance, the Company recorded revenue on a gross basis for the reimbursement of development costs.

License Agreement with Acura

In January 2015, the Company entered into a License Agreement with Acura to commercialize OXAYDO (oxycodone hydrochloride) tablets containing Acura s Aversion® Technology. OXAYDO (formerly known as Oxecta®) is currently approved by the FDA for marketing in the U.S. in 5 and 7.5 mg strengths. Under the terms of the License Agreement, Acura transferred the approved NDA for OXAYDO to the Company and the Company was granted an exclusive license under Acura s intellectual property rights for development and commercialization of OXAYDO worldwide (the Territory) in all strengths.

The Company paid Acura an upfront payment of $5.0 million in January 2015 and will pay a $2.5 million milestone on the earlier to occur of first commercial sale of OXAYDO or January 1, 2016, but in no event earlier than June 30, 2015. In addition, Acura will be entitled to a one-time $12.5 million milestone payment when OXAYDO net sales reach a specified level of $150 million in a calendar year.

The Company has recorded an intangible asset of $7.7 million related to the License Agreement, which includes $172,000 of transaction costs related to the agreement. The intangible asset is being amortized over a useful life of 7 years, which coincides with the patent protection of the product in the U.S.

Asset Purchase Agreement with Luitpold

In January 2015, the Company entered into and consummated the transactions contemplated by the Purchase Agreement with Luitpold. Pursuant to the Purchase Agreement, the Company acquired specified assets and liabilities associated with SPRIX® (ketorolac tromethamine) Nasal Spray for a purchase price of $7.0 million, of which $315,000 was deposited into an escrow account to secure Luitpold s indemnification obligations under the Purchase Agreement. The Company concurrently purchased an additional $1.1 million of glassware, equipment and active pharmaceutical ingredient from Luitpold, and agreed to purchase an additional $340,000 of active pharmaceutical ingredient (API) after closing within two business days of the release of such API from Luitpold s supplier. SPRIX is a NSAID indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level.

The Company accounted for the acquisition as a business combination and the purchase price has been preliminarily allocated to the acquisition date fair values as follows:

		Allocation
Inventory	$	2,581
Property, plant & equipment		100
Finite lived intangible-intellectual property		2,080
Goodwill		3,367
Net assets acquired	$	8,128

During the three months ended March 31, 2015, management determined that the API acquired could not be used in commercially available product prior to its expiration date and that excess quantities of glassware were included in the purchase. The above table reflects this change in the fair value of inventory and the related increase in goodwill.

The above estimated fair values of assets acquired are provisional and are based on the information that was available from the acquisition date through the three months ended March 31, 2015 to estimate the fair value of assets acquired. The Company believes that information provides a reasonable basis for estimating the fair values but the Company is waiting for additional

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information and analyses necessary to finalize all of the amounts listed above. Thus, the provisional measurements of fair value reflected above are subject to change. Such changes could be significant. The Company expects to finalize the valuation and complete the purchase price allocation as soon as practicable but no later than one year from the acquisition date.

The fair value of the intellectual property was estimated using an income approach, specifically known as the relief from royalty method. The relief from royalty method is based on a hypothetical royalty stream that would be received if the Company were to license the SPRIX. Thus, the Company derived the hypothetical royalty income from the projected revenues. Cash flows were assumed to extend through the remaining economic useful life of the intellectual property, which is 5 years.

The excess of the acquisition date consideration over the fair values assigned to the assets acquired and the liabilities assumed of $3.4 million was recorded as goodwill, [which is not expected to be deductible for tax purposes] and represents the future economic benefits arising from the acquisition that could not be individually identified and separately recognized and the other benefits that the Company believes will result from the acquisition of SPRIX.

The Company incurred $1.1 million of SPRIX acquisition-related costs.

The following table presents supplemental pro forma information for the three months ended March 31, 2015 as if the acquisition of SPRIX had occurred on January 1, 2014 (unaudited). Due to the acquisition date of January 8, 2015 there is no material difference between the Company s results presented in the consolidated statement of operations and the pro forma results for the three months ended March 31, 2015:

(in thousands, except per share data)		**Three months ended March 31, 2014 (unaudited)**
Pro forma revenue	$	1,454
Pro forma net loss		(14,536)
Pro forma net loss per share	$	(1.51)

10. Income Taxes

In accordance with ASC Topic No. 270 Interim Reporting and ASC Topic No. 740 Income Taxes (Topic No. 740) at the end of each interim period, the Company is required to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three months ended March 30, 2014 and 2015, the Company had tax expense of $35,000 and $26,000, respectively.

As of December 31, 2014 and March 31, 2015, the Company had a non-current deferred tax liability of $25,000 and $49,000 respectively. The deferred tax liability relates to an indefinite-lived intangible that was recorded in connection with the Danish IPR&D and the tax amortization of goodwill that was generated in acquisition accounting in the U.S. The Company maintains a full valuation against all deferred tax assets as management has determined that it is not more likely than not that the Company will realize these future tax benefits.

11. Related-Party Transactions

Related Party Receivables

The Company has derived a portion of revenue for the three months ended March 31, 2014 and 2015 under its license and collaboration agreement with Shionogi, who is also an investor in the Company. As of December 31, 2014 and March 31, 2015, related party receivables with Shionogi were $679,000 and $10.5 million, respectively and consisted of revenue from development costs incurred under the Company s collaborative research and license agreement of $679,000 and $470,000, respectively. The March 31, 2015 balance also includes the $10.0 million milestone payment related to the filing of an IND in the three months ended March 31, 2015.

12. Subsequent Events

5.50% Convertible Senior Notes Due 2020

On April 1, 2015 the Company issued through a private placement $60.0 million in aggregate principal amount of 5.50% convertible senior notes due April 1, 2020 (the 5.50% Notes). Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing October 1, 2015.

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The 5.50% Notes are general, unsecured and unsubordinated obligations and will rank senior in right of payment to all of the Company s indebtedness that is expressly subordinated in right of payment to the notes. The 5.50% Notes rank equal in right of payment to the Company s existing and future indebtedness and other liabilities that are not so subordinated. The 5.50% Notes are effectively subordinated to any of the Company s future secured indebtedness to the extent of the value of the assets securing such indebtedness, and rank structurally junior to all indebtedness and other liabilities incurred by the Company s subsidiaries, including trade payables.

