Egalet Corp
Form 10-Q
November 06, 2015
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2015

Or

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

For the transition period from to

Commission File Number 001-36295

Egalet Corporation

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

(Title of Class)

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

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

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

Large accelerated filer o	Accelerated filer x

Non-accelerated filer o (Do not check if a smaller reporting company)

Smaller reporting company o

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

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

Common Stock, $0.001 par value	Shares outstanding as of November 6, 2015: 25,059,474

Table of Contents

TABLE OF CONTENTS

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 September 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	September 30, 2015 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 52,738	$ 77,158
Marketable securities, available for sale		91,911
Related party receivable	679	102
Inventory		3,552
Other current assets		577
Prepaid expenses	698	1,374
Other receivables	1,011	922
Total current assets	55,126	175,596
Intangible assets, net	184	10,993
Property and equipment, net	4,417	4,106
Deposits and other assets	843	3,263
Total assets	$ 60,570	$ 193,958
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable	$ 4,209	$ 3,469
Accrued expenses	2,554	5,103
Deferred revenue	588	13,718
Debt - current		3,970
License fee payable		2,500
Other current liabilities	78	68
Total current liabilities	7,429	28,828
Debt non-current portion, net		50,647
Deferred income tax liability	25	27
Deferred revenue non-current portion	8,855	16,508
Derivative liability		1,097
Other liabilities		185
Total liabilities	16,309	97,292
Stockholders equity:		
Common stock $0.001 par value; 75,000,000 shares authorized at December 31, 2014 and September 30, 2015; 17,283,663 and 25,059,474 shares issued and outstanding at	17	25

December 31, 2014 and September 30, 2015, respectively				
Additional paid-in capital		121,028		224,034
Accumulated other comprehensive (loss) income		(171)		389
Accumulated deficit		(76,613)		(127,782)
Total stockholders equity		44,261		96,666
Total liabilities and stockholders equity	$	60,570	$	193,958

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 September 30,		Nine Months Ended September 30,	
	2014	2015	2014	2015
Revenues:				
Net product sales	$	$ 1,296	$	$ 2,065
Related party revenues	346	390	1,094	1,361
Total revenues	346	1,686	1,094	3,426
Cost and Expenses:				
Cost of sales (excluding amortization of product rights)		349		650
Amortization of product rights		505		1,468
General and administrative	3,827	5,515	11,708	16,014
Sales and marketing	367	6,283	482	11,142
Research and development	6,346	4,602	16,487	19,905
Total costs and expenses	10,540	17,254	28,677	49,179
Loss from operations	(10,194)	(15,568)	(27,583)	(45,753)
Other (income) expense:				
Change in fair value of derivative liability		(592)		181
Interest (income) expense	(5)	2,380	7,084	5,146
Other (gain) loss				(2)
(Gain) loss on foreign currency exchange	(46)	2	(3)	87
	(51)	1,790	7,081	5,412
Loss before provision for income taxes	(10,143)	(17,358)	(34,664)	(51,165)
Provision for income taxes	35	1	84	4
Net loss	$ (10,178)	$ (17,359)	$ (34,748)	$ (51,169)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.63)	$ (0.81)	$ (2.49)	$ (2.81)
Weighted-average shares outstanding, basic and diluted	16,206,530	21,530,153	13,934,824	18,182,781

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

Egalet Corporation and Subsidiaries

Consolidated Statements of Comprehensive Loss (Unaudited)

(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2015	2014	2015
Net loss	$ (10,178)	$ (17,359)	$ (34,748)	$ (51,169)
Other comprehensive income (loss):				
Unrealized gain (losses) on available for sale securities		53		(31)
Foreign currency translation adjustment	(1,037)	(65)	(986)	591
Comprehensive loss	$ (11,215)	$ (17,371)	$ (35,734)	$ (50,609)

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

Egalet Corporation and Subsidiaries

Consolidated Statements of Changes in Stockholders Equity

For the Nine Months Ended September 30, 2015 (Unaudited)

(in thousands, except share data)

	Stockholders Equity					
	Common Stock					
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Accumulated Deficit	Accumulated Comprehensive Income (loss)	Total
Balance, December 31, 2014	17,283,663	$ 17	$ 121,028	$ (76,613)	$ (171)	$ 44,261
Issuance of warrants			329			329
Exercise of warrants	61,644					
Issuance of restricted shares of common stock	40,000					
Issuance of common stock, net of costs	7,666,667	8	80,775			80,783
Issuance of convertible debt			18,105			18,105
Exercise of stock options	7,500		82			82
Stock-based compensation expense			3,715			3,715
Unrealized loss on available for sales securities					(31)	(31)
Foreign currency translation adjustment					591	591
Net loss				(51,169)		(51,169)
Balance, September 30, 2015	25,059,474	$ 25	$ 224,034	$ (127,782)	$ 389	$ 96,666

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

Egalet Corporation and Subsidiaries

Consolidated Statements of Cash Flows (Unaudited)

(in thousands)

