

Egalet Corp  
Form 10-Q  
August 07, 2015  
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**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 10-Q**

(Mark One)

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

For the quarterly period ended June 30, 2015

Or

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-36295

## Egalet Corporation

(Exact Name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction of  
Incorporation or Organization)

**46-3575334**  
(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
Common Stock, par value \$0.001 per share

Name of each exchange on which registered
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 ☒ No ☐

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

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(Do not check if a  
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 ☐ No ☒

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  
of August 7, 2015: 25,059,474

Shares outstanding as

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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 June 30, 2015.

[Table of Contents](#)**PART I****ITEM 1. FINANCIAL STATEMENTS****Egalet Corporation and Subsidiaries****Consolidated Balance Sheets**

(in thousands, except share and per share data)

	December 31, 2014	June 30, 2015 (unaudited)
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 52,738	\$ 57,666
Marketable securities, available for sale		50,764
Related party receivable	679	537
Inventory		3,887
Other current assets		275
Prepaid expenses	698	378
Other receivables	1,011	931
Total current assets	55,126	114,438
Intangible assets, net	184	11,497
Property and equipment, net	4,417	4,330
Deposits and other assets	843	562
Total assets	\$ 60,570	\$ 130,827
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 4,209	\$ 3,723
Accrued expenses	2,554	5,504
Deferred revenue	588	15,108
Debt - current		2,616
License fee payable		2,500
Other current liabilities	78	118
Total current liabilities	7,429	29,569
Debt - non-current portion		50,758
Deferred income tax liability	25	27
Deferred revenue - non-current portion	8,855	16,703
Derivative liability		1,689
Other liabilities		120
Total liabilities	16,309	98,866
Stockholders' equity:		
Common stock \$0.001 par value; 75,000,000 shares authorized at December 31, 2014 and June 30, 2015; 17,283,663 and 17,331,163 shares issued and outstanding at December 31, 2014 and June 30, 2015, respectively	17	17

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Additional paid-in capital	121,028	141,964
Accumulated other comprehensive (loss) income	(171)	401
Accumulated deficit	(76,613)	(110,421)
Total stockholders' equity	44,261	31,961
Total liabilities and stockholders' equity	\$ 60,570	\$ 130,827

See accompanying notes to unaudited consolidated financial statements.

Table of Contents**Egalet Corporation and Subsidiaries****Consolidated Statements of Operations (Unaudited)**

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,					
	2014	2015	2014	2015				
<b>Revenues:</b>								
Net product sales	\$	\$	607	\$	769			
Related party revenues		490		352	746	973		
Total revenues		490		959	746	1,742		
<b>Cost and Expenses:</b>								
Cost of sales (excluding amortization of product rights)				207		301		
Amortization of product rights				585		963		
General and administrative		4,516		5,804		7,778	10,499	
Sales and marketing		212		3,284		218	4,859	
Research and development		7,361		4,903		10,141	15,303	
Total costs and expenses		12,089		14,783		18,137	31,925	
Loss from operations		(11,599)		(13,824)		(17,391)	(30,183)	
<b>Other (income) expense:</b>								
Change in fair value of derivative liability				773			773	
Interest (income) expense		(4)		2,306		7,088	2,766	
Other (gain) loss				(2)			(2)	
Loss on foreign currency exchange		47		188		43	85	
		43		3,265		7,131	3,622	
Loss before provision for income taxes		(11,642)		(17,089)		(24,522)	(33,805)	
Provision for income taxes		16		(23)		51	3	
Net loss	\$	(11,658)	\$	(17,066)	\$	(24,573)	\$	(33,808)
<b>Per share information:</b>								
Net loss per share of common stock, basic and diluted	\$	(0.73)	\$	(1.03)	\$	(1.92)	\$	(2.05)
Weighted-average shares outstanding, basic and diluted		15,887,503		16,506,798		12,780,145		16,481,354

See accompanying notes to unaudited consolidated financial statements.

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**Egalet Corporation and Subsidiaries**

**Consolidated Statements of Comprehensive Loss (Unaudited)**

(in thousands)

	<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
	<b>2014</b>	<b>2015</b>	<b>2014</b>	<b>2015</b>
Net loss	\$ (11,658)	\$ (17,066)	\$ (24,573)	\$ (33,808)
Other comprehensive income (loss):				
Unrealized losses on available for sale securities		(83)		(83)
Foreign currency translation adjustment	(54)	1,470	51	655
Comprehensive loss	\$ (11,712)	\$ (15,679)	\$ (24,522)	\$ (33,236)

See accompanying notes to unaudited consolidated financial statements.



[Table of Contents](#)**Egalet Corporation and Subsidiaries****Consolidated Statements of Changes in Stockholders' Equity****For the Six Months Ended June 30, 2015 (Unaudited)****(in thousands, except share data)**

	<b>Common Stock</b>		<b>Stockholders' Equity</b>				
	<b>Number of Shares</b>	<b>\$0.001 Par Value</b>	<b>Additional Paid-in Capital</b>	<b>Accumulated Deficit</b>	<b>Accumulated Comprehensive Income (loss)</b>	<b>Total</b>	
Balance, December 31, 2014	17,283,663	\$ 17	\$ 121,028	\$ (76,613)	\$ (171)	\$ 44,261	
Issuance of warrants			329			329	
Issuance of restricted shares of common stock	40,000						
Issuance of convertible debt			18,105			18,105	
Exercise of stock options	7,500		82			82	
Stock-based compensation expense			2,420			2,420	
Unrealized loss on available for sales securities					(83)	(83)	
Foreign currency translation adjustment					655	655	
Net loss				(33,808)		(33,808)	
Balance, June 30, 2015	17,331,163	\$ 17	\$ 141,964	\$ (110,421)	\$ 401	\$ 31,961	

See accompanying notes to unaudited consolidated financial statements.

