Egalet Corp
Form 10-Q
November 14, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2014

Or

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

For the transition period from to

Commission File Number 001-36295

Egalet Corporation

(Exact Name of Registrant as Specified in Its Charter)

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

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

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

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

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

(Title of Class)

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

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

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

Large accelerated filer o	Accelerated filer o

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

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

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

Common Stock, $0.001 par value Shares outstanding as of November 14, 2014: 17,283,663

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On November 26, 2013, Egalet Corporation (the Company) acquired all of the outstanding shares of Egalet Limited (Egalet UK). As a result, Egalet UK became a wholly-owned subsidiary of the Company, and the former shareholders of Egalet UK received shares of the Company (the Share Exchange). Unless the context indicates otherwise, as used in this Quarterly Report on Form 10-Q, the terms Egalet, we, us, our, our company and our business refers to the Company for all periods subsequent to the Share Exchange, and to Egalet UK for all periods prior to the Share Exchange. The Egalet logo is our trademark and Egalet is our registered trademark. All other trade names, trademarks and service marks appearing in this Quarterly Report on Form 10-Q are the property of their respective owners. We have assumed that the reader understands that all such terms are source-indicating. Accordingly, such terms, when first mentioned in this Quarterly Report on Form 10-Q, appear with the trade name, trademark or service mark notice and then throughout the remainder of this Quarterly Report on Form 10-Q without the trade name, trademark or service mark notices for convenience only and should not be construed as being used in a descriptive or generic sense. Unless otherwise indicated, all statistical information provided about our business in this report is as of September 30, 2014.

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PART I

ITEM 1. FINANCIAL STATEMENTS

Egalet Corporation and Subsidiaries

Consolidated Balance Sheets

	December 31, 2013	September 30, 2014 (unaudited)
Assets		
Current assets:		
Cash and cash equivalents	$ 15,700,000	$ 59,725,000
Related party receivable		186,000
Prepaid expenses	1,774,000	829,000
Other receivables	231,000	213,000
Total current assets	17,705,000	60,953,000
Property and equipment, net	2,378,000	2,430,000
Intangible asset	209,000	192,000
Deposits and other assets	71,000	2,297,000
Total assets	$ 20,363,000	$ 65,872,000
Liabilities, redeemable convertible preferred stock and stockholders (deficit) equity		
Current liabilities:		
Related party senior convertible debt, net of discount	$ 17,209,000	$
Accounts payable	1,046,000	1,285,000
Accrued expenses	1,755,000	2,874,000
Deferred revenue		551,000
Other current liabilities	55,000	76,000
Total current liabilities	20,065,000	4,786,000
Deferred income tax liability	22,000	22,000
Deferred revenue non-current portion	10,149,000	9,041,000
Total liabilities	30,236,000	13,849,000
Commitments and contingencies (Note 7)		
Redeemable convertible preferred stock:		
Redeemable convertible Series A-1 preferred stock $0.01 par value; 1,406,894 shares and 0 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively	1,443,000	
Redeemable convertible Series A-2 preferred stock $0.01 par value; 593,106 shares and 0 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively	770,000	
Redeemable convertible Series B preferred stock $0.01 par value; 2,327,301 shares and 0 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively	12,628,000	
	116,000	

Redeemable convertible Series B-1 preferred stock $0.01 par value; 113,916 shares and 0 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively		
Total redeemable convertible preferred stock	14,957,000	
Stockholders (deficit) equity:		
Common stock $0.01 par value and $0.001 par value at December 31, 2013 and September 30, 2014, respectively; 75,000,000 shares authorized at September 30, 2014; 1,292,307 and 17,283,663 shares issued and outstanding at December 31, 2013 and September 30, 2014, respectively	13,000	17,000
Additional paid-in capital	7,431,000	120,014,000
Accumulated other comprehensive income	1,125,000	139,000
Accumulated deficit	(33,399,000)	(68,147,000)
Total stockholders (deficit) equity	(24,830,000)	52,023,000
Total liabilities, redeemable convertible preferred stock and stockholders (deficit) equity	$ 20,363,000	$ 65,872,000

