Egalet Corp
Form 10-Q
August 05, 2016
Table of Contents

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2016

Or

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

For the transition period from to

Commission File Number 001-36295

Egalet Corporation

(Exact Name of Registrant as Specified in Its Charter)

Delaware	46-3575334
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
600 Lee Road Suite 100 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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T

(§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company

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

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

Common Stock, $0.001 par value	Shares outstanding as of August 5, 2016: 25,124,122

Table of Contents

TABLE OF CONTENTS

Unless otherwise indicated or the context otherwise requires, references to the "Company", "we", "us" and "our" refer to Egalet Corporation and its subsidiaries, including its predecessor Egalet Limited ("Egalet UK"), which was acquired on November 26, 2013. The Egalet logo is our trademark and Egalet is our registered trademark. All other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this Quarterly Report on Form 10-Q, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Quarterly Report on Form 10-Q without the trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense. Unless otherwise indicated, all statistical information provided about our business in this report is as of June 30, 2016.

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, 2015	June 30, 2016 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 46,665	$ 35,021
Marketable securities, available for sale	99,042	68,647
Accounts receivable	295	820
Related party receivable	57	-
Inventory	1,837	1,742
Prepaid expenses and other current assets	1,295	1,142
Other receivables	1,047	1,089
Total current assets	150,238	108,461
Intangible assets, net	10,380	9,405
Property and equipment, net	7,801	12,268
Deposits and other assets	3,997	3,440
Total assets	$ 172,416	$ 133,574
Liabilities and stockholders’ equity		
Current liabilities:		
Accounts payable	7,417	6,112
Accrued expenses	7,616	9,026
Deferred revenue	10,128	7,182
Debt - current	3,320	6,809
Other current liabilities	183	383
Total current liabilities	28,664	29,512
Debt - non-current portion, net	52,442	51,439

Deferred income tax liability	1,084	662
Derivative liability	656	3
Other liabilities	348	1,504
Total liabilities	83,194	83,120
Commitments and contingencies (Note 10)		
Stockholders’ equity		
Common stock--$0.001 par value; 75,000,000 shares authorized at December 31, 2015 and June 30, 2016; 25,085,554 and 25,094,122 shares issued and outstanding at December 31, 2015 and June 30, 2016, respectively	25	25
Additional paid-in capital	223,784	226,808
Accumulated other comprehensive (loss) income	(41)	495
Accumulated deficit	(134,546)	(176,874)
Total stockholders' equity	89,222	50,454
Total liabilities and stockholders’ equity	$ 172,416	$ 133,574

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

Egalet Corporation and Subsidiaries

Consolidated Statements of Operations (Unaudited)

(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2016	2015	2016
Revenues				
Net product sales	$ 607	$ 3,450	$ 769	$ 6,013
Collaboration revenues	—	—	—	100
Related party revenues	352	—	973	—
Total revenue	959	3,450	1,742	6,113
Cost and Expenses				
Cost of sales (excluding amortization of product rights)	207	784	301	1,666
Amortization of product rights	585	503	963	1,004
General and administrative	5,804	8,854	10,499	14,852
Sales and marketing	3,284	6,280	4,859	12,482
Research and development	4,903	8,697	15,303	14,816
Total costs and expenses	14,783	25,118	31,925	44,820
Loss from operations	(13,824)	(21,668)	(30,183)	(38,707)
Other (income) expense:				
Change in fair value of derivative liability	773	(43)	773	(653)
Interest expense, net	2,306	2,315	2,766	4,624
Other (gain) loss	(2)	69	(2)	66
Loss on foreign currency exchange	188	5	85	3
	3,265	2,346	3,622	4,040
Loss before provision (benefit) for income taxes	(17,089)	(24,014)	(33,805)	(42,747)
Provision (benefit) for income taxes	(23)	(237)	3	(422)
Net loss	$ (17,066)	$ (23,777)	$ (33,808)	$ (42,325)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (1.03)	$ (0.97)	$ (2.05)	$ (1.73)
Weighted-average shares outstanding, basic and diluted	16,506,798	24,468,747	16,481,354	24,437,497

See accompanying notes to unaudited consolidated financial statements.

2

Table of Contents

Egalet Corporation and Subsidiaries

Consolidated Statements of Comprehensive Loss (Unaudited)

(in thousands)

	Three Months Ended June 30,		Six months ended June 30,	
	2015	2016	2015	2016
Net loss	$ (17,066)	$ (23,777)	$ (33,808)	$ (42,325)
Other comprehensive income (loss):				
Unrealized (gain) loss on available for sale securities	(83)	7	(83)	165
Foreign currency translation adjustments	1,470	(216)	655	371
Comprehensive loss	$ (15,679)	$ (23,986)	$ (33,236)	$ (41,789)

See accompanying notes to unaudited consolidated financial statements.

Table of Contents

Egalet Corporation and Subsidiaries

Consolidated Statements of Cash Flows (Unaudited)

(in thousands)

	Six Months Ended June 30,	
	2015	2016
Operating activities:		
Net loss	$ (33,808)	$ (42,325)
Adjustment to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,482	1,705
Change in fair value of derivative liability	773	(653)
Stock based compensation expense	2,420	2,868
Noncash interest and amortization of debt discount	1,530	2,593
Amortization of premium on marketable securities	—	451
Deferred income taxes	4	(422)
Changes in assets and liabilities:		
Related party receivable	88	59
Accounts receivable	—	(525)
Inventory	(479)	95
Prepaid expenses and other current assets	15	153
Other receivables	—	(13)
Deposits and other assets	214	557
Accounts payable	(470)	(46)
Accrued expenses	2,999	1,397
Deferred revenue	23,124	(2,947)
Other current liabilities	46	195
Other liabilities	—	902
Net cash used in operating activities	(2,062)	(35,956)
Investing activities:		
Payments for purchase of property and equipment	(674)	(6,262)
Purchases of investments	(53,418)	(41,094)
Sales of investments	2,388	5,400
Maturity of investments	—	65,802
Purchase of SPRIX Nasal Spray	(8,128)	—
License of OXAYDO	(5,172)	—
Net cash (used in) provided by investing activities	(65,004)	23,846
Financing activities:		
Net proceeds from issuance of common stock	82	155
Net proceeds from debt	71,496	—
Net cash provided by financing activities	71,578	155
Effect of foreign currency translation on cash and cash equivalents	416	311

Net increase (decrease) in cash and cash equivalents	4,928	(11,644)
Cash at beginning of period	52,738	46,665
Cash at end of period	$ 57,666	$ 35,021
Supplemental disclosures of cash flow information:		
Non-cash financing activities:		
Issuance of warrants	$ 329	$ —
Cash interest payments	$ 564	$ 2,412
Liability for contractual payment associated with OXAYDO License	$ 2,500	$ —

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

Organization and Business Overview

Egalet Corporation (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 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 (the "Share Exchange"). 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.

The Company is a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative treatments for pain and other conditions. The Company was founded around its proprietary Guardian™ Technology that can be applied broadly across different classes of pharmaceutical products. Using this technology, the Company has two late-stage product candidates; ARYMO™ ER, an abuse-deterrent ("AD"), extended-release ("ER") oral morphine formulation, and Egalet-002, an AD, ER, oral oxycodone formulation, which is in a Phase 3 program (the Company's "lead product candidates"). Both lead product candidates are being developed for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The Company's Guardian Technology also can be used to develop combination products that include multiple active pharmaceutical ingredients ("APIs") with similar or different release profiles and offers the Company a number of long term growth opportunities. In January 2015, the Company acquired SPRIX® (ketorolac tromethamine) Nasal Spray and in-licensed OXAYDO® (oxycodone HCI, USP) tablets for oral use only—"CII",—both of which are approved by the Food and Drug Administration ("FDA") (the Company's "approved products"). The Company has patents and filed patent applications to protect its inventions covering both the Guardian technology and its products.

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

The accompanying consolidated financial information at June 30, 2016 and for the three and six months ended June 30, 2015 and 2016 is unaudited. The interim unaudited financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of June 30, 2016 and for the three and six months ended June 30, 2015 and 2016. The financial data and other information disclosed in these notes related to the three and six months ended June 30, 2015 and 2016 are not necessarily indicative of the results to be expected for the year ending December 31, 2016, any other interim periods or any future year or period. These

Table of Contents

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, 2015 filed on March 11, 2016 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, 2015. Since the date of those financial statements, there have been no changes to the Company's significant accounting policies.