	Nine months Ended September 30,	
	2014	**2015**
Operating activities:		
Net loss	$ (34,748)	$ (51,169)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	466	2,267
Change in fair value of derivative liability		181
Stock-based compensation expense	7,504	3,715
Noncash interest	6,987	184
Amortization of premium on marketable securities		497
Amortization of debt discount		2,484
Deferred income taxes	2	4
Changes in assets and liabilities, net of business acquisitions:		
Related party receivable	(199)	523
Inventory		(144)
Prepaid expenses	(639)	(708)
Other current assets		(577)
Other receivables		(1)
Deposits and other assets		(1,288)
Accounts payable	334	(724)
Accrued expenses	1,702	2,595
Deferred revenue	(410)	21,415
Other current liabilities	27	(4)
Net cash used in operating activities	(18,974)	(20,750)
Investing activities:		
Payments for purchase of property and equipment	(427)	(704)
Deposits for purchases of property and equipment	(2,389)	(1,177)
Purchases of investments		(96,625)
Sales of investments		3,388
Maturity of investments		798
Purchase of SPRIX		(8,128)
License of OXAYDO		(5,172)
Net cash used in investing activities	(2,816)	(107,620)
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	80,783
Net cash provided by financing activities	66,982	152,361
Effect of foreign currency translation on cash and cash equivalents	(1,167)	429
Net increase in cash and cash equivalents	44,025	24,420
Cash and cash equivalents beginning of period	15,700	52,738
Cash and cash equivalents end of period	$ 59,725	$ 77,158
Supplemental disclosure of cash flow information:		

Issuance of warrants	$		$	329
Liability for contractual payment associated with OXAYDO license	$		$	2,500
Cash interest payments	$		$	2,546
Conversion of convertible preferred stock	$	14,957	$	
Conversion of related party convertible debt	$	24,713	$	

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

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 treatments for pain and other conditions. 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 OXAYDOTM (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 an immediate-release (IR) oral formulation of oxycodone HCl indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. OXAYDO is the first and only approved IR oxycodone product formulated to discourage abuse via snorting. In addition, using our proprietary Guardian Technology, the Company is developing a pipeline of clinical-stage, opioid-based product candidates, as well as a stimulant product candidate, 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 patents and filed patent applications to protect its inventions covering both the Guardian technology and its products.

Liquidity

The Company has incurred recurring operating losses since inception. As of September 30, 2015, the Company had an accumulated deficit of $127.8 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 below), 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 anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research and development of its preclinical and clinical product candidates, and the development of its administrative organization. As the Company continues to incur losses, a transition to profitability is dependent upon the successful commercialization of its approved products, the successful development, approval and commercialization of its approved products and 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.

Table of Contents

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.

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.

On July 31, 2015, the Company completed an underwritten public offering (the Follow-On 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 net offering proceeds to the Company from the sale were $80.8 million, after deducting underwriting discounts and commissions of $5.2 million and offering costs of $293,000.

During the nine months ended September 30, 2015, the Company had 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.

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 September 30, 2015 and for the three and nine months ended September 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 September 30, 2015 and for the three and nine months ended September 30, 2014 and 2015. The financial data and other information disclosed in these notes related to the three and nine months ended September 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 Condensed Consolidated Balance Sheets based upon the nature of the securities and their intended use to fund operations.

Table of Contents

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 the Financial Accounting Standards Board (FASB) Standards Codification (ASC) 320, *Investments Debt and Equity Securities*. The Company s 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 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. 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 price 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 September 30, 2015, the Company had deferred revenue of $12.6 million related to sales of SPRIX to its specialty pharmaceutical distributor. In the event the related units are not dispensed pursuant to patient prescriptions prior to their expiration in April and May of 2016, they may be returned to the Company.

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. Refer to 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 September 30, 2015, the deferred revenue balance consisted of $12.6 million for SPRIX product sales, all of which is classified as current, and $17.6 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:

Table of Contents

Specialty Pharmacy Discounts. The Company offers a discount to a certain specialty pharmaceutical distributor based on a contractually determined rate. 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 for SPRIX to patients, 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 September 30, 2015, inventory consisted of raw materials and deferred cost of goods.

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

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%.

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 5.50% 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 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 has determined that this feature is an embedded derivative and have recognized the fair value of this derivative as a liability on the Company s balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company s 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.

Table of Contents

Recent Accounting Pronouncements

On April 7, 2015, the FASB issued Accounting Standards Update (ASU) 2015-03,1 *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 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 FASB issued 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 FASB 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 ASU No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern, 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 for annual reporting periods beginning in 2016 and for interim reporting periods starting in the first quarter of 2017. The Company is currently evaluating the impact of the adoption of ASU 2014-15 on its financial statements.

3. Investments

Marketable Securities

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

	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	$ 91,942	$	$ (31)	$ 91,911
Total	$ 91,942	$	$ (31)	$ 91,911

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

The fair value of marketable securities with a maturity of less than one year is $63.7 million. All remaining securities have a maturity of one to two years.

4. Inventory

Inventory is stated at the lower of cost or market using actual cost net of reserve for excess and obsolete inventory. The following represents the components of inventory at September 30, 2015. There was no inventory at December 31, 2014.