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Operations (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Related party revenues	$	$ 346,000	$	$ 1,094,000
Operating Expenses:				
General and administrative	1,252,000	4,194,000	3,223,000	12,190,000
Research and development	1,057,000	6,346,000	3,220,000	16,487,000
Total operating expenses	2,309,000	10,540,000	6,443,000	28,677,000
Loss from operations	(2,309,000)	(10,194,000)	(6,443,000)	(27,583,000)
Other income (expense):				
Interest (expense) income	(3,076,000)	5,000	(4,443,000)	(7,084,000)
Gain (loss) on foreign currency exchange	(124,000)	46,000	(113,000)	3,000
	(3,200,000)	51,000	(4,556,000)	(7,081,000)
Loss before provision for income taxes	(5,509,000)	(10,143,000)	(10,999,000)	(34,664,000)
Provision for income taxes		(35,000)		(84,000)
Net loss	$ (5,509,000)	$ (10,178,000)	$ (10,999,000)	$ (34,748,000)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (4.26)	$ (0.63)	$ (8.51)	$ (2.49)
Weighted-average shares outstanding, basic and diluted	1,292,307	16,206,530	1,292,307	13,934,824

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Comprehensive Loss (Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Net loss	$ (5,509,000)	$ (10,178,000)	$ (10,999,000)	$ (34,748,000)
Other comprehensive income (loss):				
Foreign currency translation adjustment	(342,000)	(1,037,000)	53,000	(986,000)
Comprehensive loss	$ (5,851,000)	$ (11,215,000)	$ (10,946,000)	$ (35,734,000)

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders (Deficit) Equity

For the Nine Months Ended September 30, 2014

(unaudited)

	Redeemable Convertible Preferred Stock									Common Stock		Stockholders (D	
	Series A-1		Series A-2		Series B		Series B-1				$0.001	Additional	
	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Number of Shares	Amount	Total	Number of Shares	Par Value	Paid-in Capital	Acc
Balance, December 31, 2013	1,406,894	$ 1,443,000	593,106	$ 770,000	2,327,301	$ 12,628,000	113,916	$ 116,000	$ 14,957,000	1,292,307	$ 13,000	$ 7,431,000	$ (3
Issuance of common stock upon conversion of related party convertible debt										2,585,745	3,000	24,710,000	
Issuance of common stock upon exercise of common stock warrants										600,000	1,000	(1,000)	
Issuance of common stock in connection with IPO, net of offering costs of $6,497,000										4,830,000	5,000	51,458,000	
Issuance of common stock upon conversion of convertible preferred stock	(1,406,894)	(1,443,000)	(593,106)	(770,000)	(2,327,301)	(12,628,000)	(113,916)	(116,000)	(14,957,000)	5,329,451	(7,000)	14,964,000	
Issuance of common stock to Shionogi, net of offering costs of $1,050,000										1,250,000	1,000	13,949,000	
Issuance of restricted shares of common										1,396,160	1,000	(1,000)	

Stock-based compensation expense							7,504,000	
Foreign currency translation adjustment								
Net loss								(3
Balance, September 30, 2014	$	$	$	$	17,283,663	$ 17,000	$ 120,014,000	$ (6

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Consolidated Statements of Cash Flows

(unaudited)

	Nine Months Ended September 30,	
	2013	**2014**
Operating activities:		
Net loss	$ (10,999,000)	$ (34,748,000)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	313,000	466,000
Stock-based compensation		7,504,000
Noncash interest	4,263,000	6,987,000
Deferred income taxes, net		2,000
Changes in assets and liabilities:		
Related party receivable	2,000	(199,000)
Prepaid expenses	(1,147,000)	(639,000)
Other receivables	(59,000)	
Other current assets	(75,000)	
Accounts payable	97,000	334,000
Accrued expenses	41,000	1,702,000
Deferred revenue		(410,000)
Other current liabilities	90,000	27,000
Net cash used in operating activities	(7,474,000)	(18,974,000)
Investing activities:		
Payments for purchase of property and equipment	(727,000)	(427,000)
Deposits for purchases of property and equipment	(2,000)	(2,389,000)
Net cash used in investing activities	(729,000)	(2,816,000)
Financing activities:		
Proceeds from issuance of convertible debt	15,000,000	
Payment of lender fees	(98,000)	
Proceeds from IPO, net of costs		53,032,000
Proceeds from issuance of common stock, net of costs		13,950,000
Net cash provided by financing activities	14,902,000	66,982,000
Effect of foreign currency translation on cash	360,000	(1,167,000)
Net increase (decrease) in cash and cash equivalents	7,059,000	44,025,000
Cash and cash equivalents beginning of period	3,404,000	15,700,000
Cash and cash equivalents end of period	$ 10,463,000	$ 59,725,000
Non-cash financing activities:		
Recording of gain (loss) on extinguishment of debt	$ (657,000)	$
Recording of beneficial conversion features	$ 5,000,000	$
Conversion of convertible preferred stock	$	$ 14,957,000
Conversion of related party convertible debt	$	$ 24,713,000

See accompanying notes to unaudited consolidated financial statements.