Net Product Sales

The Company recognizes revenue in accordance with Financial Accounting Standards Board ("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 Nasal Spray in the United States to a single specialty pharmaceutical distributor subject to rights of return. The Company has limited SPRIX Nasal Spray 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 Nasal Spray until the right of return no longer exists, which occurs at the earlier of the time SPRIX Nasal Spray 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.

The Company sells OXAYDO in the U.S. to several wholesalers, all subject to rights of return. The Company has limited OXAYDO sales history under the current distribution model and pricing, and 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 OXAYDO until the right of return no longer exists, which occurs at the earlier of the time OXAYDO 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.

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 that may result in future reductions of revenue and discounts taken. In certain cases, such as patient assistance programs, the Company recognizes the cost of patient assistance programs as a reduction of revenue based on actual or estimated utilization. If actual future results vary from estimates used, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company's product sales allowances include:

Specialty Pharmacy Fees. The Company pays a fee to a certain specialty pharmaceutical distributor based on a contractually determined rate. The Company accrues the fee on shipment to the respective distributor and recognizes the fee as a reduction of revenue in the same period the related revenue is recognized.

Wholesaler Fees. The Company pays certain pharmaceutical wholesalers fees based on a contractually determined rate. The Company accrues the fees on shipment to the respective wholesalers and recognizes the fees as a reduction of revenue in the same period the related revenue is recognized.

Table of Contents

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

Recent Accounting Pronouncements

In March 2016, the FASB issued Accounting Standards Update (“ASU”) 2016-09, Improvements to Employee Share-Based Payment Accounting, which provides for simplification of certain aspects of employee share-based payment accounting including income taxes, classification of awards as either equity or liabilities, accounting for forfeitures and classification on the statement of cash flows. ASU 2016-09 will be effective for the Company in the first quarter of 2017 and will be applied either prospectively, retrospectively or using a modified retrospective transition approach depending on the area covered in this update. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will be.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will be.

In January 2016, the FASB issued ASU 2016-01, Financial Instruments - Overall (Subtopic 825-10), Recognition and Measurement of Financial Assets and Financial Liabilities, which addresses certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. ASU 2016-01 will be effective for annual periods and interim periods within those annual periods beginning after December 15, 2017 and early adoption is not permitted. The Company is currently evaluating the impact that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will be.

In November 2015, the FASB issued ASU 2015-17, Income Taxes: Balance Sheet Classification of Deferred Taxes. ASU 2015-17 simplifies the balance sheet classification of deferred taxes and requires that all deferred taxes be presented as noncurrent. ASU 2015-17 is effective for fiscal years beginning after December 15, 2016 with early adoption permitted. The adoption of this update is not expected to have a material effect on the Company's financial statements.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements—Going Concern. ASU 2014-15 requires management of all entities to evaluate whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued, and to make certain disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the entity's ability to continue as a going concern. 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 that the standard will have on the financial statements, and has not yet determined what effect, if any, the impact of adoption will be.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers. ASU 2014-09 will supersede and replace nearly all existing U.S. GAAP revenue recognition guidance, including industry-specific

Table of Contents

guidance. The guidance is effective for annual reporting periods beginning after December 15, 2017, including interim periods therein. The Company is evaluating ASU 2014-09 and has not yet determined what, if any, effect ASU 2014-09 will have on its results of operations or financial condition.

3. Investments

Marketable Securities

Marketable securities consisted of the following at December 31, 2015:

(in thousands)	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	$ 99,189	$ —	$ (147)	$ 99,042
Total	$ 99,189	$ —	$ (147)	$ 99,042

Marketable securities consisted of the following as of June 30, 2016:

(in thousands)	Cost Basis	Unrealized Gains	Unrealized Losses	Fair Value
Corporate notes and bonds	$ 68,630	$ 28	$ (11)	$ 68,647
Total	$ 68,630	$ 28	$ (11)	$ 68,647

The fair value of marketable securities as of June 30, 2016, with a maturity of less than one year is $54.5 million. The fair value of marketable securities with a maturity of greater than one year is $14.2 million.

At June 30, 2016, the Company held 11 marketable securities which were in a continuous loss position for less than one year. The unrealized losses are the result of current economic and market conditions and the Company has determined that no other than temporary impairment exists at June 30, 2016.

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 June 30, 2016:

(in thousands)	December 31, 2015	June 30, 2016
Raw materials	$ 589	$ 720
Work in process	349	340
Finished goods	230	418
Deferred cost of sales	669	264
Total	$ 1,837	$ 1,742

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 December 31, 2015:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	$ 7,552	$ (1,055)	$ 6,497	6.00
SPRIX Nasal Spray product rights	4,620	(903)	3,717	4.00
IP R&D	166	—	166	Indefinite
Total	$ 12,338	$ (1,958)	$ 10,380	

Table of Contents

The following represents the balance of the intangible assets at June 30, 2016:

(in thousands)	Gross Intangible Assets	Accumulated Amortization	Net Intangible Assets	Remaining Useful Life (in years)
OXAYDO product rights	$ 7,581	$ (1,600)	$ 5,981	5.50
SPRIX Nasal Spray product rights	4,620	(1,365)	3,255	3.50
IP R&D	169	—	169	Indefinite
Total	$ 12,370	$ (2,965)	$ 9,405	

There was no impairment to intangible assets recognized in the three and six months ended June 30, 2015 and 2016.

Collaboration and License Agreement with Acura Pharmaceuticals, Inc. (“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 (the “OXAYDO License Agreement”). The Company paid Acura an upfront payment of $5.0 million in January 2015 and a $2.5 million milestone in October 2015 as a result of the first commercial sale of OXAYDO. The Company also incurred transaction costs of $172,000 associated with the OXAYDO License Agreement. Refer to Note 11 — Acquisitions and License and Collaboration Agreements for additional details.

During the three and six months ended June 30, 2015, the Company recognized amortization expense of $249,000 and $523,000, respectively, related to the OXAYDO product right intangible. During the three and six months ended June 30, 2016 the Company recognized amortization expense of $272,000 and $542,000, respectively, related to the OXAYDO product right intangible.

Purchase Agreement with Luitpold Pharmaceuticals, Inc. (“Luitpold”)

In January 2015, the Company entered into and consummated the transactions contemplated by the Purchase Agreement with Luitpold (the “SPRIX Purchase Agreement”). Pursuant to the SPRIX 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 — Acquisitions and License and Collaboration Agreements for additional details.

During the three and six months ended June 30, 2015, the Company recognized amortization expense of $336,000 and $440,000, respectively, related to the SPRIX Nasal Spray product rights intangible asset. During the three and six months ended June 30, 2016, the Company recognized amortization expense of $231,000 and $462,000, respectively, related to the SPRIX Nasal Spray 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, 2015 and June 30, 2016, the carrying value of IP R&D was $166,000, and $169,000, 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 and Security Agreement, which was subsequently amended in December 2015 (as amended, the "Loan Agreement"), with Hercules Technology Growth Capital, Inc.

Table of Contents

("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%. Under the Loan Agreement the Company made interest only payments through July 1, 2016, with the potential for the interest only period to be extended to January 1, 2017, subject to the FDA's acceptance of the Company's new drug application for its product candidate ARYMO ER, the Company's receipt of at least $5.0 million of product revenue for any consecutive three month period prior to June 30, 2016 and there being no event of default under the Loan Agreement. The Company did not receive at least $5.0 million of product revenue in a consecutive three month period prior to June 30, 2016, and as a result began repaying the principal balance on July 1, 2016. After the interest only payment period, the Company will then repay the principal balance of the loan in 25 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.

5.50% Convertible Senior Notes Due 2020 (the "5.50% Notes")

On April 7, 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 option 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 Loan Agreement, 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 5.50% 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 the Company's common stock for at least 20 trading days (whether or not

Table of Contents

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 5.50% 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 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 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 5.50% Notes, in multiples of $1,000 principal amount, at the option of the holder regardless of the foregoing circumstances.

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 5.50% 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 of 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 5.50% Note.

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 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 5.50% 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 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%. 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 5.50% 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 5.50% 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 5.50% 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.