(in thousands)	September 30, 2015
Raw materials	$ 1,066
Work in process	
Finished goods	
Deferred cost of sales	2,486
Total	$ 3,552

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 September 30, 2015:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	$ 7,672	$ (797)	$ 6,875	6.25
SPRIX product rights	4,620	(672)	3,948	4.25
IP R&D	170		170	Indefinite
Total	$ 12,462	$ (1,469)	$ 10,993	

Table of Contents

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

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

There was no impairment to intangible assets recognized in the nine months ended September 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 nine months ended September 30, 2015, the Company recognized amortization expense of $274,000 and $797,000, respectively, related to the OXAYDO product right intangible.

Purchase Agreement with Luitpold

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 nine months ended September 30, 2015, the Company recognized amortization expense of $231,000 and $672,000, respectively, related to the SPRIX product rights intangible asset.

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

In connection with the acquisition of Egalet A/S, the Company recognized an IP R&D asset related to the drug delivery platform specifically designed to help deter physical abuse of pain medications. The IP R&D is considered an indefinite-lived intangible asset and is assessed for impairment annually or more frequently if impairment indicators exist. As of December 31, 2014 and September 30, 2015, the carrying value of IP R&D was $184,000, and $170,000, 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 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.

Table of Contents

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	

On August 3, 2015, Hercules exercised the warrant in full, electing the net issuance option. As a result, the Company issued 61,644 shares of the Company s common stock to Hercules.

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.

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.

Table of Contents

The conversion rate for the 5.50% 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 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.

The conversion criteria for the 5.50% Notes have not been met at September 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.

Table of Contents

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

		September 30, 2015
Gross proceeds	$	61,000
Unamortized debt discount		(20,895)
Carrying value	$	40,105

7. Fair Value Measurements

The Company measures certain assets and liabilities at fair value in accordance with 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 September 30, 2015			
	Level 1	Level 2	Level 3	Balance as of September 30, 2015
Assets				
Money market funds	$ 55,455	$	$	$ 55,455
Marketable securities, available-for-sale		91,911		91,911
Total assets	$ 55,455	$ 91,911	$	$ 147,366

Liabilities				
Interest make-whole derivative	$	$	$ 1,097	$ 1,097
Total assets	$	$	$ 1,097	$ 1,097

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

There were no financial liabilities subject to fair value measurement on a recurring basis at December 31, 2014.

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%. The Company has determined that this feature is an embedded derivative and have recognized the fair value of this derivative as a liability in the Company s balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the Company s 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.

Table of Contents

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

	December 31, 2014	Additions	Fair Value Change in 2015	September 30, 2015
Interest make-whole derivative		$ 916	$ 181	$ 1,097
Total liabilities	$	$ 916	$ 181	$ 1,097

As of September 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 the Company s convertible debt at September 30, 2015 was as follows:

	Fair Value	Carrying Value	Face Value
5.50% convertible senior notes due April 1, 2020	$ 40,249	$ 40,105	$ 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 September 30, 2014	2015	Nine months ended September 30, 2014	2015
Basic and diluted net loss per common share calculation:				
Net loss	$ (10,178)	$ (17,359)	$ (34,748)	$ (51,169)
Weighted-average common shares outstanding	16,206,530	21,530,153	13,934,824	18,182,781
Net loss per share of common stock basic and diluted	$ (0.63)	$ (0.81)	$ (2.49)	$ (2.81)

The following outstanding securities at September 30, 2014 and 2015 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	September 30,	
	2014	2015
Options outstanding	238,957	1,219,721
Unvested restricted stock awards	881,240	693,572
Common shares issuable upon conversion of the 5.50% notes		4,102,360
Total	1,120,197	6,015,653

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 number of shares of common stock initially reserved for issuance under the Plan was 1,680,000, in the form of restricted stock and

Table of Contents

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 the Company s 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 September 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	(1,219,721)
Restricted stock awards granted	(1,436,160)
Remaining shares available for future issuance	1,024,119

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:

	Three Months Ended September 30,		Nine months Ended September 30,	
(in thousands)	**2014**	**2015**	**2014**	**2015**
Research and development	$ 842	$ 235	$ 3,225	$ 775
General and administrative	1,154	988	4,279	2,796
Sales and marketing		72		144
Total stock-based compensation expense	$ 1,996	$ 1,295	$ 7,504	$ 3,715

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	639,910	10.34	
Exercised	(7,500)	10.99	
Forfeited	(46,237)	10.63	
Expired	(5,000)	11.50	
Balance, September 30, 2015	1,219,721	$ 8.82	9.29
Vested or expected to vest at September 30, 2015	1,188,379	$ 8.82	9.29
Exercisable at September 30, 2015	56,553	$ 11.01	8.73

The intrinsic value of 1,219,721 options outstanding as of September 30, 2015 was $5.4 million, based on a per share price of $13.18, the Company s closing stock price on that date, and a weighted-average exercise price of $8.82 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 nine months ended September 30, 2015 was estimated at $6.99 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.72%
Expected term of options (in years)	6.25
Expected volatility	76.13%
Dividend yield	

Table of Contents

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 September 30, 2015, there was $6.0 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 3.33 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 operating officer and senior vice president of research and development. On March 3, 2014, the Company granted an aggregate of 250,560 shares of restricted stock to three individuals who were providing research and development consulting services to the Company. On May 1, 2014, the Company granted an aggregate of 257,800 shares of restricted stock to certain employees at a grant date fair value of $11.15 per share. On August 5, 2014, the Company granted 25,000 shares of restricted stock to its chief medical officer. On January 2, 2015 the Company granted 40,000 shares of restricted stock to its chief commercial officer.