The 5.50% Notes are effectively junior to the $15.0 million principal amount of secured indebtedness outstanding under the Senior Secured Loan Agreement with Hercules and certain other lenders, to the extent of the value of the assets securing such indebtedness.

The Company may not redeem the 5.50% Notes prior to maturity. The 5.50% Notes are convertible prior to maturity, subject to certain conditions described below, into shares of the Company s common stock at an initial conversion rate of 67.2518 shares per $1,000 principal amount of the 5.50% Notes (equivalent to an initial conversion price of approximately $14.87 per share of common stock). This conversion rate is subject to adjustment upon the occurrence of certain specified events but will not be adjusted for accrued and unpaid interest. The Company will satisfy the conversion obligation by paying or delivering, as the case may be, cash, shares of common stock or a combination thereof, at the Company s election.

Holders may convert all or any portion of their notes, in multiples of $1,000 principal amount, at their option at any time prior to the close of business on the business day immediately preceding January 1, 2020 only under the following circumstances:

- on or after the date that is six months after the last date of original issuance of the notes, if the last reported sale price of the Company s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending within the five trading days immediately preceding a conversion date is greater than or equal to the conversion price for the notes on each applicable trading day;

- during the five business day period after any five 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; or

- upon the occurrence of specified corporate events.

On or after January 1, 2020 until the close of business on the second scheduled trading day immediately preceding the maturity date, holders may convert all or any portion of their notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

- The conversion rate for the notes is initially 67.2518 shares of common stock per $1,000 principal amount of notes (equivalent to an initial conversion price of approximately $14.87 per share of common stock), subject to adjustment.

- Upon conversion, the Company will pay or deliver, as the case may be, cash, shares of common stock or a combination of cash and shares of common stock, at the Company s election, and an interest make-whole payment in shares of the common stock, if applicable. If the Company satisfies the conversion obligation solely in cash or through payment and delivery, as the case may be, of a combination of cash and shares common stock, the amount of cash and shares of common stock, if any, due upon conversion will be based on a daily conversion value calculated on a proportionate basis for each trading day in a 50 trading day observation period.

In addition, following certain corporate events that occur prior to the maturity date, the Company will increase the conversion rate for a holder who elects to convert its notes in connection with such a corporate event in certain circumstances. Holders will not receive any additional cash payment or additional shares representing accrued and unpaid interest, if any, upon conversion of a note, except in limited circumstances. Instead, interest will be deemed to be paid by the cash, shares the Company s common stock or a combination of cash and shares of the Company s common stock paid or delivered, as the case may be, to the holders upon conversion of a note.

On or after the date that is six months after the last date of original issuance of the notes, if the last reported sale price of the Company s common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending within the five trading days immediately preceding a conversion date is greater than or equal to the conversion price for the notes on each applicable trading day, the Company will, in addition to the other consideration payable or deliverable in connection

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with such conversion, make an interest make-whole payment to the converting holder equal to the sum of the present value of the remaining scheduled payments of interest that would have been made on the notes to be converted had such notes remained outstanding from the conversion date through April 1, 2018, computed using a discount rate equal to 2%. The Company will pay any interest make-whole payment by delivering shares of the Company s common stock valued at 95% of the simple average of the daily volume weighted average price for the 10 trading days ending on and including the trading day immediately preceding the conversion date. Notwithstanding the foregoing, the number of shares the Company may deliver in connection with a conversion of the notes, including those delivered in connection with an interest make-whole payment, will not exceed 77.3395 shares of common stock per $1,000 principal amount of notes, subject to adjustment. The Company will not be required to make any cash payments in lieu of any fractional shares or have any further obligation to deliver any shares of common stock or pay any cash in excess of the threshold described above. In addition, if in connection with any conversion the conversion rate is adjusted, then such holder will not receive the interest make-whole payment with respect to such note.

The Company will account for convertible debt instruments by recording the liability and equity components of the convertible debt separately. The liability will be computed based on the fair value of a similar liability that does not include the conversion option. The liability component will include both the value of the embedded interest make-whole derivative and the carrying value of the notes. The equity component will be computed based on the total debt proceeds less the fair value of the liability component. The equity component will also recorded as debt discount and amortized as interest expense over the expected term of the notes, using the effective interest method.

On May 6, 2015, the Company received an additional $1 million from the purchasers exercise of their 30-day over-allotment.

Appointments to Board of the Directors

On April 13, 2015, the Company announced the appointment of Nicholas C. Nicolaides, president and chief executive officer of Morphotek, a subsidiary of Eisai North America, and John Osborn, executive-in-residence at Warburg Pincus and senior advisor at Hogan Lovells, to its board of directors.

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

The following discussion and analysis of our financial condition and result of operations should be read in conjunction with our 2014 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words may, might, will, could, would, should, expect, intend, plan, objective, an estimate, predict, project, potential, continue and ongoing, or the negative of these terms, or other comparable terminology intended to ide statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these

forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain, including, but not limited to, risks related to: our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; the success and timing of our preclinical studies and clinical trials; the difficulties in obtaining and maintaining regulatory approval of our products and product candidates, and the labeling under any approval we may obtain; our plans and ability to develop and commercialize our products and product candidates; our ability to achieve the milestones set forth in our collaboration agreement with Shionogi; our failure to recruit or retain key scientific or management personnel or to retain our executive officers; the accuracy of our estimates of the size and characteristics of the potential markets for our product candidates and our ability to serve those markets; regulatory developments in the U.S. and foreign countries; the rate and degree of market acceptance of any of our product candidates; our use of the proceeds from our IPO and the concurrent private placement; our ability to obtain additional financing; obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology; our ability to operate our business without infringing the intellectual property rights of others; the successful development of our commercialization capabilities, including sales and marketing capabilities; recently enacted and future legislation regarding the healthcare system; the success of competing products that are or become available; our ability to service the Hercules debt and 5.5% Notes and to repay them at maturity (if, with respect to the 5.5% Notes, they re not converted) and the performance of third parties, including contract research organizations and manufacturers.

You should refer to the Risk Factors section of our most recent Annual Report on Form 10-K as filed with the SEC and which are incorporated herein by reference, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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Overview

We are a Delaware corporation formed in August 2013. On November 26, 2013, we acquired all of the outstanding shares of Egalet UK in the Share Exchange. As a result, Egalet UK became our wholly-owned subsidiary, and the former shareholders of Egalet UK received shares of the Company. The historical discussion below relates to Egalet UK prior to the Share Exchange, except that any share and per share information has been restated on a pro forma basis to give effect to such exchange.