Table of Contents**Egalet Corporation and Subsidiaries****Consolidated Statements of Cash Flows (Unaudited)****(in thousands)**

	<b>Six months Ended June 30,</b>	
	<b>2014</b>	<b>2015</b>
Operating activities:		
Net loss	\$ (24,573)	\$ (33,808)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	311	1,482
Change in fair value of derivative liability		773
Stock-based compensation expense	5,507	2,420
Noncash interest	6,987	119
Amortization of debt discount		1,411
Deferred income taxes		4
Changes in assets and liabilities, net of business acquisitions:		
Related party receivable	(345)	88
Inventory		(479)
Prepaid expenses	(326)	290
Other receivables	(1)	
Other current assets		(275)
Deposits and other assets		214
Accounts payable	1,527	(470)
Accrued expenses	319	2,999
Deferred revenue	(262)	23,124
Other current liabilities	19	46
Net cash used in operating activities	(10,837)	(2,062)
Investing activities:		
Payments for purchase of property and equipment	(482)	(674)
Deposits for purchases of property and equipment	(2,017)	
Purchases of investments		(53,418)
Sales of investments		2,388
Purchase of SPRIX		(8,128)
License of OXAYDO		(5,172)
Net cash used in investing activities	(2,499)	(65,004)
Financing activities:		
Proceeds from debt issuance, net of costs		71,496
Proceeds from exercise of stock options		82
Proceeds from IPO, net of costs	53,032	
Proceeds from issuance of common stock, net of costs	13,950	
Net cash provided by financing activities	66,982	71,578
Effect of foreign currency translation on cash and cash equivalents	(87)	416
Net increase in cash and cash equivalents	53,559	4,928
Cash and cash equivalents beginning of period	15,700	52,738
Cash and cash equivalents end of period	\$ 69,259	\$ 57,666
Supplemental disclosure of cash flow information:		
Issuance of warrants	\$	\$ 329
Liability for contractual payment associated with OXAYDO license	\$	\$ 2,500
Cash interest payments	\$	\$ 564

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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 discourage 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 HCl, 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.

**Liquidity**

The Company has incurred recurring operating losses since inception. As of June 30, 2015, the Company had an accumulated deficit of \$110.4 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, the Hercules term loan (see Note 6), the 5.50% Senior Convertible Notes (see Note 6), and the Follow-On Offering (see Note 14), together with its pre-existing cash and cash equivalents, will enable it to fund its operating expenses and capital expenditure requirements through December 31, 2016. The Company

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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 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, until profitability is achieved, if ever. 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 6 - Long term debt for additional information.

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). On May 6, 2015, the Company issued an additional \$1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment, for aggregate gross proceeds of \$61.0

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million. 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. Refer to Note 6 - Long term debt for additional information.

On July 31, 2015 the Company completed an underwritten public offering of 7,666,667 shares of common stock (including the exercise in full of the underwriters' option to purchase additional shares) at an offering price of \$11.25 per share for gross proceeds of \$86.3 million. The Company estimates net proceeds from the offering to be \$80.8 million, after deducting the underwriting discounts and estimated expenses.

During the six months ended June 30, 2015, the Company had significant cash outflows 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 upon the earlier to occur of first commercial sale of OXAYDO or January 1, 2016. Refer to Note 11 - 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 June 30, 2015 and for the three and six months ended June 30, 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 June 30, 2015 and for the three and six months ended June 30, 2014 and 2015. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 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.

#### **Marketable Securities, Available-for-Sale**

Marketable securities consist of securities with original maturities greater than three months, and are comprised of securities issued by U.S. government agencies and corporate debt securities. Marketable securities have been classified as current assets in the accompanying Consolidated Balance Sheets based upon the nature of the securities and their intended use to fund operations.

Management determines the appropriate classification of securities at the time of purchase. The Company has classified its investment portfolio as available-for-sale in accordance with ASC 320, *Investments - Debt and Equity Securities*. The Company's

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available-for-sale securities are carried at fair value with unrealized gains and losses reported in other comprehensive income (loss). Marketable securities are evaluated periodically for impairment. If it is determined that a decline of any investment is other than temporary, then the carrying amount of the investment is written down to fair value and the write-down is included in the statements of comprehensive income as a loss.

**Fair Value Measurements**

The carrying amounts reported in the Company's consolidated financial statements for cash, accounts receivable, accounts payable and accrued liabilities approximate their respective fair values because of the short-term nature of these accounts. The Company's marketable securities are carried at fair value based on quoted market prices and other observable inputs. The carrying value of the derivative liabilities are the estimated fair value of the liability as further described below.

**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 in transit. The Company calculates patient prescriptions dispensed using an analysis of third-party information. As of June 30, 2015, the Company had deferred revenue of \$14.0 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, an investor in the Company. 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. 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 11 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 payments are due under a collaborative research and license agreement but the revenue recognition criteria has not been met. As of June 30, 2015 the deferred revenue balance consisted of \$14.0 million for product sales, all of which is classified as current, and \$17.8 million related to the collaborative research and license agreement with Shionogi, \$1.1 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:

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*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 June 30, 2015, inventory consisted of raw materials and finished goods 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.

**Long Term Debt**

Long term debt consists of the Loan Agreement with Hercules and certain other lenders, and the 5.50% Notes.

Pursuant to the Loan Agreement with Hercules, the Company borrowed \$15.0 million in January 2015 under a term loan (see Note 6). 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%.

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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 ). On May 6, 2015, the Company issued an additional \$1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment, for aggregate gross proceeds of \$61.0 million. 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. Refer to Note 6 - Long term debt for additional information.

### Interest Make-Whole Derivative

The 5.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the Notes prior to April 1, 2018, subject to certain restrictions, they are entitled, in addition to the other consideration payable or deliverable in connection with such conversion, to 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%. We have determined that this feature is an embedded derivative and have recognized the fair value of this derivative as a liability on our balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on our statements of operations and comprehensive loss as change in fair value of derivative liabilities. The fair value of this embedded derivative was determined based on a binomial tree lattice model.

### 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 on the date of grant, was recorded as a debt discount.

### Recent Accounting Pronouncements

On April 7, 2015, the FASB issued ASU 2015-03, *Interest - Imputation of Interest* which changes the presentation of debt issuance costs in financial statements. Under the ASU, an entity presents such costs in the balance sheet as a direct deduction from the

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related debt liability rather than as an asset. Amortization of the costs is reported as interest expense. The Company has adopted this standard during the current period and as a result reclassified \$171,000 in deferred financing fees associated with the Hercules Loan Agreement to debt discount.

In May 2014, the Financial Accounting Standards Board ( FASB ) issued Accounting Standards Update ( ASU ) 2014-09, Revenue from Contracts with Customers, or ASU 2014-09, which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Areas of revenue recognition that will be affected include, but are not limited to, transfer of control, variable consideration, allocation of transfer pricing, licenses, time value of money, contract costs and disclosures. In July 2015, the FASB decided to delay the effective date of the new revenue standard by one year. The board also agreed to allow entities to choose to adopt the standard as of the original effective date of January 1, 2017. The FASB decided, based on its outreach to various stakeholders and the forthcoming amendments to the new revenue standard, that a deferral is necessary to provide adequate time to effectively implement the new revenue standard. The new standard will be effective for the Company on January 1, 2018. The Company is currently evaluating the method of adoption and the potential impact that ASU 2014-09 may have on its financial position and results of operations.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (ASU 2014-15), to provide guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and to provide related footnote disclosures. ASU 2014-15 is effective for the Company beginning in the first quarter of 2016 with early adoption permitted. The Company is currently evaluating the impact of adopting this standard on its consolidated financial statements.