A summary of the status of the Company s restricted stock awards at September 30, 2015 and of changes in restricted stock awards outstanding under the Plan for the nine months ended September 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
Forfeited	(13,920)	$	13.04
Vested restricted stock awards	(165,043)	$	11.63
Outstanding balance at September 30, 2015	693,572	$	11.38

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 September 30, 2015, there was $5.7 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.64 years.

Table of Contents

10. Commitments and Contingencies

Employment Agreements

The Company has entered into employment agreements with its president and chief executive officer, chief financial officer, chief operating 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. On June 3, 2015, Apotex filed a Motion to Enforce Settlement alleging that Apotex, Luitpold and Recordati came to an agreement on the essential terms of a settlement prior to Egalet s acquisition of SPRIX from Luitpold. Based on a thorough investigation, Egalet strongly denied Apotex s allegations as baseless. A hearing on the motion will be set for the near future. Aside of this motion, the 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 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. The Company has reviewed Purdue s assertion and, consistent with our answer filed on May 29, 2015, believe that the Company does not infringe a valid 007 patent. 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.

Based on the information currently available, the Company does not believe a loss is probable or reasonably estimable related to the above matters, and no accrual was recorded as of September 30, 2015

Table of Contents

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 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 September 30, 2015. For the nine months ended September 30, 2014 and 2015, the Company recognized revenue of $409,000 and $719,000, respectively, related to the amortization of deferred revenue.

Additionally, during the nine months ended September 30, 2014 and 2015, the Company recognized revenue of $685,000 and $642,000, 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 new drug application (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 $150.0 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 the Comany, a stepped royalty at percentage rates ranging from mid-single digits to double-digits on net sales during a calendar year based on OXAYDO 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. The Company 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 U.S.). 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.

Table of Contents

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 (API) from Luitpold, and agreed to purchase an additional $340,000 of 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 three 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 nine months ended September 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 recorded as general and administrative expense in the consolidated statement of operations.

The following table presents supplemental pro forma information for the three and nine months ended September 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 nine months ended September 30, 2015:

(in thousands, except per share data)		Three months ended September 30, 2014 (unaudited)	Nine months ended September 30, 2014 (unaudited)
Pro forma product sales	$	808	2,814
Pro forma net loss		(10,885)	(37,960)
Pro forma net loss per share	$	(0.67)	(2.72)

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 September 30, 2014 and 2015, the Company recorded tax expense of $35,000 and $1,000, respectively. For the nine months ended September 30, 2014 and 2015, the Company recorded tax expense of $84,000 and $4,000, respectively

As of December 31, 2014 and September 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 IP R&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 nine months ended September 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 September 30, 2015, related party receivables with Shionogi were $679,000 and $102,000, respectively and consisted entirely of revenue from development costs incurred under the Company s collaborative research and license agreement.

Table of Contents

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 re not converted) and the performance of third parties, including contract research organizations and manufacturers.

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

Overview

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

We are a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative medicines for patients with pain and other conditions. In January 2015, we announced the acquisition and license of two FDA-approved innovative pain products, SPRIX® (ketorolac tromethamine) Nasal Spray and OXAYDO (oxycodone HCl, USP) tablets for oral use only CII, respectively. 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 an immediate-release (IR) oral formulation of oxycodone HCl indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. OXAYDO is the first and only approved IR oxycodone product formulated to discourage abuse via snorting. In addition, using our proprietary Guardian Technology, we are developing a pipeline of clinical-stage, opioid-based product candidates and a stimulant product candidate that are specifically designed to deter abuse by physical and chemical manipulation.

In the third quarter of 2015, we initiated the commercial promotion of OXAYDO to target the approximately 7,000 physicians in the high-decile of prescribing pain medicines in the U.S. We grew sales of SPRIX approximately 114 percent from the second quarter to the third quarter of 2015. We completed a successful pre-NDA meeting with the FDA regarding the NDA for ARYMOTM, the conditionally approved name for our product candidate previously known as Egalet-001, and are on track to file the

Table of Contents

NDA in the fourth quarter of 2015. During the annual PainWeek conference in Las Vegas, we presented five scientific abstracts: one on SPRIX Nasal SPRAY, three on ARYMO and one on Egalet-002. Also in the third quarter of 2015, we announced plans to submit an IND application to begin development of an abuse-deterrent stimulant, Egalet-003, in the second half of 2016.

Commercial Products

OXAYDO

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

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

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 has been 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.

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 announced in the third quarter of 2015 that we plan to expand the sales force, now with OXAYDO on the market and ARYMO potentially, if approved, on the market in 2016. We expect to have an additional 21 sales representatives in place by the beginning of 2016. 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.