We are a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative medicines for patients with acute and chronic pain while helping to protect physicians, families and communities from the burden of prescription drug abuse. On January 8, 2015 we completed the acquisition and license of two innovative pain products, SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO (oxycodone HCI, USP) tablets for oral use only CII, both approved by the FDA. SPRIX Nasal Spray, a NSAID , is indicated in adult patients for the short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. OXAYDO is the first and only approved immediate-release (IR) oxycodone product formulated to discourage abuse via snorting; it is indicated for the management of acute and chronic moderate to severe pain where an opioid is appropriate. In addition, using our proprietary Guardian Technology, we are developing a pipeline of clinical-stage, opioid-based product candidates that are specifically designed to deter abuse by physical and chemical manipulation. We initiated a pivotal bioequivalence study for our lead product candidate in the first quarter of 2015 and will start a Phase 3 program for our second product candidate in the second quarter of 2015. We plan to submit a NDA for our first product candidate in the fourth quarter of 2015 and a NDA for our second product candidate in the second half of 2016. We also have a collaboration and license agreement with Shionogi to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our Guardian Technology. Our Guardian Technology can be applied broadly across different classes of pharmaceutical products and can be used to develop combination products that include multiple active pharmaceutical ingredients with similar or different release profiles.

OXAYDO is the first and only approved immediate-release oxycodone product formulated to discourage abuse via snorting. It is indicated for the management of acute and chronic moderate to severe pain where an opioid is appropriate. OXAYDO was approved in 2011 and has data in its label from a Category 3 intranasal human abuse liability (HAL) study. The study compared drug liking and potential to take drug again in a population of recreational non-dependent opioid users after snorting crushed OXAYDO and crushed IR oxycodone. The responses on both take drug again and drug liking were lower for OXAYDO compared to IR oxycodone.

Immediate-release oxycodone is more often abused than extended-release (ER) oxycodone and is most often abused via the route of snorting. There has been a 40 percent increase in the abuse of IR oxycodone since the reformulation of ER oxycodone according to the National Poison Data System survey. With 52.3 million prescriptions of IR oxycodone written in 2013, there is a substantial need for an IR oxycodone product like OXAYDO which is designed to discourage abuse via snorting.

SPRIX Nasal Spray is the first and only approved nasal spray formulation of ketorolac, an NSAID, used for short-term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. This product targets the significant short-acting analgesic market, of which there are approximately 97 million prescriptions written annually. As an NSAID, SPRIX provides analgesia at the opioid level without the side effects or issues of misuse or abuse common to opioids. Our initial commercial focus will be to introduce the product and its unique profile to pain care specialists who routinely see patients that require short-term analgesics requiring opioid level analgesia. We began our promotional efforts on this product in the first quarter of 2015.

To commercialize SPRIX and OXAYDO and ultimately our pipeline product candidates, we are building a 50 to 60 person specialty sales force targeting the approximately 5,700 physicians in the high-decile of prescribing pain medicines in the U.S. We intend to consider partnerships to

access third-party sales representatives who target primary care and internal medicine physicians in the U.S. and collaborations with other companies to develop and commercialize our product candidates outside the U.S.

Formulated using our proprietary Guardian Technology, we are developing two late-stage product candidates specifically designed to deter abuse by physical and chemical manipulation. The lead program, Egalet-001, an abuse-deterrent, extended-release, oral morphine formulation, and our second product candidate Egalet-002, an abuse-deterrent, extended-release, oral oxycodone formulation, are in late-stage clinical development for the management of pain severe enough to require daily, around-the-clock opioid treatment and for which alternative treatments are inadequate.

Using our proprietary Guardian Technology, we have produced oral formulations of morphine and oxycodone with physical characteristics that make particle size reduction difficult and that also resist dissolution by becoming gelatinous in the presence of water or other common household solvents. Our Guardian Technology allows us to create physical and chemical barriers intended to deter the most common methods of abuse, and those that are more rigorous, that are specific to a particular drug. For instance with Egalet-001, an abuse-deterrent, extended-release morphine, it was designed to deter all forms of abuse but primarily abuse via the route of injection the most common method of abuse of morphine. The Egalet-001 system consists of a hard matrix that erodes as it passes through the gastrointestinal tract. This polymer matrix construct makes extracting the API into a solution which could be drawn

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into a syringe very difficult making this product very difficult to be abused via the route of injection.

We believe that Egalet-001, if approved, would fill a significant unmet need in the marketplace. Clinically, we have completed multiple Phase 1 pharmacokinetic (PK) studies and are in the process of completing the pivotal bioequivalence studies of Egalet-001. Also, we have completed Category 1 abuse-deterrent studies demonstrating physical and chemical properties of the product. We announced in January of 2015 positive top-line data from a Category 3 abuse-deterrent HAL study. This was the first clinical demonstration in which Egalet-001 showed lower abuse potential compared to MS Contin when taken orally. We are currently conducting a Category 3 intranasal HAL study as well. In the first quarter of 2015, we also initiated a pivotal bioequivalence study to establish the bioequivalence of Eglalet-001 60 mg to MS Contin 60 mg with results expected in the third quarter of 2015. We plan to seek U.S. regulatory approval of Egalet-001 pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. Under this proposed approval pathway, we anticipate submitting an NDA for Egalet-001 in the fourth quarter of 2015.

Also using our Guardian Technology, for Egalet-002, we designed a tablet with a similar matrix construct but have added a hard impermeable shell, around the outside. The shell, which passes through the gastrointestinal (GI) tract intact, adds a layer of rigidity to the tablet which makes particle size reduction even more difficult. This is important because oxycodone is abused most often via particle size reduction and insufflation, or snorting through the nose. In addition Egalet-002 was designed to inhibit alcohol dose dumping and does not produce clinically significant changes in the rate of absorption of the API in the GI tract based on the presence or absence of food, also known as a food effect.