**3. Investments****Marketable Securities**

Marketable securities consisted of the following as of June 30, 2015:

	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	\$ 50,847	\$	(83)	\$ 50,764
Total	\$ 50,847	\$	(83)	\$ 50,764

The Company had no marketable securities at December 31, 2014.

All of the Company's marketable securities at June 30, 2015 mature within 12 months.

**4. Inventory**

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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 June 30, 2015. There was no inventory at December 31, 2014.

(in thousands)	June 30, 2015
Raw materials	\$ 845
Work in process	
Finished goods	279
Deferred cost of sales	2,763
Total	\$ 3,887

The deferred costs of sales will be recognized upon release of the product to patients.

### 5. Intangible Assets

The following represents the balance of the intangible assets at June 30, 2015:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	\$ 7,672	\$ (523)	\$ 7,149	6.5
SPRIX product rights	4,620	(440)	4,180	4.5
IP R&D	168		168	Indefinite
Total	\$ 12,460	\$ (963)	\$ 11,497	

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

(in thousands)		<b>Gross Intangible Assets</b>	<b>Accumulated Amortization</b>		<b>Net Intangible Assets</b>
IP R&D	\$	184		\$	184
Total	\$	184	\$	\$	184

There was no impairment to intangible assets recognized in the six months ended June 30, 2014 and 2015.

### *Collaboration and License Agreement with Acura*

In January 2015, the Company entered into a Collaboration and 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. The Company also incurred transaction costs of \$172,000 associated with the deal. Refer to Note 11 Acquisitions and license and collaboration agreements for additional details.

During the three and six months ended June 30, 2015 the Company recognized amortization expense of \$249,000 and \$523,000, respectively, 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 \$4.6 million related to this transaction. Refer to Note 11 for additional details.

During the three and six months ended June 30, 2015 the Company recognized amortization expense of \$336,000 and \$440,000, respectively, related to the SPRIX product rights intangible asset.

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

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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 June 30, 2015, the carrying value of IPR&D was \$184,000, and \$168,000, respectively. The change in value was entirely due to fluctuation in foreign currency exchange rates.

### 6. 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

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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.

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 a fair value of \$328,610 that is included in stockholders' equity. The fair value of the Warrant was recorded as a debt discount and 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	

*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 the 5.50% Notes. On May 6, 2015, the Company issued an additional \$1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment for aggregate gross proceeds of \$61.0 million. 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.

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 the Company's common stock or a combination thereof, at the Company's election.



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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.

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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 the Company's 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 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 accounts for convertible debt instruments by recording the liability and equity components of the convertible debt separately. The liability is computed based on the fair value of a similar debt instrument that does not include the conversion option. The liability component includes both the value of the embedded interest make-whole derivative and the carrying value of the 5.50% Notes. The equity component is computed based on the total debt proceeds less the fair value of the liability component. The equity component is also recorded as debt discount and amortized as interest expense over the expected term of the 5.50% Notes, using the effective interest method.

The liability component of the 5.50% Notes on the date of issuance was computed as \$41.6 million, including of the value of the embedded interest make-whole derivative of \$0.9 million and the carrying value of the 5.50% Notes of \$40.6 million. Accordingly, the equity component on the date of issuance was \$19.4 million. The discount on the 5.50% Notes is being amortized to interest expense over the term of the Notes, using the effective interest method.

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The conversion criteria for the 5.50% Notes have not been met at June 30, 2015. Should the Notes become convertible, management will determine whether the intent is to settle in cash which would result in the liability component of the convertible notes being classified as a current liability and the equity component being presented as redeemable equity if the liability is considered current.

Transaction costs of \$4.1 million related to the issuance of the 5.50% Notes are allocated to the liability and equity components in proportion to the allocation of the proceeds and accounted for as debt discount and equity issuance costs, respectively. Approximately \$1.3 million of this amount was allocated to equity and the remaining \$2.8 million was recorded as debt discount.

The following table summarizes how the issuance of the 5.50% Notes is reflected in our balance sheet at June 30, 2015:

June 30, 2015		
Gross proceeds	\$	61,000
Unamortized Debt Discount		(22,059)
Carrying value	\$	38,941

Table of Contents**7. Fair Value Measurements**

The Company measures certain assets and liabilities at fair value in accordance with Accounting Standards Codification (ASC) 820, *Fair Value Measurements and Disclosures*. ASC 820 defines fair value as the price that would be received to sell an asset or paid to transfer a liability (the exit price) in an orderly transaction between market participants at the measurement date. The guidance in ASC 820 outlines a valuation framework and creates a fair value hierarchy in order to increase the consistency and comparability of fair value measurements and the related disclosures. In determining fair value, the Company maximizes the use of quoted prices and observable inputs. Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from independent sources. The fair value hierarchy is broken down into three levels based on the source of inputs as follows:

- Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.
- Level 2 Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.
- Level 3 Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

The following fair value hierarchy table presents information about each major category of our financial assets and liabilities measured at fair value on a recurring basis:

Fair Value Measurements as of June 30, 2015				
	Level 1	Level 2	Level 3	Balance as of June 30, 2015
<b>Assets</b>				
Money market funds	\$ 31,732	\$	\$	\$ 31,732
Marketable securities, available-for-sale		50,764		50,764
Total assets	\$ 31,732	\$ 50,764	\$	\$ 82,496
<b>Liabilities</b>				
Interest make-whole derivative	\$	\$	\$ 1,689	\$ 1,689
Total assets	\$	\$	\$ 1,689	\$ 1,689

Fair Value Measurements as of December 31, 2014				
	Level 1	Level 2	Level 3	Balance as of December 31, 2014
<b>Assets</b>				
Money market funds	\$ 45,011	\$	\$	\$ 45,011
Marketable securities, available-for-sale				
Total assets	\$ 45,011	\$	\$	\$ 45,011

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There were no financial liabilities subject to fair value measurement on a recurring basis at December 31, 2104.

The 5.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the Notes prior to April 1, 2018, the Company will, in addition to the other consideration payable or deliverable in connection 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%. We have determined that this feature is an embedded derivative and have recognized the fair value of this derivative as a liability in our balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on our statements of operations and comprehensive loss as change in fair value of derivative liabilities. The fair value of this embedded derivative was determined based on a binomial tree lattice model.