At the same time, we are recruiting for some of our current territories where we have had expected turnover. It is important that we have effective territory managers, not just for the commercial success of SPRIX and OXAYDO but ultimately for the potential launch of ARYMO, if

approved, in 2016.

Pipeline Products

We are developing two late-stage product candidates specifically designed to deter abuse by physical and chemical manipulation. The clinical development program for ARYMO has been completed and Egalet-002 is in late-stage clinical development; both of these product candidates are 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.

ARYMO

ARYMO, an abuse-deterrent, ER morphine, was designed using our Guardian Technology to deter all forms of abuse but primarily abuse via the route of injection the most common method of abuse of morphine. The ARYMO tablet consists of a hard matrix that erodes as it passes through the gastrointestinal (GI) 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 ARYMO, if approved, would fill a significant unmet need in the marketplace. Clinically, we have completed multiple Phase 1 pharmacokinetic (PK) studies and completed pivotal bioequivalence studies demonstrating bioequivalence of ARYMO 15 mg, 30 mg and 60 mg to comparable doses of MS Contin. In the pivotal 60 mg BE Study, an additional fed arm also demonstrated the lack of any clinically significant food effect with ARYMO. Also, we have completed Category 1 abuse-deterrent studies demonstrating the unique physical and chemical properties of the product. We announced in January of 2015 positive top-line data

Table of Contents

from a Category 3 abuse-deterrent oral HAP study, which demonstrated lower drug liking of ARYMO compared to MS Contin. We completed and reported top-line results from a Category 3 abuse-deterrent intranasal HAP study which demonstrated lower drug liking for ARYMO compared to MS Contin. In addition, ARYMO was designed not to have any significant alcohol dose dumping and this was supported with data from an in vitro alcohol interaction study which showed no evidence of dose dumping in the presence of alcohol. We plan to seek U.S. regulatory approval of ARYMO pursuant to Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. Having completed pivotal BE and abuse-deterrent studies for ARYMO, we anticipate submitting an NDA in the fourth quarter of 2015.

Egalet-002

Egalet-002, an abuse-deterrent, ER oxycodone is designed using our Guardian Technology, as a tablet with a similar matrix construct, but with an added hard impermeable shell, around the outside. The shell, which passes through the 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 not to have any significant interaction with food (e.g. 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 is the difference between the highest concentration of an API in the bloodstream and the lowest concentration of such API in the bloodstream. We believe the low variability we have observed in Egalet-002 will result in better, more consistent pain relief and reduced use of rescue medication to treat breakthrough pain, as compared to oxycodone-based products that exhibit higher variability.

We 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 that demonstrated that Egalet-002 was more resistant to common and rigorous forms of physical manipulation used to defeat the tablet compared to reformulated, abuse-deterrent OxyContin. These are the manipulations that are attempted in order to snort oxycodone intranasally, which is the most common route of abuse of 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 HAP study which tested a more rigorous method of manipulation than previously conducted oral HAP studies. Many oral HAP 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 HAP study. The method for Egalet-002 involved serial manipulations, using both mechanical and electrical instruments, as compared to both IR oxycodone and OxyContin, which both required only a one-step manipulation process. The results of the oral HAP 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 pivotal oral and intranasal HAP studies for Egalet-002. We are conducting our 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 have an ongoing Phase 3 safety and efficacy program for Egalet- 002. We anticipate

submitting an NDA for Egalet-002 in mid-2017.

Egalet-003

Given the growing problem of prescription stimulant abuse, we have selected a stimulant as our Egalet-003 product candidate to be developed using our Guardian Technology. According to the Office of Applied Studies, Substance Abuse and Mental Health Services Administration, National Survey on Drug Use and Health, in 2010, 1.1 million Americans reported abusing stimulants. We plan to file an IND in the second half of 2016 and will seek a path to approval similar to that of ARYMO, using bioequivalence and abuse-deterrent studies.

Collaboration

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

Table of Contents

candidates using our Guardian 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 IPO. 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 future milestone payments upon development and approval of product candidates under the agreement, which may exceed $290.0 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.

Financial Operations

Our net losses were $10.2 million and $17.4 million for the three months ended September 30, 2014 and 2015, respectively, and net losses were $34.7 million and $51.2 million for the nine months ended September 30, 2014 and 2015 respectively. We recognized revenues of $346,000 and $1.7 million for the three months ended September 30, 2014 and 2015, respectively, and revenues of $1.1 million and $3.4 million for the nine months ended September 30, 2014 and 2015, respectively. As of September 30, 2015, we had an accumulated deficit of $127.8 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, as well as scale-up manufacturing capabilities, protect and expand our intellectual property portfolio and hire additional personnel. Additionally, we expect to incur significant commercialization expenses in establishing a sales, marketing and distribution infrastructure to sell our products in the U.S.

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.

Table of Contents

Inventory

Inventories are stated at the lower of cost or market net of reserve for excess and obsolete inventory. At September 30, 2015, inventory consisted of raw materials 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 tablets, and IP R&D related to our drug delivery platform technology we acquired as part of the acquisition of Egalet A/S.