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Egalet Corporation and Subsidiaries

Notes to Unaudited Consolidated Financial Statements

1. Organization and Description of the Business

Egalet Corporation (the Company) is a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent pharmaceutical products for the treatment of pain and in other indications. The Company was incorporated in Delaware in August 2013 and until its initial public offering (IPO) in February 2014, had nominal assets and no operations. Egalet Limited (Egalet UK), incorporated in July 2010 in England and Wales, owned all of the Company s current assets and operations and acquired them in July 2010 pursuant to an agreement to purchase the business and certain assets of Egalet A/S, which was founded under the laws of Denmark. This transaction was accounted for as a business combination. In November 2013, all of the issued and outstanding ordinary shares and preferred shares of Egalet UK were exchanged for an identical number of shares of common stock and preferred stock of the Company, which resulted in Egalet UK becoming a wholly-owned subsidiary of the Company. As Egalet UK and Egalet US Inc. are entities under common control, the consolidated financial statements reflect the historical carrying values of Egalet UK s assets and liabilities and its results of operations as if they were consolidated for all periods presented. As a result of these transactions, the Company has a late-stage portfolio of product candidates that are being developed using the Company s broad-based drug delivery platform specifically designed to resist manipulation, to prevent easy extraction and to deter the abuse of medications via known routes of abuse, including chewing, snorting, and injecting. The Company s product candidates being developed using its proprietary Guardian Technology offer a tailored pharmacokinetic profile, lack a significant food effect and resist the effect of alcohol dose dumping. The Company s technology platform can be used with a broad range of opioids and non-opioids. The Company has filed patents to protect its inventions covering both the technology and product-specific patents.

Initial Public Offering

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

The Company paid to the underwriters discounts and commissions of approximately $5.1 million in connection with the offering, including discounts and commissions from the exercise of the over-allotment option. In addition, the Company incurred legal, accounting, and other offering-related expenses of approximately $2.4 million in connection with the offering, which when added to the underwriting discounts and commissions paid by the Company, amounts to total expenses of approximately $7.5 million. Thus, the net proceeds to the Company from the IPO, after deducting underwriting discounts and commissions and offering expenses, were approximately $51.5 million. Additionally, after deducting the expenses related to the private placement with Shionogi, the net proceeds to the Company from the private placement were approximately $14.0 million.

Liquidity

The Company has incurred recurring operating losses since inception. As of September 30, 2014, the Company had an accumulated deficit of $68.1 million and will require substantial additional capital to fund its research and development. The Company reasonably expects that the net proceeds from the Company s IPO, together with its pre-existing cash and cash equivalents, will enable it to fund its operating expenses and capital expenditure requirements through September 30, 2015. The Company anticipates operating losses to continue for the foreseeable future due to, among other things, costs related to research funding, development of its product candidates and its preclinical programs, and the development of its administrative organization. As the Company continues to incur losses, a transition to profitability is dependent upon the successful development, approval and commercialization of its product candidates and the achievement of a level of revenue adequate to support the Company s cost structure. The Company may never achieve profitability, and unless and until it does, the Company will continue to need to raise additional capital. Management intends to fund future operations through the sale of equity, debt financings or other sources, including potential additional collaborations. There can be no assurances, however, that additional funding will be available on terms acceptable to the Company, or at all.

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Forward Stock Split

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

2. Summary of Significant Accounting Policies and Basis of Accounting

Basis of Presentation

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

The accompanying consolidated financial information at September 30, 2014 and for the three and nine months ended September 30, 2013 and 2014, is unaudited. The interim unaudited financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair statement of the Company s financial position as of September 30, 2014 and for the three and nine months ended September 30, 2013 and 2014. The financial data and other information disclosed in these notes related to the three and nine months ended September 30, 2013 and 2014 are not necessarily indicative of the results to be expected for the year ending December 31, 2014, any other interim periods or any future year or period. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and the notes thereto for the year ended December 31, 2013 filed on March 31, 2014 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, 2013. Since the date of those financial statements, there have been no changes to the Company s significant accounting policies, except where noted below.

Reclassification

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

Fair Value Measurements

The carrying amounts reported in the Company s consolidated financial statements for cash, accounts receivable, accounts payable, accrued liabilities, and notes payable approximate their respective fair values because of the short-term nature of these accounts.