The following tables set forth a summary of changes in the fair value of Level 3 liabilities for the six months ended June 30, 2015:

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	December 31, 2014	Additions	Fair Value Change in 2015	June 30, 2015
Interest make-whole derivative	\$	916	\$ 773	\$ 1,689
Total liabilities	\$	\$ 916	\$ 773	\$ 1,689

As of June 30, 2015, the fair value and carrying value of our convertible debt, based on a valuation by a third party expert utilizing the binomial lattice tree model. This fair value measurement is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. The fair value measurement was based on several factors including:

- Credit spread at the issuance date
- Credit spread at the valuation date
- Discount yield as of the valuation date

The fair value and carrying value of our convertible debt at June 30, 2015 was as follows:

	Fair Value	Carrying Value	Face Value
5.50% convertible senior notes due April 1, 2020	\$ 40,645	\$ 38,941	\$ 61,000

## 8. Net Loss Per Common Share

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

(in thousands, except share and per share data)	Three Months Ended June 30, 2014	Three Months Ended June 30, 2015	Six Months Ended June 30, 2014	Six Months Ended June 30, 2015
Basic and diluted net loss per common share calculation:				
Net loss	\$ (11,658)	\$ (17,066)	\$ (24,573)	\$ (33,808)
Weighted-average common shares outstanding	15,887,503	16,506,798	12,780,145	16,481,354
Net loss per share of common stock basic and diluted	\$ (0.73)	\$ (1.03)	\$ (1.92)	\$ (2.05)

The following outstanding securities for the three and six months ended June 30, 2014 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

Three Months Ended June 30, 2014	Three Months Ended June 30, 2015	Six Months Ended June 30, 2014	Six Months Ended June 30, 2015
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Options outstanding	121,293	1,142,548	121,293	1,142,548
Unvested restricted stock awards	1,371,160	767,536	1,371,160	767,536
Hercules warrants		113,421		113,421
Common shares issuable upon conversion of the 5.50% notes		4,102,360		4,102,360
Total	1,492,453	6,125,865	1,492,453	6,125,865

### 9. 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

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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 June 30, 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	(1,142,548)
Restricted stock awards granted	(1,436,160)
Remaining shares available for future issuance	1,101,292

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:

(in thousands)	Three Months Ended June 30,				Six Months Ended June 30,			
	2014		2015		2014		2015	
Research and development	\$	1,855	\$	277	\$	2,382	\$	540
General and administrative		1,969		976		3,125		1,806
Sales and marketing				52				74
Total stock-based compensation expense	\$	3,824	\$	1,305	\$	5,507	\$	2,420

## 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	\$ 7.47	
Granted	544,000	10.05	
Exercised	(7,500)	10.99	
Forfeited	(32,500)	9.25	
Balance, June 30, 2015	1,142,548	\$ 8.63	9.46
Vested or expected to vest at June 30, 2015	1,142,548	\$ 8.63	9.46
Exercisable at June 30, 2015	29,569	\$ 11.07	8.84



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The intrinsic value of 1,112,979 unvested options as of June 30, 2015 was \$6.6 million, based on a per share price of \$14.43, the Company's closing stock price on that date, and a weighted-average exercise price of \$8.63 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 six months ended June 30, 2015 was estimated at \$6.71 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.71%
Expected term of options (in years)	6.25
Expected volatility	77.32%
Dividend yield	

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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%.

As of June 30, 2015, there was \$5.8 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 3.54 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.

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A summary of the status of the Company's restricted stock awards at June 30, 2015 and of changes in restricted stock awards outstanding under the Plan for the six months ended June 30, 2015 is as follows:

	Shares	Weighted-average Grant Date Fair Value per Share
Outstanding balance at December 31, 2014	832,535	\$ 11.75
Granted	40,000	\$ 5.18
Vested restricted stock awards	(104,999)	\$ 12.03
Outstanding balance at June 30, 2015	767,536	\$ 11.37

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 June 30, 2015, there was \$6.8 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.85 years.

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**10. 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 in federal district court in New Jersey for infringement of the '044 patent against Amneal Pharmaceuticals, LLC et al. in response to Amneal's submission of ANDA No. 23-382 to the FDA for a generic version of SPRIX. Luitpold sought an injunction to prevent Amneal's launch of a generic version of SPRIX. 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 in federal district court in New Jersey against Apotex Corp. and Apotex, Inc. (collectively, 'Apotex'), involving the SPRIX Nasal Spray. Apotex submitted ANDA No. 20-5486 to the FDA seeking approval for a generic version of SPRIX. On July 11, 2014, Luitpold had filed a complaint for infringement of the '044 patent against Apotex, prompting a 30-month stay on the approval of Apotex's ANDA 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.

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. In response, Acura filed a complaint for infringement of U.S. Patent No. 7,510,726 (the '726 Patent') against each generic challenger in federal district court in Delaware. 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

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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. The Company is aggressively defending its legal position 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, on February 20, 2015, 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.

### 11. 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

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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: (i) the exclusive, royalty-bearing, worldwide license to its abuse-deterrent hydrocodone-based product candidates using certain of the Company's core technologies, (ii) the research and development services to be completed by the Company and (iii) 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.

Due to the lack of standalone value for the license, research and development services and the joint committee obligation, 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 payment as deferred revenue within its consolidated balance sheet as of June 30, 2015. For the six months ended June 30, 2014 and 2015, the Company recognized revenue of \$262,000 and \$433,000, respectively, related to the amortization of deferred revenue.

Additionally, during the six months ended June 30, 2014 and 2015, the Company recognized revenue of \$487,000 and \$540,000, respectively, related to certain development costs incurred under the Company's collaborative research and license agreement

*Collaboration and License Agreement with Acura*

In January 2015, the Company entered into a Collaboration and 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, but was not actively marketed. Under the terms of the Collaboration and 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. 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 a product rights intangible asset of \$7.7 million related to the arrangement, 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.

In addition, Acura will receive from Egalet, a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on Oxyado net sales during such year. In any calendar year in which net sales exceed a specified threshold, Acura will receive a double digit royalty on all Oxaydo net sales in that year. Egalet's royalty payment obligations commence on the first commercial sale of Oxaydo and expire, on a country-by-country basis, upon the expiration of the last to expire valid patent claim covering Oxaydo in such country (or if there are no patent claims in such country, then upon the expiration of the last valid claim in the United States). Royalties will be reduced upon the entry of generic equivalents, as well for payments required to be made by Egalet to acquire intellectual property rights to commercialize Oxaydo, with an aggregate minimum floor.

*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

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\$340,000 of active pharmaceutical ingredient ( API) after closing within two business days of the release of such API from Luitpold's supplier.

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

	Allocation	
Inventory	\$	3,408
Property, plant & equipment		100
Finite lived intangible-product rights		4,620
Net assets acquired	\$	8,128

During the six months ended June 30, 2015, management determined that the allocation of the purchase price to inventory and the intangible should be adjusted based on the valuation of the acquired assets. As a result, an adjustment was recorded to increase the allocation of the purchased price of the acquired finished goods inventory by \$827,000 and increase the fair value of the intellectual property by \$2.5 million. These adjustments reduced goodwill related to the acquisition to \$0.