Table of Contents

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 June 30, 2016. Should the 5.50% Notes become convertible, management will determine whether the intent is to settle in cash which would result in the liability component of the convertible notes being classified as a current liability and the equity component being presented as redeemable equity if the liability is considered current.

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

The following table summarizes how the issuance of the 5.50% Notes is reflected in the Company's balance sheet at December 31, 2015 and June 30, 2016:

(in thousands)	December 31, 2015	June 30, 2016
Gross proceeds	$ 61,000	$ 61,000
Unamortized debt discount	(19,734)	(17,413)
Carrying value	$ 41,266	$ 43,587

7. Fair Value Measurements

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

- Level 1—Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities.

- Level 2—Valuations based on observable inputs and quoted prices in active markets for similar assets and liabilities.

- Level 3—Valuations based on inputs that are unobservable and models that are significant to the overall fair value measurement.

Table of Contents

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

(in thousands)	Fair Value Measurements as of December 31, 2015			
	Level 1	Level 2	Level 3	Balance as of December 31, 2015
Assets				
Cash equivalents (money market funds)	$ 29,992	$ —	$ —	$ 29,992
Marketable securities, available-for-sale	—	99,042	—	99,042
Total assets	$ 29,992	$ 99,042	$ —	$ 129,034
Liabilities				
Interest make-whole derivative	$ —	$ —	$ 656	$ 656
Total liabilities	$ —	$ —	$ 656	$ 656

(in thousands)	Fair Value Measurements as of June 30, 2016			
	Level 1	Level 2	Level 3	Balance as of June 30, 2016
Assets				
Cash equivalents (money market funds)	$ 21,094	$ —	$ —	$ 21,094
Marketable securities, available-for-sale	—	68,647	—	68,647
Total assets	$ 21,094	$ 68,647	$ —	$ 89,741
Liabilities				
Interest make-whole derivative	$ —	$ —	$ 3	$ 3
Total liabilities	$ —	$ —	$ 3	$ 3

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, 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.

The following tables set forth a summary of changes in the fair value of Level 3 liabilities for the June 30, 2016:

(in thousands)	December 31, 2015	Additions	Fair Value Change in 2016	June 30, 2016
Interest make-whole derivative	656	$ —	$ (653)	$ 3
Total liabilities	$ 656	$ —	$ (653)	$ 3

Table of Contents

As of June 30, 2016, the fair value of the 5.50% Notes was estimated 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 valuation date
- Discount yield as of the valuation date

The fair value and carrying value of the Company's 5.50% Notes at June 30, 2016 was as follows:

(in thousands)	Fair Value	Carrying Value	Face Value
5.50% Notes due April 1, 2020	$ 45,051	$ 43,587	$ 61,000

The fair value of the Company's term loan under the Loan Agreement with Hercules approximates its carrying value of $14.7 million as the interest rate is reflective of the interest rates on debt the Company could currently obtain with similar terms and conditions and thus represents a Level 2 measurement within the fair value hierarchy.

8. Net Loss Per Common Share

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

(in thousands, except share and per share data)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2016	2015	2016
Basic and diluted net loss per common share calculation:				
Net loss	$ (17,066)	$ (23,777)	$ (33,808)	$ (42,325)
Weighted average common stock outstanding	16,506,798	24,468,747	16,481,354	24,437,497
Net loss per share of common stock—basic and diluted	$ (1.03)	$ (0.97)	$ (2.05)	$ (1.73)

The following outstanding securities for the three and six months ended June 30, 2015 and 2016 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	June 30, 2015	2016
Options outstanding	1,142,548	2,124,947
Unvested restricted stock awards	767,536	550,130
Warrants outstanding	113,421	—
Common shares issuable upon conversion of the 5.50% Notes	4,102,360	4,102,360
Total	6,125,865	6,777,437

9. Stock-based Compensation

2013 Stock-Based Incentive Compensation Plan

In November 2013, the Company adopted its 2013 Stock-Based Incentive Compensation Plan (the "2013 Plan"). Pursuant to the 2013 Plan, the compensation committee (the "Compensation Committee) of the Company's board of directors 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 2013 Plan was 1,680,000, in the form of restricted stock and stock options. Share increases of 2,000,000 and 2,600,000 to the number of shares reserved for issuance under the 2013 Plan were authorized by the Company's stockholders in June 2014 and June 2016, respectively. The amount, terms of grants and exercisability provisions are determined by the Compensation

Table of Contents

Committee, and in certain circumstances pursuant to delegated authority, the Company's chief executive officer and the Company's chief financial officer. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the Compensation Committee. All options vest over time as stipulated in the individual award agreements.

Shares Available for Future Grant

As of June 30, 2016, the Company has reserved the following shares to be granted under the 2013 plan:

Shares initially reserved under the 2013 Plan	1,680,000
Authorized increase to the 2013 Plan	4,600,000
Common stock options granted	(2,467,857)
Restricted stock awards granted	(1,471,160)
Stock options and awards forfeited	335,762
Remaining shares available for future issuance	2,676,745

Shares Reserved for Future Issuance

As of June 30, 2016, the Company has reserved the following shares of common stock for issuance:

Stock options outstanding	2,124,947
Shares available for future grant under the 2013 Plan	2,676,745
Employee stock purchase plan	750,000
Shares reserved for future issuance	5,551,692

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2015	2016	2015	2016

General and administrative	$ 976	$ 1,263	$ 1,806	$ 2,390
Sales and marketing	52	52	74	135
Research and development	277	239	540	343
Total stock based compensation expense	$ 1,305	$ 1,554	$ 2,420	$ 2,868

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)
Outstanding at December 31, 2015	1,755,808	$ 8.93	
Granted	635,264	8.46	
Exercised	(30,000)	5.18	
Forfeited	(225,500)	8.06	
Cancelled	(10,625)	12.65	
Outstanding at June 30, 2016	2,124,947	$ 8.91	9.02
Vested or expected to vest at June 30, 2016	1,986,963	$ 8.91	9.02
Exercisable at June 30, 2016	265,579	$ 9.15	8.36

The intrinsic value of the 2,124,947 options outstanding as of June 30, 2016 was $0, based on a per share price of $4.96, the Company’s closing stock price on that date, and a weighted-average exercise price of $8.91 per share.

Table of Contents

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 common 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 common stock.

The per-share weighted-average grant date fair value of the options granted to employees during the six months ended June 30, 2016 was estimated at $5.48 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

	2016
Risk-free interest rate	1.69 %
Expected term of options (in years)	6.11
Expected volatility	69.31%
Dividend yield	—

The weighted-average valuation assumptions were determined as follows:

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

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

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

- Expected annual dividend yield: The Company estimated the expected dividend yield based on consideration of its historical dividend experience and future dividend expectations. The Company has not historically declared or paid dividends to stockholders. Moreover, it does not intend to pay dividends in the future, but instead expects to retain

any earnings to invest in the continued growth of the business. Accordingly, the Company assumed an expected dividend yield of 0.0%.

As of June 30, 2016, there was $9.5 million of total unrecognized compensation expense, related to unvested options granted under the 2013 Plan, which will be recognized over the weighted-average remaining period of 2.99 years.

Table of Contents

Restricted Stock

A summary of the status of the Company's restricted stock awards at June 30, 2016 and of changes in restricted stock awards outstanding under the 2013 Plan for the six months ended June 30, 2016 is as follows:

	Number of Shares	Weighted-average Grant Date Fair Value per Share
Unvested at December 31, 2015	679,866	$ 11.19
Forfeited	(21,432)	$ 5.18
Vested restricted stock awards	(108,304)	$ 11.39
Unvested at June 30, 2016	550,130	$ 11.40

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

As of June 30, 2016, there was $3.0 million of total unrecognized compensation expense, related to restricted stock under the 2013 Plan, which will be recognized over the weighted-average remaining period of 1.13 years.

Employee Stock Purchase Plan

In January 2016, the Company established an Employee Stock Purchase Plan (the "Purchase Plan"). Under the Company's Purchase Plan, eligible employees can purchase the Company's common stock through accumulated payroll deductions at such times as are established by the administrator. The Purchase Plan is administered by the Compensation Committee. Under the Purchase Plan, eligible employees may purchase the Company's common stock at 85% of the lower of the fair market value of a share of the Company's common stock on the first day of an offering period or on the last day of the offering period. Eligible employees may contribute up to 10% of their eligible compensation. A participant may purchase a maximum of 1,500 shares of common stock per offering period. Under the Purchase Plan, a participant may not accrue rights to purchase more than $25,000 worth of the Company's common stock for each calendar year in which such right is outstanding.