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

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

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

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

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

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

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

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

An adjustment to the pricing method used within either Level 1 or Level 2 inputs could generate a fair value measurement that effectively falls in a lower level in the hierarchy. The Company had no assets or liabilities classified as Level 1 or Level 2 as of December 31, 2013 and September 30, 2014 and there were no material re-measurements of fair value with respect to financial assets and liabilities, during those years, other than those assets and liabilities that are measured at fair value on a recurring basis. There were no transfers between Level 1 and Level 2 in any of the periods reported.

Revenue Recognition

During 2013, the Company entered into a collaborative research and license agreement with Shionogi. The terms of this agreement contain multiple deliverables which include (i) licenses; (ii) research and development activities and (iii) certain of the Company s core technologies and improvements thereon. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectability of the resulting receivable is reasonably assured, and the Company has fulfilled its performance obligations under the contract. The Company has adopted the provisions of Accounting Standards Update (ASU) 2009-13, *Multiple-Deliverable Revenue Arrangements*, which amends ASC 605-25, and also adopted ASU 2010-17, *Revenue Recognition Milestone Method*. In accordance with ASU 2009-13, the Company considered whether the deliverables under the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have stand-alone value. See Note 8 License and Collaboration Agreement for further discussion of the Company s accounting for collaborative research and license agreement.

Stock-Based Compensation

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

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

Share-based payments issued to non-employees are recorded at their fair values, and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period in accordance with the provisions of ASC 718 and ASC Topic 505, *Equity*. See Note 6 for a discussion of the assumptions used by the Company in determining the grant date fair value of options granted under the Black-Scholes option pricing model, as well as a summary of the stock option activity under the Company s stock-based compensation plan for the three and nine months ended September 30, 2014.

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

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Income Taxes

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

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2013 and September 30, 2014, the Company does not have any significant uncertain tax positions.

Foreign Currency Translation

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

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2014-09 *Revenue from Contracts with Customers* . ASU 2014-09 is a comprehensive new revenue recognition model requiring a company to recognize revenue to depict the transfer of goods or services to a customer at an amount reflecting the consideration it expects to receive in exchange for those goods or services. ASU 2014-09 may be applied using either a full retrospective or a modified retrospective approach and is effective for the Company s fiscal years, and interim periods within those years, beginning after December 15, 2016, and early adoption is not permitted. The Company is currently evaluating the impact of this amendment to its financial position and results of operations.

In June 2014, the FASB issued ASU No. 2014-12, *Compensation - Stock Compensation (Topic 718): Accounting for Share-Based Payments When the Terms of an Award Provide that a Performance Target Could be Achieved after the Requisite Service Period*, (ASU 2014-12). ASU 2014-12 requires that a performance target that affects vesting, and that could be achieved after the requisite service period, be treated as a performance condition. As such, the performance target should not be reflected in estimating the grant date fair value of the award. This update further clarifies that compensation cost should be recognized in the period in which it becomes probable that the performance target will be achieved and should represent the compensation cost attributable to the period(s) for which the requisite service has already been rendered. The Company does not anticipate that the adoption of this standard will have a material impact on its financial statements.

In August 2014, FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern*. The amendments in this update require management to assess an entity s ability to continue as a going concern by incorporating and expanding upon certain principles that are currently in U.S. auditing standards. Specifically, the amendments (1) provide a definition of the term substantial doubt, (2) require an evaluation every reporting period, including interim periods, (3) provide principles for considering the mitigating effect of management s plans, (4) require certain disclosures when substantial doubt is alleviated as a result of consideration of management s plans, (5) require an express statement and other disclosures when substantial doubt is not alleviated, and (6) require an assessment for a period of one year after the date that the financial statements are issued (or available to be issued). The amendments in this update are effective for the Company as of January 1, 2017. Early application is permitted. The Company is currently assessing the impact of this update on its future discussion of its liquidity position in Management s Discussion and Analysis.

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3. Net Loss Per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30	
	2013	2014	2013	2014
Basic and diluted net loss per common share calculation:				
Net loss attributable to common stockholders	$ (5,509,000)	$ (10,178,000)	$ (10,999,000)	$ (34,748,000)
Weighted-average common shares outstanding	1,292,307	16,206,530	1,292,307	13,934,824
Net loss per share of common stock basic and diluted	$ (4.26)	$ (0.63)	$ (8.51)	$ (2.49)

The following outstanding securities for the three and nine months ended September 30, 2013 and 2014 have been excluded from the computation of diluted weighted shares outstanding, as they would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Redeemable convertible preferred stock	4,441,217		4,441,217	
Options outstanding		238,957		238,957
Unvested restricted stock awards		881,240		881,240
Total	4,441,217	1,120,197	4,441,217	1,120,197

4. Intangible Asset

In connection with the acquisition of Egalet A/S, the Company recognized an in-process research and development (IPR&D) asset related to the drug delivery platform specifically designed to help deter physical abuse of pain medications. The IPR&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, 2013 and September 30, 2014, the carrying value of IPR&D was $209,000, and $192,000, respectively.