We make 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 ASC Topic 718, Compensation Stock Compensation. 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 nine months ended September 30, 2015:

Risk-free interest rate	1.72%
Expected term of options (in years)	6.25
Expected volatility	76.13%
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 operating 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.

Table of Contents

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 September 30, 2015, there was $5.7 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.64 years.

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 5.50% Notes) are not required to be separately accounted for as derivatives. However, since the 5.50% 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 5.50% 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 5.50% 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 5.50% Notes was estimated at $40.6 million at issuance. Therefore, the difference between the $61.0 million face value of the 5.50% Notes and the $40.6 million estimated fair value of the liability component will be amortized to interest expense over the term of the 5.50% 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 our 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 5.50% notes, if the last reported sale price of our 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 the 5.50% notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; or

- upon the occurrence of specified corporate events.

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

Table of Contents

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 5.50% 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 5.50% 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.

Results of Operations

Comparison of the three months ended September 30, 2014 and 2015

	Three months ended September 30,		
(in thousands)	**2014**	**2015**	**Change**
Revenues:			
Net product sales	$	$ 1,296	$ 1,296
Related party revenues	346	390	44
Total revenues	346	1,686	1,340
Costs and Expenses:			
Cost of sales (excluding product rights amortization)		349	349
Amortization of product rights		505	505
General and administrative	3,827	5,515	1,688
Sales and marketing	367	6,283	5,916
Research and development	6,346	4,602	(1,744)
Total costs and expenses	10,540	17,254	6,714
Loss from operations	(10,194)	(15,568)	5,374
Change in fair value of derivative liability		(592)	(592)
Interest (income) expense	(5)	2,380	2,385
Loss (gain) on foreign currency exchange	(46)	2	48
Loss from operations before income taxes	(10,143)	(17,358)	7,215
Provision for income taxes	35	1	(34)
Net loss	$ (10,178)	$ (17,359)	$ 7,181

Net Product Sales

Net product sales were $1.3 million for the three months ended September 30, 2015 and consisted entirely of SPRIX product sales. There were no product sales in 2014.

Related Party Revenues

Related party revenues increased from $346,000 for the three months ended September 30, 2014 to $390,000 for the three months ended September 30, 2015 as a result of an increase in amortization of deferred revenue related to the $10.0 million payment received from Shionogi in the second quarter of 2015, partially offset by a decrease in research and development services performed under our collaboration agreement with Shionogi.

Table of Contents

Cost of Sales (excluding Amortization of Product Rights)

Cost of sales (excluding product amortization rights) were $349,000 in the three months ended September 30, 2015 related entirely to the sale of SPRIX. The cost of sales (excluding product amortization rights) 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 of product rights was $505,000 for the three months ended September 30, 2015 and was comprised of $274,000 for the OXAYDO and $231,000 for the SPRIX intangible assets. There was no intangible amortization in 2014.

General and Administrative Expenses

General and administrative expenses increased by $1.7 million, or 44.1%, from $3.8 million for the three months ended September 30, 2014 to $5.5 million for the three months ended September 30, 2015. This was primarily attributable to increases in employee salary and benefits of $1.0 million and $940,000 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 $166,000.

Sales and Marketing Expenses

Sales and marketing expenses increased $5.9 million from $367,000 to $6.3 million for the three months ended September 30, 2015 related to the establishment of the commercial operations in the U.S. and launch activities for SPRIX and OXAYDO. Expenses for the three months ended September 30, 2015 consisted primarily of $3.9 million in salary, benefits and our contract sales force and marketing support for SPRIX and OXAYDO of $1.5 million and $844,000, respectively. Sales and marketing costs were de minimis for 2014.

Research and Development Expenses

Research and development expenses decreased by $1.7 million, or 27.5%, from $6.3 million for the three months ended September 30, 2014 to $4.6 million for the three months ended September 30, 2015. This decrease was driven primarily by a decrease in our development costs for ARYMO of $2.8 million and a decrease in stock compensation expense of $607,000. These decreases were partially offset by an increase in our development costs of EG-002 of $2.0 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 $592,000 is due primarily to the decrease in the value of our common stock during the three months ended September 30, 2015. There was no change in derivative liability for the three months ended September 30, 2014.

Interest expense

Interest expense was $2.4 million for the three months ended September 30, 2015 compared to interest income of $5,000 for the three months ended September 30, 2014. The increase was attributable to the $2.4 million in interest expense that was recorded in the 2015 period in connection with the Hercules Loan and the 5.50% Notes.

Gain on Foreign Currency Exchange

For the three months ended September 30, 2014, we recognized a gain on foreign currency exchange of $46,000. For the three months ended September 30, 2015, we recognized a loss on foreign currency exchange of $2,000. This difference is primarily attributable the change in the average rates of currency in which we transacted during 2014 when compared to 2015.

Provision for Income Taxes

We had a provision for income taxes of $35,000 and $1,000 for the three months ended September 30, 2014 and 2015, respectively. During the three months ended September 30, 2015, tax expense was recorded due to amortization of the indefinite-lived intangible asset.