Effective January 1, 2016, employees who elected to participate in the Purchase Plan commenced payroll withholdings that accumulate during the offering period that ended on June 30, 2016, at which time shares of the Company's common stock were purchased at 85% of the lower of the fair market value of the Company's common stock on January 1 or June 30, 2016. In accordance with the guidance in ASC 718-50 – Compensation – Stock Compensation, the ability to purchase shares of the Company's common stock at the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the Purchase Plan is a compensatory plan under this guidance. Accordingly, stock-based compensation cost is determined based on the option's grant-date fair value and is recognized over the requisite service period of the option. The Company has estimated the option's fair value to be $3.47 using the Black-Scholes valuation model and recognized stock-based compensation expense of $52,000 during the six months ended June 30, 2016.

10. Commitments and Contingencies

Legal Proceedings

As previously reported, in April 2015, Purdue Pharma L.P., Purdue Pharmaceuticals L.P. and The P.F. Laboratories, Inc. ("Acura") in the U. S. District Court for the District of Delaware (Civ. No. 15-cv-00292 (D. Del.)) alleging the Company's OXAYDO product infringes Purdue's U.S. Patent No. 8,389,007 (the "007 Patent"). In April 2016, Purdue commenced a second patent infringement lawsuit against the Company and Acura in the United States District Court for the District of Delaware (Civ. No. 16-cv-00256-RGA (D. Del.)) alleging the Company's OXAYDO

Table of Contents

product infringes Purdue's newly issued U.S. Patent No. 9,308,171 (the "171 Patent"). On April 6, 2016, Acura filed a petition for Inter Parties Review (IPR 2016-00849) with the U.S. Patent and Trademark Office ("USPTO") seeking to invalidate Purdue's 007 Patent (the "IPR Review").

On May 20, 2016, Purdue on behalf of themselves and certain affiliates, Acura, on behalf of itself and its affiliates and the Company, on behalf of the Company and its affiliates, entered into a settlement agreement (the "Settlement Agreement") to settle the Actions and the IPR Review. Under the Settlement Agreement the parties agreed to dismiss or withdraw the Actions, request that the USPTO terminate the IPR Review and exchange mutual releases. On May 24, 2016, the Actions were dismissed and on July 6, 2016, the USPTO terminated IPR Review. No payments of money were made under the Settlement Agreement.

The Settlement Agreement also provides that Purdue will not, in the future, assert certain Purdue U.S. patents, including the 007 Patent, the 171 Patent and related technologies (the "Purdue Patents") against any Acura Settlement Product or Egalet Settlement Product (except generally in an action or interference by Acura or Egalet challenging a Purdue Patent). Egalet Settlement Products, generally, are certain immediate-release products and extended-release products containing morphine, including OXAYDO and ARYMO ER. In addition, the Settlement Agreement provides that Purdue will not challenge, with certain exceptions, the Acura/Egalet Patents with respect to the Purdue Settlement Products (as defined below) and that Purdue provides Acura and/or Egalet certain waivers of non-patent marketing exclusivity with respect to Purdue Settlement Products.

The Settlement Agreement also provides that Acura and Egalet will not, in the future, assert certain Acura and/or Egalet. patents (the "Acura/Egalet Patents"), including ARYMO ER patents, against any Purdue Settlement Products (except generally in an action or interference by Purdue challenging an Acura/Egalet Patent). Purdue Settlement Products are certain immediate-release and selected extended-release products. In addition, the Settlement Agreement provides that Acura and Egalet will not challenge, with certain exceptions, the Purdue Patents with respect to the Acura Settlement Products and Egalet Settlement Products and that Acura and Egalet provide Purdue certain waivers of non-patent marketing exclusivity with respect to the Acura Settlement Products and Egalet Settlement Products. In addition, Purdue has certain rights to exclusively negotiate, under a specified time period, for potential distribution of an authorized generic version of certain Egalet Settlement Products, including, in some circumstances, OXAYDO and ARYMO ER, and other products using Acura's Aversion® Technology if licensed to Egalet.

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 (the "Shionogi Agreement"), 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 allowed 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. In December 2015, the Company received notice from Shionogi that it was terminating the Shionogi Agreement for convenience.

Under the terms of the Shionogi 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 was 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 was eligible to receive up to an aggregate of $185.0 million based on successful achievement of specified net sales thresholds of licensed products.

Table of Contents

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 and research and development services, the upfront and IND payments were recorded as deferred revenue and were being recognized ratably using the straight line method through November 2030, the expected term of the Shionogi Agreement. As a result of the termination of the Shionogi Agreement, the Company recognized all remaining deferred revenue related to the Shionogi agreement as revenue in the fourth quarter of 2015 as the Company had no further material obligations under the agreement at that time. For the three and six months ended June 30, 2015, the Company recognized revenue of $262,000 and $433,000, respectively, related to the amortization of deferred revenue. Additionally, during the three and six months ended June 30, 2015, the Company recognized revenue of $487,000 and $540,000, respectively, related to certain development costs incurred under Shionogi Agreement. Given the termination of the Shionogi Agreement, there was no revenue in 2016 related to the Shionogi Agreement.

Collaboration and License Agreement with Acura

In January 2015, the Company entered the OXAYDO 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 mg and 7.5 mg strengths, but was not actively marketed at the time of the OXAYDO License Agreement. Under the terms of the OXAYDO 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 in all strengths.

The Company paid Acura an upfront payment of $5.0 million in January 2015 and a $2.5 million milestone payment in October 2015 as a result of the first commercial sale of OXAYDO. In addition, Acura will be entitled to a one-time $12.5 million milestone payment when OXAYDO net sales reach a 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 License 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 receives from the Company, 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 the Company to acquire intellectual property rights to commercialize OXAYDO, with an aggregate minimum floor.

Asset Purchase Agreement with Luitpold

In January 2015, the Company entered into and consummated the transactions contemplated by the SPRIX Purchase Agreement with Luitpold. Pursuant to the SPRIX 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 API

Table of Contents

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 allocated to the acquisition date fair values as follows:

(in thousands)	Purchase Price Allocation
Inventory	$ 3,408
Property, plant & equipment	100
Finite lived intangible-intellectual property	4,620
Net assets acquired	$ 8,128

As the Purchase Agreement was executed on January 8, 2015, there was no material difference between the Company's results presented in the consolidated statement of operations and the pro forma results for the three and six months ended June 30, 2015.

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 and six months ended June 30, 2015, the Company recorded a tax benefit of $23,000 and tax expense of $3,000, respectively. For the three and six months ended June 30, 2016, the Company recorded a tax benefit of $237,000 and $422,000, respectively.

As of December 31, 2015 and June 30, 2016, the Company had a non-current deferred tax liability of $1.1 million and $662,000 respectively. The deferred tax liability relates to the state tax treatment of the 5.50% Notes. 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 during the three and six months ended June 30, 2015 from the Shionogi Agreement, who is also an investor in the Company. As of December 31, 2015, the related party receivable with Shionogi was $57,000 and consisted entirely of revenue from development costs incurred under the Shionogi Agreement. As of June 30, 2016, there was no related party receivable due to the termination of the Shionogi Agreement (See Note 11 – Acquisitions and License and Collaboration Agreements).

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 2015 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," "believe," "estimate," "project," "potential," "continue" and "ongo 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: whether our product candidates approve regulatory approval, our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; our current and future indebtedness; our ability to obtain additional financing; the level of commercial success of our products and, if approved, our product candidates; the continued development of our commercialization capabilities, including sales and marketing capabilities; our ability to execute on our sales and marketing strategy, including developing relationships with customers, physicians, payors and other constituencies; the difficulties in obtaining and maintaining regulatory approval of our products and product candidates, and any related restrictions, limitations and/or warnings in the product label under any approval we may obtain; the success and timing of our preclinical studies and clinical trials; 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; the rate and degree of market acceptance of any of our product candidates; the performance of third parties, including contract research organizations, manufacturers and collaborators; our failure to recruit or retain key scientific or management personnel or to retain our executive officers; regulatory developments in the U.S. and foreign countries; 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; recently enacted and future legislation regarding the healthcare system; the success of competing products that are or become available; and our ability to integrate and grow any businesses or products that we may acquire.