We believe our second product candidate, Egalet-002, if approved, will have advantages over commercially available, long-acting, abuse-deterrent oxycodone products, such as OxyContin®, due to its differentiated abuse-deterrent properties and a PK profile that demonstrates low peak-to-trough concentration variability in drug exposure. We have conducted Phase 1 PK trials of Egalet-002 and completed initial Category 1 abuse-deterrent studies in compliance with the FDA guidance on Abuse-Deterrent Opioids Evaluation and Labeling. We plan to initiate a Phase 3 safety and efficacy program for Egalet- 002 in the second quarter of 2015. Peak-to-trough concentration variability means the difference between the highest concentration of an API in the bloodstream and the lowest concentration of such API in the bloodstream. We believe the low variability we have observed in Egalet-002 will result in better, more consistent pain relief and reduced use of rescue medication to treat breakthrough pain, as compared to oxycodone-based products that exhibit higher variability. We are also conducting additional abuse-deterrent studies in accordance with the FDA guidance on abuse-deterrent opioids, with the goal of obtaining abuse-deterrent claims in our product label. We plan to seek U.S. regulatory approval of Egalet-002 pursuant to Section 505(b)(2), and anticipate submitting an NDA for Egalet-002 in the second half of 2016.

In November 2013, we entered into a collaboration and license agreement with Shionogi, granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using our technology. Shionogi is responsible for all expenses associated with the development of these product candidates. Under the terms of the agreement, Shionogi made an upfront payment of $10.0 million. Shionogi invested $15.0 million in a private placement concurrently with our initial public offering. In the first quarter of 2015, Shionogi made an additional $10.0 million milestone payment related to the filing of an IND with the FDA. We are eligible to receive milestone payments upon development and approval of product candidates under the agreement, which may exceed $300.0 million if multiple product candidates are approved, as well as royalties at percentage rates ranging from mid-single digit to low-teens on net sales of licensed products.

Our net losses were $12.9 million and $16.7 million for the three months ended March 31, 2014 and 2015, respectively. We recognized revenues of $256,000 and $805,000 for the three months ended March 31, 2014 and 2015, respectively. As of March 31, 2015, we had an accumulated deficit of $93.3 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, as well as scale-up manufacturing capabilities, protect and expand our intellectual property portfolio and hire additional personnel. Additionally, we expect to incur significant commercialization expenses in

establishing a sales, marketing and distribution infrastructure to sell our products in the U.S., including launching our recently licensed product, OXAYDO, and our recently acquired product, SPRIX.

We will seek to register and license the commercial rights to our products outside the U.S. to a third-party organization that has an established track record of success in commercializing pain products outside the U.S..

Until we become profitable, if ever, we will seek to fund our operations primarily through public or private equity or debt financings or other sources. Other additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed could have a material adverse effect on our financial condition and our ability to pursue our business strategy. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

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Critical Accounting Policies and Significant Judgments and Estimates

We believe there have been no significant changes in our critical accounting policies as discussed in our audited consolidated financial statements and the notes thereto for the year ended December 31, 2014 filed on March 16, 2015 with the SEC other than as described below.

Net Product Sales

We recognize revenue in accordance with the FASB ASC 605, *Revenue Recognition*, when the following criteria have been met: persuasive evidence of an arrangement exists; delivery has occurred and risk of loss has passed; the seller s price to the buyer is fixed or determinable and collectability is reasonably assured. We determine that persuasive evidence of an arrangement exists based on written contracts that define the terms of the arrangements. Pursuant to the contract terms, we determine when title to products and associated risk of loss has passed on to the customer. We assess whether the fee is fixed or determinable based on the payment terms associated with the transaction and whether the sales price is subject to refund or adjustment. We assess collectability based primarily on the customer s payment history and creditworthiness.

We sell SPRIX product in the United States to a single specialty pharmaceutical distributor subject to rights of return. SPRIX has limited sales history, and we cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on product shipments of SPRIX until the right of return no longer exists, which occurs at the earlier of the time SPRIX units are dispensed through patient prescriptions or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. We estimate patient prescriptions dispensed using an analysis of third-party information.

Related Party Revenue

During 2013, we entered into a collaborative research and license agreement with Shionogi. The terms of this agreement contain multiple deliverables which include (i) licenses; (ii) research and development activities and (iii) certain of our core technologies and improvements thereon. We have adopted the provisions of ASU 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends ASC 605-25, and also adopted ASU 2010-17, *Revenue Recognition Milestone Method*. In accordance with ASU 2009-13, we considered whether the deliverables under the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have stand-alone value.

Inventory

Inventories are stated at the lower of cost or market net of reserve for excess and obsolete inventory. At March 31, 2015, inventory consisted of raw materials and deferred cost of goods.

Goodwill and Intangible Assets

Intangible assets consist of technological process and know how related to the SPRIX acquisition, product rights associated with the License Agreement with Acura to commercialize OXAYDO (oxycodone hydrochloride) tablets, and IPR&D related to our drug delivery platform technology we acquired as part of the acquisition of Egalet A/S.

Goodwill represents the excess of the purchase price over the fair value of tangible and identified intangible net assets of businesses acquired. Goodwill is not amortized, but is evaluated for impairment on an annual basis or more often when impairment indicators are present. The Company has one reporting unit. Therefore, the Company s consolidated net assets, including existing goodwill and other intangible assets, are considered to be the carrying value of the reporting unit. If the carrying value of the reporting unit is in excess of its fair value, an impairment may exist, and the Company must perform the second step of the analysis, in which the implied fair value of the goodwill is compared to its carrying value to determine the impairment charge, if any. If the estimated fair value of the reporting unit exceeds the carrying value of the reporting unit, goodwill is not impaired and no further analysis is required.

The Company makes judgments about the recoverability of purchased intangible assets with finite lives whenever events or changes in circumstances indicate that impairment may exist. Recoverability of purchased intangible assets with finite lives is measured by comparing the carrying amount of the asset to the future undiscounted cash flows the asset is expected to generate. Impairment, if any, is measured as the amount by which the carrying value exceeds the fair value of the impaired asset.

Stock-Based Compensation Expense

We account for all share-based compensation payments issued to employees, directors and non-employees using an option pricing model for estimating fair value. Accordingly, share-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single

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option method. In accordance with authoritative accounting guidance, we re-measure the fair value of non-employee share-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

The stock-based compensation expense for restricted stock awards is determined based on the closing market price of our common stock on the grant date of the awards applied to the total number of awards that are anticipated to vest.