Table of Contents

Comparison of the nine months ended September 30, 2014 and 2015

(in thousands)	Nine months ended September 30, 2014	2015	Change
Revenues:			
Net product sales	$	$ 2,065	$ 2,065
Related party revenues	1,094	1,361	267
Total revenues	1,094	3,426	2,332
Costs and Expenses:			
Cost of sales (excluding product rights amortization)		650	650
Amortization of product rights		1,468	1,468
General and administrative	11,708	16,014	4,306
Sales and marketing	482	11,142	10,660
Research and development	16,487	19,905	3,418
Total costs and expenses	28,677	49,179	20,502
Loss from operations	(27,583)	(45,753)	18,170
Change in fair value of derivative liability		181	181
Interest expense	7,084	5,146	(1,938)
Other (gain) loss		(2)	(2)
Loss (gain) on foreign currency exchange	(3)	87	90
Loss from operations before income taxes	(34,664)	(51,165)	16,501
Provision for income taxes	84	4	(80)
Net loss	$ (34,748)	$ (51,169)	$ 16,421

Net Product Sales

Net product sales were $2.1 million for the nine months ended September 30, 2015 and consisted entirely of the sale of SPRIX. There were no product sales in 2014.

Related Party Revenues

Related party revenues increased from $1.1 million for the nine months ended September 30, 2014 to $1.4 million for the nine months ended September 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)

Cost of sales (excluding product amortization rights) was $650,000 in 2015 related entirely to the sale of SPRIX. The cost of sales (excluding product amortization rights) 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 of product rights was $1.5 million for the nine months ended September 30, 2015 and was comprised of $796,000 for the OXAYDO and $672,000 for the SPRIX intangible assets. There was no intangible amortization in 2014.

General and Administrative Expenses

General and administrative expenses increased by $4.3 million, or 36.8%, from $11.7 million for the nine months ended September 30, 2014 to $16.0 million for the nine months ended September 30, 2015. This was primarily attributable to an increase in professional fees (legal, accounting and tax, and insurance) of $3.1 million and an increase in employee salary and benefits of $2.5 million as we continue to expand our U.S. operations. These increases were offset by a decrease in stock compensation expense of $1.5 million.

Table of Contents

Sales and Marketing Expenses

Sales and marketing expenses increased $10.7 million from $482,000 to $11.1 million for the nine months ended September 30, 2015 related to the establishment of the commercial operations in the U.S. and launch activities for SPRIX and OXAYDO. Expenses for the nine months ended September 30, 2015 consisted primarily of $5.2 million in salary, benefits and our contract sales force and marketing support for SPRIX and OXAYDO of $1.8 million and $1.8 million, respectively. Sales and marketing costs were de minimis for 2014.

Research and Development Expenses

Research and development expenses increased by $3.4 million, or 20.7%, from $16.5 million for the nine months ended September 30, 2014 to $19.9 million for the nine months ended September 30, 2015. This increase was driven primarily by an increase in our development costs for Egalet-002 of $6.1 million and an increase is employee salary and benefits of $474,000. This was partially offset by a decrease in our development costs for ARYMO of $1.4 million and a decrease in stock compensation expense of $2.4 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 $181,000 is due primarily to the increase in the value of our common stock from the date of issuance of the 5.50% Notes on April 1, 2015 through September 30, 2015. There was no change in derivative liability for the nine months ended September 30, 2014.

Interest Expense

Interest expense decreased by $2.0 million, from $7.1 million for the nine months ended September 30, 2014, to $5.1 for the nine months ended September 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 $5.1 million for the nine months ended September 30, 2015 due to interest on the Hercules Loan and the 5.50% Notes.

Other Gain

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

Loss on Foreign Currency Exchange

For the nine months ended September 30, 2014 we recognized a gain on foreign currency exchange of $3,000 and for the nine months ended September 30, 2015 we recognized a loss on foreign currency exchange of $87,000. 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 $84,000 and $4,000 for the nine months ended September 30, 2014 and 2015, respectively. During the nine months ended September 30, 2015, tax expense was recorded due to amortization of the indefinite-lived intangible asset.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and generally negative cash flows from our operations. We incurred net losses of $34.7 million and $51.2 million for the nine months ended September 30, 2014 and 2015, respectively. Our operating activities used $19.0 million of cash during the nine months ended September 30, 2014 and used $20.8 million of cash during the nine months ended September 30, 2015. At September 30, 2015, we had an accumulated deficit of $127.8 million, a working capital surplus of $146.8 million and cash, cash equivalents and marketable securities totaling $169.1 million.

Table of Contents

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 September 30, 2015 we have also financed our operations with the $3.9 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 $15.0 million under a term loan. Refer to Note 6 Long Term Debt in the Notes to our Unaudited Consolidated Financial Statements, for additional information.

In April 2015, we issued through a private placement $60.0 million in aggregate principal amount of 5.50% 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 2, 2015, we entered into a sale agreement with Cantor Fitzgerald & Co. (Cantor) to offer shares of our common stock from time to time through Cantor, as our sales agent for the offer and sale of the shares, in an at-the-market offering. We may offer and sell shares of common stock for an aggregate offering price of up to $30.0 million.