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 additional 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.

Our Business

We are a fully integrated specialty pharmaceutical company developing, manufacturing and commercializing innovative treatments for pain and other conditions. Egalet was founded around our proprietary Guardian™ Technology that can be applied broadly across different classes of pharmaceutical products. Using this technology, we have two late-stage product candidates in development; ARYMO™ ER, an abuse-deterrent ("AD"), extended-release ("ER") oral morphine formulation, which, if approved by the U.S. Food and Drug Administration ("FDA"), could be approved in 2016, and Egalet-002, an AD, ER, oral oxycodone formulation, which is in a Phase 3 program (our "lead product candidates"). In January 2015 the Company acquired SPRIX® (ketorolac tromethamine) Nasal Spray and in-licensed OXAYDO® (oxycodone HCI, USP) tablets for oral use only—CII—both approved by the Food and Drug Administration ("FDA")—and (our "approved products"). In addition, we have other Guardian Technology product candidates, an AD, ER hydrocodone and an AD stimulant, in our pipeline. Our technology also can be used to develop combination products that include multiple active pharmaceutical ingredients ("APIs") with similar or different release

Table of Contents

profiles and offers us a number of long term growth opportunities. In January 2015, we acquired SPRIX® (ketorolac tromethamine) Nasal Spray and in-licensed OXAYDO® (oxycodone HCI, USP) tablets for oral use only—CII, both of which are approved by the FDA (our "approved products"). We plan to continue to grow through business development and organic development leveraging our proprietary Guardian Technology.

We have completed bioequivalence studies and abuse-deterrent studies that were included in our new drug application ("NDA") for our lead program ARYMO ER which is under review at the FDA. This product is being developed for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. With the Prescription Drug User Fee Act ("PDUFA") goal date for a decision by the FDA of October 14, 2016, we believe ARYMO ER could be approved before the end of 2016.

To commercialize SPRIX Nasal Spray and OXAYDO and ultimately our pipeline products candidates, we are using a 71-person specialty sales force targeting approximately 11,500 physicians in the high decile of pain medicine prescribers in the U.S. SPRIX Nasal Spray is the first and only approved nasal spray formulation of a nonsteroidal anti-inflammatory drug ("NSAID"), in this case, ketorolac, used for short term (up to five days) management of moderate to moderately severe pain that requires analgesia at the opioid level. While providing analgesia at the opioid level, SPRIX Nasal Spray does not have the side effects or issues of misuse or abuse common to opioids. OXAYDO is an immediate-release ("IR") oral formulation of oxycodone indicated for the management of acute and chronic moderate to severe pain where the use of an opioid analgesic is appropriate. It is the first and only approved IR oxycodone product designed to discourage abuse via the route of snorting. Beyond targeting the high-decile of pain medicine prescribers with our sales force, we have sought to augment our commercial reach in other markets, including our agreements for SPRIX Nasal Spray with Teva Pharmaceutical Industries Ltd. ("Teva") in the Middle East and with Septodont, Inc. ("Septodont") focused on dentists in the U.S.

Future growth should come from our pipeline of product candidates developed using our Guardian Technology. Our second late-stage product candidate Egalet-002, and AD, ER, oral oxycodone formulation, also being developed for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate, is in a Phase 3 program. We also will conduct AD studies on Egalet-002 which will be submitted in cofmbination with the Phase 3 data to support an anticipated NDA filing in mid-2017. We have Egalet-003, an AD stimulant product candidate, and Egalet-004, an AD hydrocodone product candidate. In addition, we have completed initial research and development efforts on 13 potential other product candidates. We have developed prototypes, conducted feasibility studies and are exploring additional applications of our technology, both independently and in collaboration with other pharmaceutical companies, for the development of both tailored precision oral drug delivery of single agent products and combination products for indications other than pain in which a potential for abuse exists. Our exclusively owned product candidates and Guardian Technology are protected by 97 issued and 41 pending patent applications worldwide as well as unpatented know how and trade secrets.

Recent Developments

On August 4, 2016, at the joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA (the “Advisory Committees”), the Advisory Committees voted 18 to 1 to recommend approval of ARYMO ER. In addition, the Advisory Committees voted 16 to 3 that if approved, ARYMO ER should be labeled as an abuse-deterrent product by the oral route of abuse, 18 to 1 that if approved, it should be labeled as an abuse-deterrent product by the nasal route of abuse and 18 to 1 that if approved, it should be labeled as an abuse-deterrent product by the intravenous route of abuse. We intend to continue to work collaboratively with the FDA to complete the review process of ARYMO ER. The FDA will consider, but is not bound by, the Advisory Committees' recommendations as it continues its review of ARYMO ER.

Financial Operations

Our net losses for the three months ended June 30, 2015 and 2016 were $17.1 million and $23.8 million, respectively, and $33.8 million and $42.3 million for the six months ended June 30, 2015 and 2016, respectively. We recognized revenues in the three months ended June 30, 2015 and 2016 of $1.0 million and $3.5 million, respectively, and $1.7 million and $6.1 million for the six months ended June 30, 2015 and 2016, respectively. As of June 30, 2016,

Table of Contents

we had an accumulated deficit of $176.9 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, conduct scale-up manufacturing activities, and seek regulatory approval for, our product candidates, protect and expand our intellectual property portfolio and hire additional personnel. Additionally, we expect to continue to incur significant commercialization expenses as we grow our sales, marketing and distribution infrastructure to sell our products in 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 and significant judgments and estimates as discussed in our audited consolidated financial statements and the notes thereto for the year ended December 31, 2015 filed on March 11, 2016.

Results of Operations

Comparison of the three months ended June 30, 2015 and 2016

(in thousands)	Three Months Ended June 30,		
	2015	2016	Change
Revenues			
Net product sales	$ 607	$ 3,450	$ 2,843
Related party revenues	352	—	(352)
Total revenue	959	3,450	2,491
Cost and Expenses			
Cost of sales (excluding amortization of product rights)	207	784	577
Amortization of product rights	585	503	(82)
General and administrative	5,804	8,854	3,050
Sales and marketing	3,284	6,280	2,996

Research and development	4,903	8,697	3,794
Total costs and expenses	14,783	25,118	10,335
Loss from operations	(13,824)	(21,668)	(7,844)
Other (income) expense:			
Change in fair value of derivative liability	773	(43)	(816)
Interest expense, net	2,306	2,315	9
Other (gain) loss	(2)	69	71
Loss on foreign currency exchange	188	5	(183)
	3,265	2,346	(919)
Loss before provision for income taxes	(17,089)	(24,014)	(6,925)
Benefit for income taxes	(23)	(237)	(214)
Net loss	$ (17,066)	$ (23,777)	$ (6,711)

Net Product Sales

Net product sales increased from $607,000 for the three months ended June 30, 2015 to $3.5 million for the three months ended June 30, 2016. Net product sales for the three months ended June 30, 2015 consisted entirely of

Table of Contents

SPRIX Nasal Spray product sales. Net product sales in the three months ended June 30, 2016 consisted of $2.7 million in SPRIX Nasal Spray product sales and $721,000 in OXAYDO product sales.

Related Party Revenues

Related party revenues decreased from $352,000 for the three months ended June 30, 2015 to $0 for the three months ended June 30, 2016 as a result of the termination of the Shionogi Agreement in December 2015.

Cost of Sales (excluding Amortization of Product Rights)

Cost of sales (excluding product amortization rights) increased from $207,000 the three months ended June 30, 2015 to $784,000 for the three months ended June 30, 2016. The cost of sales (excluding amortization of product rights) for SPRIX Nasal Spray reflects the fair value of finished goods inventory that was acquired as part of the acquisition and the average cost of inventory produced, which was dispensed to patients during the period. The cost of sales (excluding amortization of product rights) for OXAYDO reflects the average costs of inventory dispensed to patients during the period. Cost of sales (excluding product amortization rights) for the three months ended June 30, 2016, consisted of both SPRIX Nasal Spray and OXAYDO sales, while cost of sales (excluding product amortization rights) for the three months ended June 30, 2015, consisted only of SPRIX Nasal Spray sales.