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

We apply the fair value recognition provisions of FASB Accounting Standards Codification Topic 718, Compensation Stock Compensation, or ASC 718. Determining the amount of share-based compensation to be recorded requires us to develop estimates of the fair value of stock options as of their grant date. We recognize share-based compensation expense ratably over the requisite service period, which in most cases is the vesting period of the award. Calculating the fair value of share-based awards requires that we make highly subjective assumptions.

We use the Black-Scholes option pricing model to value our stock option awards. Use of this valuation methodology requires that we make assumptions as to the volatility of our common stock, the expected term of our stock options, and the risk free interest rate for a period that approximates the expected term of our stock options and our expected dividend yield. Because we are a publicly held company with a limited operating history, we utilize data from a representative group of companies to estimate expected stock price volatility. We selected companies from the biopharmaceutical industry with similar characteristics to us, including those in the early stage of product development and with a therapeutic focus.

We use the simplified method as prescribed by the SEC SAB No. 107, Share-Based Payment, to calculate the expected term of stock option grants to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows for the three months ended March 31, 2015:

Risk-free interest rate	1.77%
Expected term of options (in years)	6.25
Expected volatility	78.04%
Dividend yield	

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. There were no forfeitures through March 31, 2015.

Restricted stock

Upon consummation of our IPO, we granted an aggregate of 862,800 shares of restricted stock to our president and chief executive officer, chief financial officer, chief business officer and senior vice president of research and development. On March 3, 2014, we granted an aggregate of 250,560 shares of restricted stock to three individuals who were providing research and development consulting services to us. On May 1, 2014, we granted an aggregate of 257,800 shares of restricted stock to certain employees at a grant date fair value of $11.15 per share. On August 5, 2014, we granted 25,000 shares of restricted stock to our chief medical officer. On January 2, 2015 we granted 40,000 shares of restricted stock to our chief commercial officer.

All restricted stock awards issued above vest over time as stipulated in the individual award agreements. In the event of a change in control, the unvested awards will be accelerated and fully vested immediately prior to the change in control. There are no performance based features or market conditions.

As of March 31, 2015, there was $7.8 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.56 years.

Basic and Diluted Net Loss Per Share

We compute basic net loss per share by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of preferred shares. We compute diluted net loss per share by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of preferred shares outstanding during the period

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calculated in accordance with the treasury stock method, but such items are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between our basic and diluted net loss per share for the three months ended March 31, 2014 and 2015.

Results of Operations

Comparison of the Three months Ended March 30, 2014 and 2015

(in thousands)	Three months Ended March 31, 2014	2015	Change
Net product sales	$	$ 162	$ 162
Related party revenues	256	643	387
Total revenues	256	805	549
Costs and Expenses:			
Cost of sales (excluding product rights amortization)		94	94
General and administrative	3,263	4,861	1,598
Sales and marketing	6	1,568	1,562
Research and development	2,780	10,251	7,471
Intangible amortization		378	378
Total costs and expenses	6,049	17,152	11,103
Loss from operations	(5,793)	(16,347)	(10,554)
Interest expense	7,092	451	(6,641)
Gain on foreign currency exchange	4	103	99
Loss from operations before income taxes	(12,881)	(16,695)	(3,814)
Provision for income taxes	35	26	(9)
Net loss	$ (12,916)	$ (16,721)	$ (3,805)

Net Product Sales

Product sales were $162,000 for the three months ended March 31, 2015 and consisted entirely of the sale of SPRIX, which was acquired on January 8, 2015. There were no product sales in 2014.

Related Party Revenues

Revenues increased from $256,000 for the three months ended March 31, 2014 to $643,000 for the three months ended March 31, 2015, as a result of the amortization of deferred revenue and certain research and development services performed under our collaboration agreement with Shionogi.

Cost of sales (excluding product amortization rights)

Cost of sales (excluding product amortization rights) was $94,000 in 2015 related entirely to the sale of SPRIX, which was acquired on January 8, 2015. The cost of sales reflects the fair value of finished goods inventory that was acquired as part of the acquisition.

General and administrative expenses

General and administrative expenses increased by $1.6 million, or 49.0%, from $3.3 million for the three months ended March 31, 2014 to $4.9 million for the three months ended March 31, 2015. This was primarily attributable to an increase in employee salary and benefits of $1.1 million as we continue to grow our U.S. operations and $1.0 million in fees associated with the acquisition of SPRIX. These increases were offset by a decrease in stock compensation expense of $325,000.

Sales and marketing expenses

Sales and marketing expenses were $1.6 million for the three months ended March 31, 2015 related to the establishment of the sales and marketing departments in the US and pre-launch activities for SPRIX and OXAYDO. Sales and marketing costs were minimal for 2014.

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Research and development expenses

Research and development expenses increased by $7.5 million, or 268.7%, from $2.8 million for the three months ended March 31, 2014 to $10.3 million for the three months ended March 31, 2015. This increase was driven primarily by an increase in our development costs for Egalet-002 of $3.5 million, an increase in our development costs for Egalet-001 of $2.4 million and an increase in employee compensation of $243,000.

Intangible amortization

Intangible amortization was $378,000 for the three months ended March 31, 2015 and was comprised of $274,000 for the OXAYDO intangible and $94,000 for the SPRIX intangible. There was no intangible amortization in 2014.

Interest expense

Interest expense decreased by $6.6 million, from $7.1 million for the three months ended March 31, 2014, to $451,000 for the three months ended March 31, 2015. The decrease was primarily attributable to the $7.0 million in additional interest expense we recognized in 2014 related to the accretion of our premium that was recorded in connection with our August 2013 convertible debt issuance, compared to interest expense of $451,000 for the three months ended March 31, 2015 primarily due to interest on the Hercules Loan.

Gain on Foreign Currency Exchange

For the three months ended March 31, 2014 and 2015 we recognized a gain on foreign currency exchange of $4,000 and $103,000, respectively. This difference is primarily attributable the change in the average rates of currency in which we transacted during 2014 when compared to 2015.

Provision for Income Taxes

We had a provision for income taxes of $35,000 and $26,000 for the three months ended March 31, 2014 and 2015, respectively. During the three months ended March 31, 2015, tax expense was recorded due to amortization of the indefinite-lived intangible and for tax goodwill recorded in acquisition accounting.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and generally negative cash flows from our operations. We incurred net losses of $12.9 million and $16.7 million for the three months ended March 31, 2014 and 2015, respectively. Our operating activities used $5.1 million of cash during the three months ended March 31, 2014 and provided $163,000 of cash during the three months ended March 31, 2015. At March 31, 2015, we had an accumulated deficit of $93.3 million, a working capital surplus of $41.6 million and cash of $53.9 million.