On July 31, 2015, we 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 net offering proceeds from the sale were $80.8 million, after deducting underwriting discounts and commissions of $5.2 million and offering costs of $293,000.

During the nine months ended September 30, 2015, we had 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 nine months ended September 30, 2014 and 2015:

(in thousands)	Nine months Ended September 30, 2014	2015
Net cash (used in) provided by:		
Operating activities	$ (18,974)	$ (20,750)
Investing activities	(2,816)	(107,620)
Financing activities	66,982	152,361
Effect of foreign currency translation on cash and cash equivalents	(1,167)	429
Net increase in cash and cash equivalents	$ 44,025	$ 24,420

Cash Flows from Operating Activities

Net cash used in operating activities was $19.0 million for the nine months ended September 30, 2014 and consisted primarily of a net loss of $34.7 million. These outflows were partially offset by non-cash items consisting of $7.5 million of stock-based compensation, $7.0 million in accretion of the debt premium to interest expense, and net cash inflows of $815,000 from the change in operating assets and liabilities.

Table of Contents

Net cash used in operating activities was $20.8 million for the nine months ended September 30, 2015 and consisted primarily of a net loss of $51.2 million offset by an increase in deferred revenue of $21.4 million generated by the Shionogi milestone received and sales of SPRIX in the first quarter of 2015, non-cash items consisting of $3.7 million of stock-based compensation, $2.3 million of amortization and depreciation expense, and $2.5 million of amortization of debt discount related to the Hercules Loan Agreement and 5.50% Notes. Net cash outflows from changes in other operating assets and liabilities were $327,000 primarily due to an increase in deposits and other assets of $1.3 million, a decrease in accounts payable of $724,000 and an increase in prepaid expenses of $707,000. These were partially offset by an increase in accrued expenses of $2.6 million.

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2014 was $2.8 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 nine months ended September 30, 2015 was $107.6 million and consisted of $96.6 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 $1.9 million for deposits and purchases of property and equipment. These outflows were offset by the sale of investments of $3.4 million and the maturity of investments of $798,000.

Cash Flows from Financing Activities

Net cash provided by financing activities was $67.0 million for the nine months ended September 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 to Shionogi.

Net cash provided by financing activities was $152.4 million for the nine months ended September 30, 2015 and consisted of the net proceeds from Hercules Loan Agreement of $14.7 million, net proceeds from the issuance of the 5.50% Notes of $56.8 million and the net proceeds from the Follow on Offering of $80.8 million.

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 ARYMO 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.

Table of Contents

We believe that our existing capital resources, including the net proceeds from our IPO and the concurrent private placement with Shionogi, the Hercules Loan Agreement, 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;

•the potential need for a Phase 3 safety and efficacy study with respect to ARYMO;

•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.

Commitments

Purchase Commitments

During the three and nine month period ended September 30, 2015, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our Quarterly Report on Form 10-Q filed with the SEC on August 7, 2015.

Employment Agreements

We have entered into employment agreements with our president and chief executive officer, chief financial officer, chief operating 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.

Table of Contents

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 September 30, 2015 and December 31, 2014, we had cash and cash equivalents and marketable securities of $52.7 million and $169.1 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 (CEO) and chief financial officer (CFO), 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 September 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 our management, including our CEO and CFO, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control Over Financial Reporting

During the nine months ended September 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.

Table of Contents

PART II

ITEM 1. LEGAL PROCEEDINGS

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 September 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. On August 3, 2015, Hercules exercised the warrant in full, electing the net issuance option. As a result the we issued 61,644 shares to Hercules.

Use of Proceeds

On February 5, 2014, our Registration Statement on Form S-1 (File No. 333-191759) (the Form S-1) was declared effective by the SEC for our IPO pursuant to which we sold an aggregate of 4,830,000 shares of our common stock at a price to the public of $12.00 per share. From the effective date of the Form S-1 through September 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.

Table of Contents

ITEM 6. EXHIBITS

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

Exhibit Number	Description
1.1	Underwriting Agreement, dated July 28, 2015, by and among Egalet Corporation and the underwriters named therein. (Incoporated by reference to Exhibit 1.1 to the Company s Current Report on Form 8-K filed with the SEC on July 28, 2015).
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	Controlled Equity OfferingSM Sales Agreement, dated July 2, 2015, by and between Egalet Corporation and Cantor Fitzgerald & Co. (Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the SEC on July 2, 2015).
10.2	Amended & Restated Egalet Corporation 2013 Stock-Based Incentive Plan.
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).

Table of Contents

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: November 6, 2015

EGALET CORPORATION

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
1.1	Underwriting Agreement, dated July 28, 2015, by and among Egalet Corporation and the underwriters named therein. (Incoporated by reference to Exhibit 1.1 to the Company s Current Report on Form 8-K filed with the SEC on July 28, 2015).
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	Controlled Equity OfferingSM Sales Agreement, dated July 2, 2015, by and between Egalet Corporation and Cantor Fitzgerald & Co. (Incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the SEC on July 2, 2015).
10.2	Amended & Restated Egalet Corporation 2013 Stock-Based Incentive Plan.
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).