Amortization of Product Rights

Amortization of product rights decreased from $585,000 for the three months ended June 30, 2015 to $503,000 for the three months ended June 30, 2016. Amortization of product rights was comprised of $249,000 for the OXAYDO and $336,000 for the SPRIX Nasal Spray intangible assets in the three months ended June 30, 2015 and $272,000 for the OXAYDO and $231,000 for the SPRIX Nasal Spray intangible assets in the three months ended June 30, 2016.

General and Administrative Expenses

General and administrative expenses increased by $3.1 million, or 52.5%, from $5.8 million for the three months ended June 30, 2015 to $8.9 million for the three months ended June 30, 2016 months ended June 30, 2016. The increase was attributable to increases in employee salary and benefits of $1.1 million and administrative expenses of $290,000 due to the expansion of the US organization as well as increases in stock based compensation expense of $299,000. There were also increased professional fees of $1.3 million which included expenses related to the

preparation for the FDA Advisory Committee meeting.

Sales and Marketing Expenses

Sales and marketing expenses increased $3.0 million from $3.3 million in the three months ended June 30, 2015, to $6.3 million for the three months ended June 30, 2016, related to the growth of the commercial operations in the U.S. The increase was attributable to increases in contract sales force expenses of $2.4 million, salary and benefits of $301,000 for the expansion of the commercial organization and sales and marketing support of SPRIX Nasal Spray and OXAYDO of $293,000.

Research and Development Expenses

Research and development expenses increased by $3.8 million, or 77.4%, from $4.9 million for the three months ended June 30, 2015 to $8.7 million for the three months ended June 30, 2016. This increase was driven primarily by increases in our development costs for EG-002 and OXAYDO of $3.0 million and $1.0 million, respectively and an increase in other non-product specific research and development expenses of $338,000.

Change in fair value of derivative liability

The interest make whole provision of the our 5.50% convertible senior notes due April 1, 2020 (the “5.50% Notes”) is subject to re-measurement at each balance sheet date and we recognize any change in fair value in our

Table of Contents

statements of operations and comprehensive loss as a change in fair value of the derivative liability. During the three months ended June 30, 2015 we had a loss of $773,000 as a result of the change in the fair value of our derivative liability, compared to a gain of $43,000 for the three months ended June 30, 2016. The change in fair value of the derivative liability is due primarily to changes in the value of our common stock during the three months ended June 30, 2015 and 2016.

Interest expense

Interest expense was $2.3 million for the three months ended June 30, 2015 and for the three months ended June 30, 2016. We incur interest expense due primarily to our Loan Agreement with Hercules and the 5.50% Notes.

Loss on Foreign Currency Exchange

For the three months ended June 30, 2015, we recognized a loss on foreign currency exchange of $188,000. For the three months ended June 30, 2016, we recognized a loss on foreign currency exchange of $5,000. This difference is primarily attributable the change in the average rates of currency in which we transacted during 2015 when compared to 2016.

Benefit for Income Taxes

We had a benefit for income taxes of $23,000 for the three months ended June 30, 2015 and an income tax benefit of $237,000 for the three months ended June 30, 2016. The income tax benefit in the three months ended June 30, 2016 relates to a state tax benefit associated with the 5.50% Notes.

Comparison of the six months ended June 30, 2015 and 2016

(in thousands)	Six months ended June 30,		
	2015	2016	Change
Revenues			
Net product sales	$ 769	$ 6,013	$ 5,244
Collaboration revenues	—	100	100

Related party revenues	973	—	(973)
Total revenue	1,742	6,113	4,371
Cost and Expenses			
Cost of sales (excluding amortization of product rights)	301	1,666	1,365
Amortization of product rights	963	1,004	41
General and administrative	10,499	14,852	4,353
Sales and marketing	4,859	12,482	7,623
Research and development	15,303	14,816	(487)
Total costs and expenses	31,925	44,820	12,895
Loss from operations	(30,183)	(38,707)	(8,524)
Other (income) expense:			
Change in fair value of derivative liability	773	(653)	(1,426)
Interest expense, net	2,766	4,624	1,858
Other (gain) loss	(2)	66	68
Loss on foreign currency exchange	85	3	(82)
	3,622	4,040	418
Loss before provision for income taxes	(33,805)	(42,747)	(8,942)
Provision (benefit) for income taxes	3	(422)	(425)
Net loss	$ (33,808)	$ (42,325)	$ (8,517)

Table of Contents

Net Product Sales

Net product sales increased from $769,000 for the six months ended June 30, 2015 to $6.0 million for the six months ended June 30, 2016. Net product sales for the six months ended June 30, 2015 consisted entirely of SPRIX Nasal Spray product sales. Net product sales in the six months ended consisted of $4.9 million in SPRIX Nasal Spray product sales and $1.1 million in OXAYDO product sales.

Collaboration Revenues

There were no collaboration revenues for the three months ended June 30, 2015. Collaboration revenues were $100,000 for the six months ended June 30, 2016, and consisted entirely of revenues recognized under our SPRIX Nasal Spray marketing agreement with Septodont, Inc.

Related Party Revenues

Related party revenues decreased from $973,000 for the six months ended June 30, 2015 to $0 for the six months ended June 30, 2016 as a result of the termination of the Shionogi Agreement in the December 2015.

Cost of Sales (excluding Amortization of Product Rights)

Cost of sales (excluding product amortization rights) increased from $301,000 in the six months ended June 30, 2015 to $1.7 million for the six months ended June 30, 2016. The cost of sales (excluding product amortization rights) for SPRIX Nasal Spray reflects the fair value of finished goods inventory that was acquired as part of the acquisition and the average cost of inventory produced, which was dispensed to patients during the period. The cost of sales (excluding product amortization rights) for OXAYDO reflects the average costs of inventory dispensed to patients during the period. Cost of sales (excluding product amortization rights) for the six months ended June 30, 2016, consisted of both SPRIX Nasal Spray and OXAYDO sales, while the cost of sales (excluding product amortization rights) for the six months ended June 30, 2015, consisted only of SPRIX Nasal Spray sales.

Amortization of Product Rights

Amortization of product rights increased from $963,000 for the six months ended June 30, 2015 to $1.0 million for the six months ended June 30, 2016. Amortization of product rights was comprised of $523,000 for the OXAYDO and $441,000 for the SPRIX Nasal Spray intangible assets in the six months ended June 30, 2015 and $542,000 for the OXAYDO and $462,000 for the SPRIX Nasal Spray intangible assets in the six months ended June 30, 2016.

General and Administrative Expenses

General and administrative expenses increased by $4.4 million, or 41.5%, from $10.5 million for the six months ended June 30, 2015 to $14.9 million for the six months ended June 30, 2016. This was primarily attributable to increases in employee salary and benefits of $2.0 million due to the growth of our U.S. operations, stock based compensation expense of $598,000, and administrative expenses of $1.4 million. There were also increased professional fees of $1.0 million which included expenses related to the preparation for the FDA Advisory Committee meeting. These increases were offset by a decrease in regulatory fees of $629,000.

Sales and Marketing Expenses

Sales and marketing expenses increased $7.6 million from $4.9 million in six months ended June 30, 2015 to $12.5 million for the six months ended June 30, 2016. The increase was attributable to increases in salary, benefits and stock based compensation expense of $1.0 million and contract sales force expenses of $5.1 million, which began operations in the second half of 2015, and sales and marketing support for OXAYDO of $1.3 million.

Table of Contents

Research and Development Expenses

Research and development expenses decreased by $487,000, or 3.2%, from $15.3 million for the six months ended June 30, 2015 to $14.8 million for the six months ended June 30, 2016. This decrease was driven primarily by a decrease in our development costs for ARYMO ER of $3.9 million, offset by increases in our development costs for EG-002 and OXAYDO of $1.9 million and $1.5 million, respectively.

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. During the six months ended June 30, 2015, we had a loss of $773,000 as a result of the change in the fair value of our derivative liability, as opposed to a gain of $653,000 during the six months ended June 30, 2016. The change in fair value of the derivative liability is due primarily to changes in the value of our common stock during the three months ended June 30, 2015 and 2016.

Interest expense

Interest expense was $2.8 million for the six months ended June 30, 2015 and $4.6 million for the six months ended June 30, 2016. The increase was attributable to the interest expense on the 5.50% Notes, which were issued in April 2015.