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 six months ended June 30, 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 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 Company incurred \$1.1 million of SPRIX acquisition-related costs, which were expensed as G&A in the consolidated statement of operations.

The following table presents supplemental pro forma information for the three and six months ended June 30, 2014 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 and six months ended June 30, 2015:

(in thousands, except per share data)	Three months ended June 30, 2014 (unaudited)		Six months ended June 30, 2014 (unaudited)	
Pro forma product sales	\$	808	\$	2,006
Pro forma net loss		(12,365)		(27,079)
Pro forma net loss per share	\$	(0.78)	\$	(2.12)

## 12. 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 June 30, 2014, the Company recorded tax expense of \$16,000 and for the three months ended June 30, 2015 the Company had a tax benefit of \$23,000. For six months ended June 30, 2014 and 2015, the Company recorded tax expense of \$51,000 and \$3,000, respectively

As of December 31, 2014 and June 30, 2015, the Company had a non-current deferred tax liability of \$25,000 and \$27,000 respectively. The deferred tax liability relates to an indefinite-lived intangible that was recorded in connection with the Danish IPR&D. 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.

### **13. Related-Party Transactions**

#### **Related Party Receivables**

The Company has derived a portion of revenue for the three and six months ended June 30, 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 June 30, 2015, related party receivables with Shionogi were \$679,000 and \$537,000, respectively and consisted of revenue from development costs

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incurred under the Company's collaborative research and license agreement of \$679,000 and \$537,000 for the six months ended June 30, 2014 and 2015, respectively.

**14. Subsequent Events**

**At The Market Offering**

On July 2, 2015, the Company entered into a sale agreement with Cantor Fitzgerald & Co. (Cantor) to offer shares of the Company's common stock from time to time through Cantor, as the Company's sales agent for the offer and sale of the shares, in an at-the-market offering. The Company may offer and sell shares of common stock for an aggregate offering price of up to \$30.0 million.

**Follow-On Offering**

On July 31, 2015 the Company completed an underwritten public offering of 7,666,667 shares of common stock (including the exercise in full of the underwriters' option to purchase additional shares) at an offering price of \$11.25 per share for gross proceeds of \$86.3 million. The Company estimates net proceeds from the offering to be \$80.8 million, after deducting the underwriting discounts and estimated expenses.

**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, anticipate, be, project, potential, continue and ongoing, or the negative of these terms, or other comparable terminology intended to identify 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 5.50% Notes and to repay them at maturity (if, with respect to the 5.50% Notes, they are 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.

## 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

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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 abuse. In January 2015, we announced the acquisition and license of two innovative pain products, SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO (oxycodone HCl, 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, 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. In the second quarter of 2015, we completed a pivotal bioequivalence study for our lead product candidate based on our Guardian Technology. Egalet-001, an abuse-deterrent extended-release oral morphine formulation. We have demonstrated bioequivalence at 15, 30 and 60 mg doses of Egalet-001 to MS Contin and plan to submit a new drug application NDA for Egalet-001 in the fourth quarter of 2015. In the second quarter of 2015, we initiated a Phase 3 program for our second product candidate, Egalet-002, an abuse deterrent, extended release, oral oxycodone formulation. We plan to submit an NDA in mid-2017. 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, which allows us to create physical and chemical barriers intended to deter the most common methods of abuse are specific to a particular drug, 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 and offers us a number of long-term growth opportunities.

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 immediate release ( IR ) oxycodone. The responses on both take drug again and drug liking were lower for OXAYDO compared to IR oxycodone.

IR oxycodone is more often abused than extended-release ( ER ) oxycodone and is most often abused via the route of snorting. There has been an increase in the abuse of IR oxycodone since the reformulation of ER oxycodone. 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. 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 selling SPRIX in the first quarter of 2015 and began promoting SPRIX with our salesforce in the second quarter of 2015.

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To commercialize SPRIX and OXAYDO and ultimately our pipeline product candidates, we have built a 50 person specialty sales force targeting the approximately 7,000 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. Our product candidates, Egalet-001 and Egalet-002 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

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passes through the gastrointestinal tract. This polymer matrix construct makes extracting the API into a solution which could be drawn 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. In June 2015, we announced positive results from a pivotal bioequivalence study in which we demonstrated bioequivalence of Egalet-001 60 mg to MS Contin 60 mg. 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. Having completed pivotal studies for Egalet-001, 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. 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 need of rescue medication to treat breakthrough pain, as compared to oxycodone-based products that exhibit higher variability. 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. In May 2015, we announced positive top-line results from Category 1 abuse-deterrent studies of Egalet-002 compared to the reformulated, abuse-deterrent OxyContin that demonstrated that Egalet-002 resisted common and rigorous forms of physical manipulation used to defeat the tablet and snort the most common route of abuse oxycodone-based products. By performing a comprehensive battery of laboratory tests to assess the physical and chemical properties of Egalet-002 with reformulated OxyContin serving as a comparator, we demonstrated that Egalet-002 has strong abuse-deterrent features. The Category 1 data demonstrated that it took five times the level of effort to manipulate Egalet-002 compared to abuse-deterrent OxyContin. The findings from the Category 1 study were used to define the optimal method for maximally challenging the product in the Category 3 oral HAL study which tested a more rigorous method of manipulation. Many oral HAL studies conducted to date have used chewing as the method of manipulating the investigational product. However, because of the extremely hard outer shell, Egalet-002 is very difficult to chew so this method of manipulation was not an option to defeat the tablet when conducting the oral HAL study. The method for Egalet-002 involved serial manipulations, using both mechanical and electrical instruments, as compared to both immediate-release (IR) oxycodone and OxyContin, which both required only a one-step manipulation process. The results of the oral HAL study showed that, after maximal manipulation, drug liking was similar for Egalet-002, IR oxycodone and OxyContin following oral administration in nondependent recreational opioid users. We plan to discuss the results with the FDA as we design a pivotal oral HAL study for Egalet-002. We are also conducting the abuse-deterrence studies in accordance with the FDA guidance on abuse-deterrent opioids with the goal of obtaining abuse-deterrent claims in our product label. In parallel, we initiated a plan to initiate a Phase 3 safety and efficacy program for Egalet- 002 in the second quarter of 2015. We anticipate submitting an NDA for Egalet-002 in mid-2017.