From our inception through March 31, 2015, we have received gross proceeds of $31.2 million from the issuance of preferred stock and convertible debt. We have also financed our operations with the $3.4 million in payments received through March 31, 2015 from our collaborative research and development agreements along with an upfront payment of $10.0 million from Shionogi under a collaboration agreement. We are potentially eligible to earn a significant amount of milestone payments and royalties under our agreement with Shionogi. Our ability to earn these payments and their timing is dependent upon the outcome of ours and Shionogi s activities and is uncertain at this time.

On February 11, 2014, 4,200,000 shares of our common stock were sold on an IPO price of $12.00 per share, for aggregate gross proceeds of $50.4 million. On March 7, 2014, in connection with the exercise by the underwriters of a portion of the over-allotment option granted to them in connection with the IPO, 630,000 additional shares of our common stock were sold at the IPO price of $12.00 per share, for aggregate gross proceeds of approximately $7.6 million. In addition, as part of the IPO, we converted all of our convertible preferred stock and related party senior convertible debt into 5,329,451 and 2,585,745 shares of common stock, respectively. Also, Shionogi, our collaboration partner, purchased 1,250,000 shares of our common stock in a separate private placement concurrent with the completion of the IPO at a price per share equal to $12.00 per share, for aggregate gross proceeds of $15.0 million. In addition, the 2013 related party senior convertible debt holders automatically exercised 600,000 warrants for shares of common stock at an exercise price of $0.0083 per share.

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In January 2015, the Company entered the Loan Agreement with Hercules and certain other lenders, pursuant to which the Company borrowed $15 million under a term loan. Refer to Note 5 Long Term Debt in the Notes to our Unaudited Consolidated Financial Statements, for additional information.

During the three months ended March 31, 2015 the Company had significant cash out flows related to the purchase of SPRIX and license of OXAYDO of $8.1 million and $5.2 million, respectively. With regards to OXAYDO, the company also owes a $2.5 million milestone on the earlier to occur of first commercial sale of OXAYDO or January 1, 2016, but in no event earlier than June 30, 2015. Refer to Note 9 - Acquisitions and License and Collaboration Agreements in the Notes to our Unaudited Consolidated Financial Statements, for additional information.

In April 2015, following the period of this report, we issued through a private placement $60.0 million in aggregate principal amount of 5.50% convertible senior notes due April 1, 2020. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing October 1, 2015.

Cash Flows

The following table summarizes our cash flows for the three months ended March 31, 2014 and 2015:

	Three Months Ended March 31,	
(in thousands)	**2014**	**2015**
Net cash (used in) provided by:		
Operating activities	$ (5,081)	$ 163
Investing activities	(196)	(13,463)
Financing activities	67,074	14,613
Effect of foreign currency translation on cash	(47)	(164)
Net increase (decrease) in cash and cash equivalents	$ 61,750	$ 1,149

Cash Flows from Operating Activities

Net cash used in operating activities was $5.1 million for the three months ended March 31, 2014 and consisted primarily of a net loss of $12.9 million and net cash outflows of $1.0 million from the change in operating assets and liabilities. These outflows were partially offset by $168,000 of noncash depreciation and amortization expense, $1.7 million of stock-based compensation, and $7.0 million in accretion of the debt premium. Cash outflows from changes in operating assets and liabilities were primarily due to decreases in accrued expenses and deferred revenues of $553,000 and $115,000, respectively, as well as increases in related party receivables and prepaid expenses of $140,000 and $459,000, respectively.

Net cash provided by operating activities was $163,000 for the three months ended March 31, 2015 and consisted primarily of a net loss of $16.7 million. These outflows were partially offset by an increase in deferred revenue of $14.5 million generated by our first quarter sales of SPRIX and non-cash items consisting of $1.1 million of stock-based compensation and $631,000 of amortization and depreciation expense. Net cash inflows from the remaining changes in operating assets and liabilities were $443,000.

Cash Flows from Investing Activities

Net cash used in investing activities for the three months ended March 31, 2014 was $196,000 and consisted of purchases of property and equipment as well as deposits on future related purchases.

Net cash used in investing activities for the three months ended March 31, 2015 was $13.5 million and consisted of $8.1 million for the purchase of SPRIX, $5.2 million for the license of OXAYDO and payments of $163,000 for the purchase of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $67.1 million for the three months ended March 31, 2014 and consisted of $53.1 million in proceeds from the completion of our IPO in February of 2014. There were additional proceeds of $14.0 million from the issuance of common stock in connection with our commitment to Shionogi.

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Net cash provided by financing activities was $14.6 million for the three months ended March 31, 2015 and consisted entirely of the net proceeds from Hercules loan.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and we expect to continue to incur net losses for the foreseeable future. Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, third-party clinical research and development services, laboratory and related supplies, clinical costs, legal and other regulatory expenses and general overhead costs. We expect our cash expenditures to increase in the near term as we fund our commercial launches of SPRIX and OXAYDO and clinical development of Egalet-001 and Egalet-002.

Because our product candidates are in various stages of clinical and preclinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings and collaboration arrangements. In order to meet these additional cash requirements, we may seek to sell additional equity or convertible debt securities that may result in dilution to our stockholders. If we raise additional funds through the issuance of convertible debt securities, these securities could have rights senior to those of our common stock and could contain covenants that restrict our operations. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. We may also seek to raise additional financing through the issuance of debt which, if available, may involve agreements that include restrictive covenants limiting our ability to take important actions, such as incurring additional debt, making capital expenditures or declaring dividends. There can be no assurance that we will be able to obtain additional equity or debt financing on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

We believe that our existing capital resources, including the net proceeds from our IPO and the concurrent private placement with Shionogi, our loan agreement with Hercules and the issuance of the 5.5% Notes, will be sufficient to fund our operations through March 31, 2016. However, our future operating and capital requirements will depend on many factors, including:

- whether Shionogi continues to pursue our collaboration arrangement for the development, manufacturing and commercialization of abuse-deterrent hydrocodone product candidates using certain of our core technologies;

- the results of our clinical trials;

- the costs, timing and outcome of regulatory review;

- the potential need for a Phase 3 safety and efficacy study with respect to Egalet-001;

- the cost of commercialization activities if any future product candidates are approved for sale, including marketing, sales and distribution costs;

- our ability to establish collaborations or product acquisitions on favorable terms, if at all;

- the scope, progress, results and costs of product development of our product candidates; and

- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending intellectual property-related claims.