Loss on Foreign Currency Exchange

For the six months ended June 30, 2015, we recognized a loss on foreign currency exchange of $85,000. For the six months ended June 30, 2016, we recognized a loss on foreign currency exchange of $3,000. This difference is primarily attributable the change in the average rates of currency in which we transacted during 2015 when compared to 2016.

Provision (benefit) for Income Taxes

We had a provision for income taxes of $3,000 for the six months ended June 30, 2015 and an income tax benefit of $422,000 for the six months ended June 30, 2016. The income tax benefit in the six months ended June 30, 2016 relates to a state tax benefit associated with the 5.50% Notes.

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 $33.8 million and $42.3 million for the six months ended June 30, 2015 and 2016, respectively. Our operating activities used $2.1 million of cash during the six months ended June 30, 2015 and $36.0 million of cash during the six months ended June 30, 2016. At June 30, 2016, we had an accumulated deficit of $176.9 million, a working capital surplus of $78.9 million and cash, cash equivalents and marketable securities totaling $103.7 million.

From our inception through our IPO on February 11, 2014, we received gross proceeds of $31.1 million from the issuance of preferred stock and convertible debt.

In February 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. In March 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 previous 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 equal to $12.00 per share, for aggregate gross proceeds of $15.0 million. In addition,

Table of Contents

the 2013 related party senior convertible debt holders automatically exercised 600,000 warrants for shares of common stock at an exercise price of $0.0083 per share. The net proceeds to us from the IPO and the private placement, after deducting underwriting discounts and commissions and offering expenses, were approximately $51.5 million and $14.0 million, respectively.

In January 2015, we entered into 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 the 5.50% Notes. In May 2015, we issued an additional $1.0 million in principal amount pursuant to the initial purchasers' exercise of their 30-day over-allotment for 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.

In July 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.

In July 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.

Through June 30, 2016, we have also financed our operations with the $4.1 million in payments from our collaborative research and development agreements along with aggregate upfront and milestone payments of $20.0 million from Shionogi under the Shionogi Agreement.

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through at least June 30, 2017.

Cash Flows

The following table summarizes our cash flows for the six months ended June 30, 2015 and 2016

(in thousands)	Six Months Ended June 30,	
	2015	2016
Net cash provided by (used in):		
Operating activities	$ (2,062)	$ (35,956)
Investing activities	(65,004)	23,846
Financing activities	71,578	155
Effect of foreign currency translation on cash	416	311
Net increase (decrease) in cash	$ 4,928	$ (11,644)

Cash Flows from Operating Activities

Net cash used in operating activities was $2.1 million for the six months ended June 30, 2015 and consisted primarily of a net loss of $33.8 million offset by an increase in deferred revenue of $23.1 million generated by the Shionogi milestone received and sales of SPRIX Nasal Spray in the first quarter of 2015, non-cash items consisting of $2.4 million of stock-based compensation expense, $1.5 million of amortization and depreciation expense, and $1.4 million of amortization of debt discount. Net cash inflows from changes in other operating assets and liabilities were primarily due to an increase in accrued expenses of $3.0 million.

Table of Contents

Net cash used in operating activities was $36.0 million for the six months ended June 30, 2016 and consisted primarily of a net loss of $42.3 million and changes in operating assets and liabilities of $173,000. The changes in operating assets and liabilities consisted of decrease in deferred revenue of $2.9 million, offset by an increase in accrued expenses of $1.4 million and an increase in other liabilities of $902,000. The $6.5 million net non-cash adjustments to reconcile net loss to net cash used in operations included stock based compensation expense of $2.9 million, non-cash interest and amortization of debt discount of $2.6 million and depreciation and amortization expense of $1.7 million.

Cash Flows from Investing Activities

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

Net cash provided by investing activities for the six months ended June 30, 2016 was $23.8 million and consisted of $65.8 million from maturity of investments, $5.4 million from the sale of investments, offset by $41.1 million for the purchase of investments and $6.3 million for the purchase of property and equipment.

Cash Flows from Financing Activities

Net cash provided by financing activities was $71.6 million for the six months ended June 30, 2015 and consisted of the net proceeds from the Hercules Loan Agreement and the 5.50% Notes of $14.8 million and $56.7 million, respectively.

Net cash provided by financing activities was $155,000 for the six months ended June 30, 2016 from the issuance of stock options.

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 continue to grow our

commercialization efforts around SPRIX Nasal Spray and OXAYDO, and if approved, ARYMO ER, and the clinical development of Egalet-002 and our other product candidates.

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 cash, cash equivalents and marketable securities will be sufficient to fund our projected operating requirements through at least June 30, 2017. However, our future operating and capital requirements will depend on many factors, including:

- the results of our clinical trials;
- the costs, timing and outcome of regulatory reviews;
- the cost of our current commercialization activities for our current products, as well as, if approved for sale in the future, our product candidates, 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 any future 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 the “Risk Factors” section of our most recent Annual Report on Form 10-K filed with the SEC on March 11, 2016 for additional risks associated with our substantial capital requirements.

Commitments

Purchase Commitments

During the six month period ended June 30, 2016, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our Annual Report on Form 10-K filed with the SEC on March 11, 2016.

Employment Agreements

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

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

Table of Contents

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 December 31, 2015, and June 30, 2016, we had cash and cash equivalents and marketable securities of $145.7 million and $103.7 million, respectively, consisting of money market funds, certificates of deposit, U.S. government agency securities and corporate debt securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities. Our marketable securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our marketable securities until maturity, and therefore we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

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

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer (“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 June 30, 2016 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 SEC 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

There were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during the period covered by this report that have 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 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.

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, 2015, and is updated for the following:

If we fail to obtain the necessary regulatory approvals, or if such approvals are limited, we will not be able to commercialize our product candidates, and we will not generate product revenues.

Even if we comply with all FDA pre-approval regulatory requirements, the FDA may not determine that some or all of our product candidates are safe and effective, and we may never obtain regulatory approval for some or all of our product candidates. If we fail to obtain regulatory approval for some or all of our product candidates, we will have fewer commercial products, and correspondingly lower product revenues.

Even if our product candidates receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products. On August 4, 2016, at the joint meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee of the FDA (the “Advisory Committees”), the Advisory Committees voted 18 to 1 to recommend approval of ARYMO ER. In addition, the Advisory Committees voted 16 to 3 that if approved, ARYMO ER should be labeled as an abuse-deterrent product by the oral route of abuse, 18 to 1 that if approved, it should be labeled as an abuse-deterrent product by the nasal route of abuse and 18 to 1 that if approved, it should be labeled as an abuse-deterrent product by the intravenous route of abuse. Even though the Advisory Committees recommended FDA approval of and abuse-deterrent labeling for ARYMO ER, the FDA is not bound by the Advisory Committees' recommendations as it continues its review of ARYMO ER. As a result, there is a risk that the FDA could determine not to approve ARYMO ER, or to approve ARYMO ER, but without abuse-deterrent labeling. If we are not able to obtain FDA-approved labeling describing of ARYMO ER’s abuse-deterrent features, then we may not be able to successfully commercialize ARYMO ER and, as a result, we may not generate any profits based on the sale of ARYMO ER, even

if ARYMO ER is otherwise approved for marketing by the FDA.

Later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us to perform lengthy Phase 4 post-approval clinical efficacy or safety trials. These trials could be very expensive. The FDA may also require us to amend our label based on outcomes of on-going Phase 4 commitment for OXAYDO. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

In jurisdictions outside the United States, we must receive marketing authorizations from the appropriate regulatory authorities before commercializing our product candidates. Regulatory approval processes outside the United States generally include requirements and risks similar to, and in many cases in excess of, the risks associated with FDA approval.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of preclinical studies and clinical trials and depends upon

Table of Contents

numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval varies among jurisdictions and may change during the course of a product candidate's clinical development. We have not obtained regulatory approval for any product candidate that we developed, and it is possible that none of our existing product candidates or any future product candidates we may in-license, acquire or develop will ever obtain regulatory approval.