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

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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 \$11.7 million and \$17.1 million for the three months ended June 30, 2014 and 2015, respectively, and net losses were \$24.6 million and \$33.8 million for the six months ended June 30, 2014 and 2015 respectively. We recognized revenues of \$490,000 and \$959,000 for the three months ended June 30, 2014 and 2015, respectively, and revenues of \$746,000 and \$1.7 million for the six months ended June 30, 2014 and 2015, respectively. As of June 30, 2015, we had an accumulated deficit of \$110.4 million.

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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.

**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 U.S. 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, an investor in the company. 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. 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 June 30, 2015, inventory consisted of raw materials, finished goods and deferred cost of goods.

### ***Intangible Assets***

Intangible assets consist of product rights related to the SPRIX acquisition, product rights associated with the Collaboration and 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.

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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.

***Significant Factors, Assumptions and Methodologies Used in Determining Fair Value***

***Stock Options***

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 six months ended June 30, 2015:

Risk-free interest rate	1.70%
Expected term of options (in years)	6.25
Expected volatility	77.94%
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.

***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 June 30, 2015, there was \$6.8 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.85 years.

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*Convertible Debt Accounting*

We perform an assessment of all embedded features of a debt instrument to determine if (1) such features should be bifurcated and separately accounted for, and (2) if bifurcation requirements are met, whether such features should be classified and accounted for as equity or liability instruments. If the embedded feature meets the requirements to be bifurcated and accounted for as a liability, the fair value of the embedded feature is measured initially, included as a liability on the consolidated balance sheet, and re-measured to fair value at each reporting period. Any changes in fair value are recorded in the consolidated statement of operations. We monitor, on an ongoing basis, whether events or circumstances could give rise to a change in our classification of embedded features.

We determined the embedded conversion options in the 5.50% convertible senior notes (the Notes) are not required to be separately accounted for as derivatives. However, since the Notes can be settled in cash or common shares or a combination of cash and common shares at our option, we are required to separate the Notes into a liability and equity component. The carrying amount of the liability component is calculated by measuring the fair value of a similar liability that does not have an associated equity component. The carrying amount of the equity component representing the embedded conversion option is determined by deducting the fair value of the liability component from the initial proceeds. The excess of the principal amount of the liability component over its carrying amount is amortized to interest expense over the expected life of the Notes using the effective interest method. The equity component is not re-measured as long as it continues to meet the conditions for equity classification for contracts in an entity's own equity.

The fair value of the liability component of the Notes was estimated at \$40.6 million at issuance. Therefore, the difference between the \$61.0 million face value of the Notes and the \$40.6 million estimated fair value of the liability component will be amortized to interest expense over the term of the Notes through April 1, 2020 using the effective interest method.

The estimated fair value of the liability component at the date of issuance was determined using valuation models that are complex and subject to judgment. Significant assumptions within the valuation models included an implied credit spread, the expected volatility and dividend yield of our common stock and the risk free interest rate for notes with a similar term.

The 5.50% Notes are convertible prior to maturity, subject to certain conditions described below, into shares of the Company's common stock:

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.

The Company will satisfy the conversion obligation by paying or delivering, as the case may be, cash, shares of the Company's common stock or a combination thereof, at the Company's election.

On a quarterly basis, we perform an assessment in order to determine whether the 5.50% Notes have become convertible at the option of the holder, based on meeting any of the conversion criteria described above. Should the 5.50% Notes become convertible, we then assess our intent and ability to settle the 5.50% Notes in cash, shares of common stock, or a combination of cash and shares of common stock.

#### ***Interest Make-Whole Derivative***

The 5.50% Notes include an interest make-whole feature whereby if a noteholder converts any of the Notes prior to April 1, 2018, we will, in addition to the other consideration payable or deliverable in connection 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%. We have determined that this feature is an embedded derivative and have

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recognized the fair value of this derivative as a liability in our balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on our statements of operations and comprehensive loss as change in fair value of derivative liabilities. The fair value of this embedded derivative was determined based on a binomial tree lattice model.

**Results of Operations***Comparison of the three months ended June 30, 2014 and 2015*

	Three months ended June 30,		
(in thousands)	2014	2015	Change
Revenues			
Net product sales	\$ 490	\$ 607	\$ 607
Related party revenues	490	352	(138)
Total revenues	490	959	469
Costs and Expenses:			
Cost of sales (excluding product rights amortization)		207	207
Amortization of product rights		585	585
General and administrative	4,516	5,804	1,288
Sales and marketing	212	3,284	3,072
Research and development	7,361	4,903	(2,458)
Total costs and expenses	12,089	14,783	2,694
Loss from operations	(11,599)	(13,824)	(2,225)
Change in fair value of derivative liability		773	773
Interest (income) expense	(4)	2,306	2,310
Other (gain) loss		(2)	(2)
Loss (gain) on foreign currency exchange	47	188	141
Loss from operations before income taxes	(11,642)	(17,089)	(5,447)
Provision for income taxes	16	(23)	(39)
Net loss	\$ (11,658)	\$ (17,066)	\$ (5,408)

*Net Product Sales*

Net product sales were \$607,000 for the three months ended June 30, 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*

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Revenues decreased from \$490,000 for the three months ended June 30, 2014 to \$352,000 for the three months ended June 30, 2015, as a result of decreased research and development services performed under our collaboration agreement with Shionogi offset by the amortization of deferred revenue related to the \$10.0 million payment received in the second quarter of 2015.

### *Cost of Sales (excluding Amortization of Product Rights)*

Cost of sales (excluding product amortization rights) was \$207,000 in the three months ended June 30, 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 and was dispensed to patients during the period.

### *Amortization of Product Rights*

Amortization was \$585,000 for the three months ended June 30, 2015 and was comprised of \$249,000 for the OXAYDO and \$336,000 for the SPRIX intangible assets. There was no intangible amortization in 2014.

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*General and Administrative Expenses*

General and administrative expenses increased by \$1.3 million, or 28.5%, from \$4.5 million for the three months ended June 30, 2014 to \$5.8 million for the three months ended June 30, 2015. This was primarily attributable to an increase in employee salary and benefits of \$1.0 million and \$1.1 million in professional and administrative fees as we continue to expand our U.S. operations. These increases were offset by a decrease in stock compensation expense of \$1.1 million.

*Sales and Marketing Expenses*

Sales and marketing expenses increased \$3.1 million from \$212,000 to \$3.3 million for the three months ended June 30, 2015 related to the establishment of the commercial operations in the U.S. and launch activities for SPRIX and pre-launch activities for OXAYDO. Sales and marketing costs were de Minimis for 2014.

*Research and Development Expenses*

Research and development expenses decreased by \$2.5 million, or 33.3%, from \$7.4 million for the three months ended June 30, 2014 to \$4.9 million for the three months ended June 30, 2015. This decrease was driven primarily by a decrease in our development costs for Egalet-001 for \$1.9 million and a decrease in stock compensation expense of \$1.6 million.