Please see Risk Factors section of our most recent annual report filed with the SEC on March 16, 2015 for additional risks associated with our substantial capital requirements.

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Contractual Obligations and Commitments

The following table represents our contractual obligations and commitments as of March 31, 2015. See Note 12 Subsequent Events in the Notes to our Unaudited Consolidated Financial Statements above for a discussion of the 5.50% Notes issued in April 2015 and are not reflected in the table below.

		Payments Due By Period			
(in thousands)	**Total**	**Less than 1 year**	**1 - 3 years**	**3 - 5 years**	**More than 5 years**
Operating lease obligations (1)	340	184	156		
Hercules Debt (2)	18,030	2,718	13,125	2,187	
Other(3)(4)	2,728	2,719	9		
Total	21,098	5,621	13,290	2,187	

(1) Operating lease obligations reflect our obligation to make payments in connection with the leases for our office space.

(2) In January 2015, we entered into the Loan Agreement with Hercules, pursuant to which we borrowed $15,000,000. The term loan bears an interest rate per annum equal to the greater of either (i) 9.40% plus the prime rate as reported in The Wall Street Journal minus 3.25% or (ii) 9.40%. Pursuant to the terms of the Loan Agreement, we will make interest-only payments for 12 months, and then repay the principal balance of the loan in 30 equal monthly payments of principal and interest through the scheduled maturity date on July 1, 2018. In connection with the Loan Agreement, we granted a security interest in substantially all of its assets, excluding intellectual property and certain new drug applications and related approvals, as collateral for the obligations under the Loan Agreement

(3) In connection with the OXAYDO license agreement, we will pay Acura $2.5 million milestone on the earlier to occur of first commercial sale of OXAYDO or January 1, 2016, but in no event earlier than June 30, 2015.

(4) We have employment agreements with our executive officers that require the funding of a specific level of payments if specified events occur, such as a change in control or termination without cause. However, because of the contingent nature of those payments, they are not presented in the table.

In addition, in the course of normal business operations, we have agreements with contract service providers to assist in the performance of our research and development and manufacturing activities. We can elect to discontinue the work under these agreements at any time. We could also enter into additional collaborative research, contract research, manufacturing and supplier agreements in the future, which may require upfront payments or long-term commitments of cash.

Purchase Commitments

Other than described above with respect to the purchase of raw materials, we have no material non-cancelable purchase commitments with service providers as we have generally contracted on a cancelable purchase order basis.

Employment Agreements

We have entered into employment agreements with our president and chief executive officer, chief financial officer, chief business officer, chief medical officer, chief commercial officer and senior vice president of research and development, that provide for, among other things, salary, bonus and severance payments.

Legal Proceedings

Please refer to Note 8 - Commitments and Contingencies Legal Proceedings in the notes to the unaudited consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

JOBS Act

As an emerging growth company under the JOBS Act of 2012, we can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are electing not to delay our adoption of such new or revised accounting standards. As a result of this election, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

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ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our market risks during the three months ended March 31, 2015 have not materially changed from those discussed in our Annual Report on Form 10-K for the year ended December 31, 2014, filed with the SEC on March 16, 2015.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the Exchange Act), as of the end of the period covered by this quarterly report on Form 10-Q. Based on that evaluation, our management, including our CEO and CFO, concluded that as of March 31, 2015 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission and that such information is accumulated and communicated to the Company s management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

During the three months ended March 31, 2015, there were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II

ITEM 1. LEGAL PROCEEDINGS

Please refer to Note 8 - Commitments and Contingencies Legal Proceedings in the notes to the unaudited consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

ITEM 1A. RISK FACTORS

We are subject to various risks and uncertainties that could have a material impact on our business, financial condition, results of operations and cash flows. The discussion of these risk factors is included in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2014. There have been no changes to these risk factors during the three months ended March 31, 2015 other than as discussed below.

Servicing our debt requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness, including the Loan Agreement and the 5.5% Notes, depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Despite our current debt levels, we may still incur substantially more debt or take other actions which would intensify the risks discussed above.

Despite our current consolidated debt levels, we and our subsidiaries may be able to incur substantial additional debt in the future, subject to the restrictions contained in our debt instruments, some of which may be secured debt. We will not be restricted under the terms of the indenture governing the notes from incurring additional debt, securing existing or future debt, recapitalizing our

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debt or taking a number of other actions that are not limited by the terms of the indenture governing the notes that could have the effect of diminishing our ability to make payments on the notes when due. The Loan Agreement restricts our ability to incur additional indebtedness, including secured indebtedness, subject to certain exceptions, but if the facility matures or is repaid, we may not be subject to such restrictions under the terms of any subsequent indebtedness.

If third parties claim that intellectual property used by us infringes upon their intellectual property, this could result in costly litigation and potentially limit our ability to commercialize our products.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the pharmaceutical industry. We may, from time to time, be notified of claims that we are infringing upon patents, trademarks, copyrights, or other intellectual property rights owned by third parties, and we cannot provide assurances that other companies will not, in the future, pursue such infringement claims against us or any third-party proprietary technologies we have licensed. For example, in April 2015 we became aware that Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. (collectively, Purdue) filed a lawsuit against us and our collaboration partner Acura Pharmaceuticals, Inc. alleging that our OXAYDO product infringes a patent held by Purdue. Our commercial success depends upon our ability to develop product candidates and commercialize future products without infringing the intellectual property rights of others. Our current or future product candidates or products, or any uses of them, may now or in the future infringe third-party patents or other intellectual property rights. This is due in part to the considerable uncertainty within the pharmaceutical industry about the validity, scope and enforceability of many issued patents in the United States and elsewhere in the world and, to date, there is no consistency regarding the breadth of claims allowed in pharmaceutical patents. We cannot currently determine the ultimate scope and validity of patents which may be granted to third parties in the future or which patents might be asserted to be infringed by the manufacture, use and sale of our products. In part as a result of this uncertainty, there has been, and we expect that there may continue to be, significant litigation in the pharmaceutical industry regarding patents and other intellectual property rights.