Our product candidates could fail to receive regulatory approval from the FDA or a comparable foreign regulatory authority for many reasons, including:

- disagreement with or disapproval of the design or implementation of our clinical trials;
- failure to demonstrate that a product candidate is safe and effective for its proposed indication;
- failure to sufficiently deter abuse;
- failure of clinical trials to meet the level of statistical significance required for approval;
- failure to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- a negative interpretation of the data from our preclinical studies or clinical trials;
- deficiencies in the manufacturing processes or failure of third party manufacturing facilities with whom we contract for clinical and commercial supplies to pass inspection; or
- insufficient data collected from clinical trials of our product candidates or changes in the approval policies or regulations that render our preclinical and clinical data insufficient to support the submission and filing of an NDA or to obtain regulatory approval.

The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or cause us to abandon the development program. For example, we are seeking FDA approval of ARYMO ER pursuant to Section 505(b)(2) ("Section 505(b)(2)") of the Federal Food, Drug and Cosmetic Act ("FFDCA"). In February 2014, the FDA granted us Fast Track status with respect to ARYMO ER. In February 2016, the FDA accepted the submission of our new drug application for ARYMO ER and set a target action date under the Prescription Drug User Fee Act ("PDUFA") of October 14, 2016. The PDUFA date is only a goal and the FDA does not always meet its PDUFA dates. The review process and the PDUFA date for ARYMO ER may be extended if the FDA requests that we provide additional information or clarification regarding the submission.

Even if we obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, such approval may be contingent on the performance of costly post-marketing clinical trials, or we may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate. For example, on August 4, 2016, the Advisory Committees voted to recommend approval of ARYMO ER and that, if approved, ARYMO ER should be labeled as an abuse-deterrent product by the oral, nasal and intravenous routes of abuse. However, the FDA is not bound by the Advisory Committees' recommendations as it continues its review of ARYMO ER. If we are not able to obtain FDA-approved labeling describing all of ARYMO ER's abuse-deterrent features, then we may not be able to successfully commercialize ARYMO ER and, as a result, we may not generate any profits based on the sale of ARYMO ER even if ARYMO ER is otherwise approved for marketing by the FDA.

Any FDA determination that our NDA or supplemental NDA ("sNDA") submission is incomplete or insufficient for filing, results in FDA refusing to file the NDA or sNDA. A refusal to file by the FDA requires us to expend additional time and resources to revise and resubmit our NDA or sNDA. There is no guarantee that any revised or resubmitted NDA or sNDA filing we make will be accepted by the FDA.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product candidate is safe and effective. FDA may grant deferrals for submission of data or full or partial waivers. We filed a supplemental NDA for SPRIX Nasal Spray in December 2015, based on pediatric data initially generated and submitted by former sponsors. We received a refusal to file notice from the FDA on February 25, 2016. FDA indicated that the filing review represents a preliminary review of the application and is not indicative of deficiencies that would be

Table of Contents

identified if FDA performed a complete review. We will work with FDA during upcoming meetings to address the identified issues.

In addition, if our product candidate produces undesirable side effects or safety issues, the FDA may require the establishment of a Risk Evaluation and Mitigation Strategies (REMS), or a comparable foreign regulatory authority may require the establishment of a similar strategy, that may, for instance, restrict distribution of our products and impose burdensome implementation requirements on us. For example, we expect that certain of our product candidates, including ARYMO ER and Egalet-002, if approved, will be subject to REMS or other post-marketing requirements, such as lengthy and costly post-marketing studies. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

To market and sell our products outside of the United States, we must obtain separate marketing approvals and comply with numerous and various regulatory requirements and regimes, which can involve additional testing, may take substantially longer than the FDA approval process, and still generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in that country. FDA approval does not ensure approval by regulatory authorities in other countries or jurisdictions, approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA, and we may not obtain any regulatory approvals on a timely basis, if at all. We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory authorities in the European Union, China or another country, the commercial prospects of that product candidate may be significantly diminished and our business prospects could decline.

Our ability to market and promote our products in the United States by describing their abuse-deterrent features will be determined by the FDA-approved labeling for them.

The commercial success of our product candidates will depend upon our ability to obtain FDA approved labeling describing their abuse-deterrent features or benefits. Our failure to achieve FDA approval of product labeling containing such information will prevent or substantially limit our advertising and promotion of the abuse-deterrent features of our product candidates in order to differentiate them from other opioid products containing the same active ingredients. This would make our products less competitive in the market.

The FDA has publicly stated that explicit claims that a product is expected to result in a meaningful reduction of abuse must be supported by randomized, double-blind, controlled clinical studies of the abuse potential of the drug and that explicit claims that a product has demonstrated reduced abuse in the community will be required to be supported by post-marketing data, including formal post-marketing studies evaluating the effect of abuse-deterrent formulations. Although we intend to conduct such studies, there can be no assurance that our product candidates in development will receive FDA-approved labeling that describes the abuse-deterrent features of such products. If the FDA does not

approve labeling containing such information, we will not be able to promote such products based on their abuse-deterrent features, may not be able to differentiate such products from other opioid products containing the same active ingredients.

Additionally, recent public comments from FDA and members of Congress have highlighted the importance of addressing the opioid abuse epidemic. Given the changing legislative and regulatory environment, it is difficult to predict how existing laws and regulations may affect the future approval and continued marketing of opioids, including those that fulfill current abuse-deterrent FDA guidance. The FDA notified us upon acceptance of the ARYMO ER NDA, that it would require an Advisory Committee to discuss our ARYMO ER application. On August 4, 2016, the Advisory Committees voted to recommend approval of ARYMO ER and that, if approved, ARYMO ER should be labeled as an abuse-deterrent product by the oral, nasal and intravenous routes of abuse. However, the FDA is not bound by the Advisory Committees' recommendations as it continues its review of ARYMO ER. If we are not able to obtain FDA-approved labeling describing all of ARYMO ER’s abuse-deterrent features, then we may not be able to successfully commercialize ARYMO ER and, as a result, we may not generate any profits based on the sale of ARYMO ER even if ARYMO ER is otherwise approved for marketing by the FDA.

Table of Contents

Because the FDA closely regulates promotional materials and other promotional activities, even if the FDA initially approves product labeling that includes a description of the abuse-deterrent characteristics of our product, the FDA may object to our marketing claims and product advertising campaigns. This could lead to the issuance of warning letters or untitled letters, suspension or withdrawal of our products from the market, recalls, fines, disgorgement of money, operating restrictions, injunctions or criminal prosecution. Any of these consequences would harm the commercial success of our products.

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

Recent Sales of Unregistered Securities

None.

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
3.1	Third Amended and Restated Certificate of Incorporation of Egalet Corporation, as amended (incorporated by reference to Exhibit 3.1 to Egalet Corporation's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2015).
3.2	Amended and Restated Bylaws of Egalet Corporation (incorporated by reference to Exhibit 3.2 to Egalet Corporation's current report on Form 8 K filed with the Securities and Exchange Commission on February 11, 2014).
10.1	Amended and Restated Egalet Corporation 2013 Stock-Based Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016 (File No. 333-212298)).
10.2	Form of Egalet Corporation Option Award Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016) (File No. 333-212298)).
10.3	Form of Egalet Corporation Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016) (File No. 333-212298)).
10.4	Egalet Corporation 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016 (File No. 333-212297)).
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 (filed herewith).
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith).
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 (furnished herewith).
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).

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: August 5, 2016

EGALET CORPORATION

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

Table of Contents

EXHIBIT INDEX

Exhibit Number	Description
3.1	Third Amended and Restated Certificate of Incorporation of Egalet Corporation, as amended (incorporated by reference to Exhibit 3.1 to Egalet Corporation's quarterly report on Form 10-Q filed with the Securities and Exchange Commission on August 7, 2015).
3.2	Amended and Restated Bylaws of Egalet Corporation (incorporated by reference to Exhibit 3.2 to Egalet Corporation's current report on Form 8 K filed with the Securities and Exchange Commission on February 11, 2014).
10.1	Amended and Restated Egalet Corporation 2013 Stock-Based Incentive Plan and forms of agreement thereunder (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016 (File No. 333-212298)).
10.2	Form of Egalet Corporation Option Award Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016) (File No. 333-212298)).
10.3	Form of Egalet Corporation Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016) (File No. 333-212298)).
10.4	Egalet Corporation 2016 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 29, 2016 (File No. 333-212297)).
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 (filed herewith).
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith).
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 (furnished herewith).
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
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).