*Change in fair value of derivative liability*

The interest make whole provision of the 5.50% Notes is subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations and comprehensive loss as a change in fair value of the derivative liability. The change in the fair value of the derivative liability of \$773,000 is due primarily to the increase in the value of our common stock from the date of issuance of the notes on April 1, 2015 through June 30, 2015.

*Interest expense*

Interest expense was \$2.3 million for the three months ended June 30, 2015 compared to interest income of \$4,000 for the three months ended June 30, 2014. The increase was attributable to the \$2.3 million in interest expense that was recorded in the 2015 period in connection with the Hercules Loan and the 5.50% Convertible Senior Notes.



*Other (Gain) Loss*

For the three months ended June 30, 2015 we recognized a gain on the sale of marketable securities of \$2,000.

*Loss on Foreign Currency Exchange*

For the three months ended June 30, 2014 and 2015 we recognized a loss on foreign currency exchange of \$47,000 and \$188,000, 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 \$16,000 for the three months ended June 30, 2014 and income tax benefit of \$23,000 for the three months ended June 30, 2015.

Table of Contents*Comparison of the six months ended June 30, 2014 and 2015*

	Six months ended June 30,			
(in thousands)	2014	2015		Change
Revenues				
Net product sales	\$	\$	769	\$ 769
Related party revenues	746	973		227
Total revenues	746	1,742		996
Costs and Expenses:				
Cost of sales (excluding product rights amortization)		301		301
Amortization of product rights		963		963
General and administrative	7,778	10,499		2,721
Sales and marketing	218	4,859		4,641
Research and development	10,141	15,303		5,162
Total costs and expenses	18,137	31,925		13,788
Loss from operations	(17,391)	(30,183)		(12,792)
Change in fair value of derivative liability		773		773
Interest expense	7,088	2,766		(4,322)
Other (gain) loss		(2)		(2)
Loss on foreign currency exchange	43	85		42
Loss from operations before income taxes	(24,522)	(33,805)		(9,283)
Provision for income taxes	51	3		(48)
Net loss	\$ (24,573)	\$ (33,808)	\$	(9,235)

*Net Product Sales*

Net product sales were \$769,000 for the six months ended June 30, 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 \$746,000 for the six months ended June 30, 2014 to \$973,000 for the six months ended June 30, 2015, as a result of the increased amortization of deferred revenue and increased research and development services performed under our collaboration agreement with Shionogi.

*Cost of Sales (excluding Amortization of Product Rights)*

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Cost of sales (excluding product amortization rights) was \$301,000 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 and was dispensed to patients during the period.

### *Amortization of Product Rights*

Amortization was \$963,000 for the six months ended June 30, 2015 and was comprised of \$523,000 for the OXAYDO and \$441,000 for the SPRIX intangible assets. There was no intangible amortization in 2014.

### *General and Administrative Expenses*

General and administrative expenses increased by \$2.7 million, or 35.0%, from \$7.8 million for the six months ended June 30, 2014 to \$10.5 million for the six months ended June 30, 2015. This was primarily attributable to an increase in professional fees (legal, accounting and tax, and insurance) of \$2.1 million and an increase in employee salary and benefits of \$1.6 million as we continue to expand our U.S. operations. These increases were offset by a decrease in stock compensation expense of \$1.3 million.

### *Sales and Marketing Expenses*

Sales and marketing expenses were \$4.9 million for the six months ended June 30, 2015 related to the establishment of the commercial operations in the U.S. and launch activities for SPRIX and the pre-launch activities for OXAYDO. Sales and marketing costs were de Minimis for 2014.

### *Research and Development Expenses*

Research and development expenses increased by \$5.2 million, or 50.9%, from \$10.1 million for the six months ended June 30, 2014 to \$15.2 million for the six months ended June 30, 2015. This increase was driven primarily by an increase in our development costs for Egalet-002 of \$4.1 million and an increase in our development costs for Egalet-001 of \$1.4 million. These increases were offset by a decrease in stock compensation expense of \$1.6 million.

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*Change in fair value of derivative liability*

The interest make whole provision of the 5.50% Notes is subject to re-measurement at each balance sheet date and we recognize any change in fair value in our statements of operations and comprehensive loss as a change in fair value of the derivative liability. The change in the fair value of the derivative liability of \$773,000 is due primarily to the increase in the value of our common stock from the date of issuance of the notes on April 1, 2015 through June 30, 2015.

*Interest Expense*

Interest expense decreased by \$4.3 million, from \$7.1 million for the six months ended June 30, 2014, to \$2.8 for the six months ended June 30, 2015. The decrease was primarily attributable to the \$7.0 million interest expense we recognized in 2014 related to the accretion of premium that was recorded in connection with our August 2013 convertible debt issuance, compared to interest expense of \$2.8 million for the six months ended June 30, 2015 due to interest on the Hercules Loan and the 5.50% Notes.

*Other (Gain) Loss*

For the six months ended June 30, 2015 we recognized a gain on the sale of marketable securities of \$2,000.

*Loss on Foreign Currency Exchange*

For the six months ended June 30, 2014 and 2015 we recognized a loss on foreign currency exchange of \$43,000 and \$85,000, respectively. This difference is attributable to 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 \$51,000 and \$3,000 for the six months ended June 30, 2014 and 2015, respectively. During the six months ended June 30, 2015, tax expense was recorded due to amortization of the indefinite-lived intangible asset.

**Liquidity and Capital Resources**

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Since our inception, we have incurred net losses and generally negative cash flows from our operations. We incurred net losses of \$24.6 million and \$33.8 million for the six months ended June 30, 2014 and 2015, respectively. Our operating activities used \$10.8 million of cash during the six months ended June 30, 2014 and used \$2.1 million of cash during the six months ended June 30, 2015. At June 30, 2015, we had an accumulated deficit of \$110.4 million, a working capital surplus of \$84.9 million and cash and cash equivalents of \$57.7 million.

From our inception through our IPO on February 11, 2014, we received gross proceeds of \$31.1 million from the issuance of preferred stock and convertible debt. Through June 30, 2015 we have also financed our operations with the \$3.4 million in payments from our collaborative research and development agreements along with aggregate upfront and milestone payments of \$20.0 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 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 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.

In January 2015, we entered the Loan Agreement with Hercules and certain other lenders, pursuant to which we borrowed \$15 million under a term loan. Refer to Note 6 Long Term Debt in the Notes to our Unaudited Consolidated Financial Statements, for additional information.