Third parties may assert infringement claims against us, or other parties we have agreed to indemnify, based on existing patents or patents that may be granted in the future. We are aware of third-party patents and patent applications related to morphine or oxycodone drugs and formulations, including those listed in the FDA s Orange Book for oxycodone products. Since patent applications are published after a certain period of time after filing, and because applications can take several years to issue, there may be currently pending third-party patent applications that are unknown to us, which may later result in issued patents. Because of the inevitable uncertainty in intellectual property litigation, any litigation could result in an adverse decision, even if the case against us was weak or flawed.

If we are found to infringe a third party s intellectual property rights, or if a third party that we were licensing technologies from was found to infringe upon a patent or other intellectual property rights of another third party, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, including treble damages and attorneys fees, if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our technology or product candidates, or reengineer or rebrand our product candidates, if feasible, or force us to cease some of our business operations.

In connection with any NDA that we file under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, we will also be required to notify the patent holder that we have certified to the FDA that any patents listed for the reference label drug in the FDA s Orange Book publication are invalid, unenforceable or will not be infringed by the manufacture, use or sale of our drug. If the patent holder files a patent infringement lawsuit against us within 45 days of its receipt of notice of our certification, the FDA is automatically prevented from approving our Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a court decision in the infringement case that is

favorable to us. Accordingly, we may invest significant time and expense in the development of our product candidates only to be subject to significant delay and patent litigation before our product candidates may be commercialized. There is always a risk that someone may bring an infringement claim against us. Even if we are found not to infringe, or a plaintiff s patent claims are found invalid or unenforceable, defending any such infringement claim would be expensive and time-consuming, and would delay launch of Egalet-002 and distract management from their normal responsibilities.

Competitors may sue us as a way of delaying the introduction of our products. Any litigation, including any interference or derivation proceedings to determine priority of inventions, oppositions or other post-grant review proceedings to patents in the United States or in countries outside the United States, or litigation against our partners may be costly and time consuming and could harm our business. We expect that litigation may be necessary in some instances to determine the validity and scope of our proprietary rights. Litigation may be necessary in other instances to determine the validity, scope or non-infringement of certain patent rights claimed by third parties to be pertinent to the manufacture, use or sale of our products. Ultimately, the outcome of such litigation

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could compromise the validity and scope of our patent or other proprietary rights or hinder our ability to manufacture and market our products.

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

Recent Sales of Unregistered Securities

As further described in our Current Report on Form 8-K filed with the Securities and Exchange Commission on January 13, 2015, in January 2015, in connection with our entering into the Loan Agreement, we issued Hercules a warrant to purchase $600,000 in shares of the Company s common stock at an exercise price of $5.29 per share (or, approximately 113,421 shares of common stock) pursuant to the exemption from registration set forth in Section 4(a)(2) of the Securities Act of 1933, as amended.

Use of Proceeds

On February 5, 2014, our Registration Statement on Form S-1 (File No. 333-191759) (the Form S-1) was declared effective by the SEC for our IPO pursuant to which we sold an aggregate of 4,830,000 shares of our common stock at a price to the public of $12.00 per share. From the effective date of the Form S-1 through March 31, 2015, we have used the proceeds from our IPO as described in our final prospectus, filed with the SEC on February 7, 2014, as well as to fund the acquisition and commercialization of our approved products, OXAYDO and SPRIX.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

The following is a list of exhibits filed as part of this Quarterly Report on Form 10-Q. Where so indicated by footnote, exhibits that were previously filed are incorporated by reference. For exhibits incorporated by reference, the location of the exhibit in the previous filing is indicated.

Exhibit Number	Description
2.1^	Asset Purchase Agreement, dated as of January 8, 2015, by and between Egalet US, Inc. and Luitpold Pharmaceuticals, Inc. (Incorporated by reference to Exhibit 2.1 to the Company s Annual Report on Form 10-K filed with the SEC on March 16, 2015).
4.2	Warrant Issued to Hercules Technology Growth Capital, Inc. dated January 7, 2015 (Incorporated by reference to Exhibit 4.2 to the Company s Annual Report on Form 10-K filed with the SEC on March 16, 2015).
10.1+	Employment Agreement, dated January 2, 2015, by and between Egalet Corporation and Deanne F. Melloy (Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the SEC on January 12, 2015).
10.2	Loan and Security Agreement, dated January 7, 2015, by and among Egalet Corporation, Egalet US, Inc., Hercules Technology Growth Capital, Inc. and the several other banks, financial institutions and entities from time to time party thereto (Incorporated by reference to Exhibit 10.1 to the Company s Annual Report on Form 10-K filed with the SEC on March 16, 2015).
10.3	Amendment No. 1, dated January 28, 2015, to the Loan and Security Agreement by and among Egalet Corporation, Egalet US, Inc., Hercules Technology Growth Capital, Inc. and the several other banks, financial institutions and entities from time to time party thereto (Incorporated by reference to Exhibit 10.2 to the Company s Annual Report on Form 10-K filed with the SEC on March 16, 2015).
10.4	Amendment No. 2, dated February 20, 2015, to the Loan and Security Agreement by and among Egalet Corporation, Egalet US, Inc., Hercules Technology Growth Capital, Inc. and the several other banks, financial institutions and entities from time to time party thereto (Incorporated by reference to Exhibit 10.3 to the Company s Annual Report on Form 10-K filed with the SEC on March 16, 2015).
10.5	Collaboration and License Agreement, dated as of January 7, 2015, by and among Egalet Corporation, Egalet US, Inc., Egalet Ltd. and Acura Pharmaceuticals, Inc (Incorporated by reference to Exhibit 10.4 to the Company s Annual Report on Form 10-K filed with the SEC on March 16, 2015).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial and Accounting 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 pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial and Accounting 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 (filed herewith).

101.SCH	XBRL Taxonomy Extension Schema Document (filed herewith).
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (filed herewith).
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (filed herewith).
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (filed herewith).
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).

+ Indicates management contract or compensatory plan.

^ All exhibits and schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. The Company will furnish the omitted exhibits and schedules to the SEC upon request by the SEC.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

Date: May 8, 2015

EGALET CORPORATION

By: /s/ ROBERT S. RADIE
Robert S. Radie
President and Chief Executive Officer

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