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In April 2015, we issued through a private placement \$60.0 million in aggregate principal amount of 5.50% convertible senior notes due April 1, 2020. On May 6, 2015, we issued an additional \$1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment for the aggregate gross proceeds of \$61.0 million. Interest on the 5.50% Notes is payable semi-annually in arrears on April 1 and October 1 of each year, commencing on October 1, 2015. Refer to Note 6- Long term debt for additional information.

On July 31, 2015 the Company completed an underwritten public offering of 7,666,667 shares of common stock (including the exercise in full of the underwriters' option to purchase additional shares) at an offering price of \$11.25 per share for gross proceeds of \$86.3 million. The Company estimates net proceeds from the offering to be \$80.8 million, after deducting the underwriting discounts and estimated expenses.

During the six months ended June 30, 2015 we had significant cash outflows related to the purchase of SPRIX and license of OXAYDO of \$8.1 million and \$5.2 million, respectively. With regards to OXAYDO, we also owe Acura a \$2.5 million milestone on the earlier to occur of first commercial sale of OXAYDO or January 1, 2016. Refer to Note 11 - Acquisitions and License and Collaboration Agreements in the Notes to our Unaudited Consolidated Financial Statements, for additional information.

### *Cash Flows*

The following table summarizes our cash flows for the six months ended June 30, 2014 and 2015:

(in thousands)	2014	Six Months Ended June 30,	2015
Net cash (used in) provided by:			
Operating activities	\$	(10,837)	\$ (2,062)
Investing activities		(2,499)	(65,004)
Financing activities		66,982	71,578
Effect of foreign currency translation on cash and cash equivalents		(87)	416
Net increase in cash and cash equivalents	\$	53,559	\$ 4,928

### *Cash Flows from Operating Activities*

Net cash used in operating activities was \$10.8 million for the six months ended June 30, 2014 and consisted primarily of a net loss of \$24.6 million and net cash outflows of \$931,000 from the change in operating assets and liabilities. These outflows were partially offset by \$311,000 of noncash depreciation and amortization expense, \$5.5 million of stock-based compensation, and \$7.0 million in accretion of the debt premium.

Net cash used in by operating activities was \$2.1 million for the six months ended June 30, 2015 and consisted primarily of a net loss of \$33.8 million offset by an increase in deferred revenue of \$23.1 million generated by the Shionogi milestone received and sales of SPRIX in the first quarter of 2015, non-cash items consisting of \$2.4 million of stock-based compensation, \$1.5 million of amortization and depreciation expense, and \$1.4 million of amortization of debt discount. Net cash inflows from changes in other operating assets and liabilities were

primarily due to an increase in accrued expenses of \$3.0 million.

*Cash Flows from Investing Activities*

Net cash used in investing activities for the six months ended June 30, 2014 was \$2.5 million and consisted of purchases of property and equipment as well as deposits on future related purchases.

Net cash used in investing activities for the six months ended June 30, 2015 was \$65.0 million and consisted of \$53.4 million for the purchase of available for sale securities, \$8.1 million for the purchase of SPRIX, \$5.2 million for the license of OXAYDO and payments of \$674,000 for the purchase of property and equipment.

*Cash Flows from Financing Activities*

Net cash provided by financing activities was \$67.0 million for the six months ended June 30, 2014 and consisted of \$53.0 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 \$71.6 million for the six months ended June 30, 2015 and consisted of the net proceeds from Hercules Loan and the 5.50% Notes of \$14.8 million and \$56.9 million, respectively.

**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, commercial infrastructure development, legal and other regulatory expense, business development opportunities 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, the issuance of the 5.50% Notes and the net proceeds from our follow on offering, will be sufficient to fund our operations through December 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;



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- the potential need for a Phase 3 safety and efficacy study with respect to Egalet-001;
- the cost of our current commercialization activities, as well as, 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.

### Contractual Obligations and Commitments

The following table represents our contractual obligations and commitments as of June 30, 2015.

(in thousands)	Total	Payments Due By Period			
		Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating lease obligations (1)	\$ 269	\$ 142	\$ 127	\$	\$
Hercules Loan (2)	17,705	3,998	13,125	582	
5.50% Notes (3)	77,719	3,299	6,710	67,710	
Other(4)(5)	2,578	2,571	7		
Total	98,271	10,010	19,969	68,292	

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(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 \$15.0 million. 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) On April 1, 2015, we issued, through a private placement, \$60.0 million in aggregate principal amount of the 5.50% Notes. On May 6, 2015, we issued an additional \$1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment for aggregate gross proceeds of \$61.0 million. 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.

(4) In connection with the OXAYDO collaboration and 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.

(5) 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 10 - 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.

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***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.

**ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We are exposed to market risk related to changes in interest rates. As of June 30, 2015 and December 31, 2014, we had cash and cash equivalents and marketable securities of \$108.4 million and \$52.7 million, respectively, consisting of money market funds, certificates of deposit, U.S. government agency securities and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

We have international operations and as a result contract with vendors internationally. We may be subject to fluctuations in foreign currency rates in connection with payments made under these agreements. Historically, we have not hedged our foreign currency exchange rate risk, as the impacts of changes in foreign currency rates on payments made under these arrangements have not been material.

**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 June 30, 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 six months ended June 30, 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.

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**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 as amended and supplemented by Part II, Item 1A of our Quarterly Report on Form 10-Q for the period ended March 31, 2015. There have been no changes to these risk factors during the three months ended June 30, 2015.

**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 SEC 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 our 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.

As further described in our Current Report on Form 8-K filed with the SEC on April 8, 2015, in April 2015, we issued through a private placement \$60.0 million in aggregate principal amount of 5.50% convertible debt senior notes due April 1, 2020 (the *5.50% Notes*). In May 2015, we issued an additional \$1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over allotment, for aggregate gross proceeds of \$61.0 million. The 5.50% Notes are convertible into shares of our common stock on the terms set forth in the indenture governing the 5.50% Notes. Refer to Note 6- Long term debt for additional information.

**Use of Proceeds**

## Edgar Filing: Egalet Corp - Form 10-Q

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 June 30, 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.

<b>Exhibit Number</b>	<b>Description</b>
3.1	Third Amended and Restated Certificate of Incorporation of Egalet Corporation, as amended.
4.1	Indenture dated April 7, 2015 between the Company and The Bank of New York Mellon, as trustee (Incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 2015).
10.1	Purchase Agreement, dated April 1, 2015, by and among Egalet Corporation and the initial purchasers named therein. (Incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on April 2, 2015).
10.2	Amendment No. 3. Dated April 2, 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 4.1 to the Company's Current Report on Form 8-K filed with the SEC on April 8, 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).



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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: August 7, 2015

EGALET CORPORATION

By:

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

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**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
2.1 <sup>^</sup>	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.
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101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (filed herewith).

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+ 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.