5. Related Party Senior Convertible Debt, Net of Discount

In April 2013, the Company entered into a $5.0 million convertible loan with several of its equity investors to provide the Company with funding to meet its short-term obligations. The loan had an interest rate of 6% and was originally scheduled to mature on December 31, 2013. During December 2013, the maturity date was extended to April 26, 2014. The loan had provisions whereby it would automatically convert into shares of common stock or convertible preferred series B or series B-1 stock, as applicable, upon (i) the closing of an IPO that yields a minimum of approximately $20 million in net proceeds to the Company at a per share price that values the Company at a minimum of $105.4 million (ii) the affirmative vote of at least sixty-five percent (65%) of the outstanding loan amount, or (iii) a change in control of the Company.

In connection with the Company s IPO on February 6, 2014 (see Note 1), the outstanding principal and interest of $5.0 million and $240,000, respectively, was converted into shares of the Company s common stock. For the three and nine months ended September 30, 2014 the Company recognized interest expense of $0 and $35,000, respectively.

On August 29, 2013, the Company entered into the 2013 Loan Agreement with several of its equity investors. The 2013 Loan Agreement was used to fund clinical and manufacturing development, working capital, and other general operational funding requirements. Upon entering into the 2013 Loan Agreement, the Company borrowed $10.0 million in debt proceeds. Borrowings under the 2013 Loan Agreement had an annual interest rate of 6% and were initially scheduled to mature on August 29, 2014. Subsequent to the maturity date, all outstanding principal and unpaid interest are due upon written request by lenders holding at least 66% of the principal amount outstanding which constitutes a lending super-majority. Prepayment of any borrowings, prior to maturity, is prohibited unless written approval from the lending super-majority is obtained.

The 2013 Loan Agreement had provisions requiring the lenders to convert any portion of the outstanding principal and interest in exchange for equity instruments upon the completion of an IPO that generates aggregate proceeds in excess of approximately $26.5 million (based on the exchange rate on August 29, 2013) (the IPO Scenario). In the event of a conversion under the IPO Scenario, the holders would obtain a number of shares of common stock at a conversion price equal to 50% of the offering price that was initially offered to the public.

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In connection with the 2013 Loan Agreement, the lenders received 600,000 warrants that automatically exercised immediately prior to consummation of the IPO, provided that such lender purchases a specified minimum amount of common stock in the IPO. Pursuant to the terms of the warrant agreement, the holders were able to exercise their warrants for shares of common stock at a price of $0.0083 per share (based on the exchange rate on August 29, 2013).

Immediately prior to completing its IPO on February 6, 2014 (See Note 1), the Company accelerated the recognition of the premium immediately prior to converting into equity. The outstanding principal, premium and interest of $10.0 million, $10.0 million, and $275,000, respectively, were converted into shares of the Company s common stock. The unamortized debt discount balance of $802,000 was also converted. For the three and nine months ended September 30, 2014 the Company recognized interest expense of $0 and $7.1 million, respectively, of which $0 and $7.0 million, respectively, was related to the accretion of premiums and the amortization of debt discounts, respectively.

In addition, the 2013 related party senior convertible debt holders automatically exercised warrants for 600,000 shares of common stock at an exercise price of $0.0083 per share in connection with the conversion of the senior convertible debt into shares of common stock.

6. Stock-based Compensation

2013 Stock-Based Incentive Plan

In November 2013, the Company adopted its 2013 Stock-Based Incentive Plan (the Plan). Pursuant to the Plan, the Company s compensation committee is authorized to grant equity-based incentive awards to its directors, executive officers and other employees and service providers, including officers, employees and service providers of its subsidiaries and affiliates. The number of shares of common stock initially reserved for issuance under the Plan was 1,680,000, in the form of restricted stock and stock options. A 2,000,000 share increase to shares reserved for issuance under the plan was authorized by the Company s stockholders in June 2014. The amount, terms of grants and exercisability provisions are determined by the board of directors. The term of the options may be up to 10 years, and options are exercisable in cash or as otherwise determined by the board of directors. All options vest over time as stipulated in the individual award agreements.

Shares Reserved for Future Issuance

As of September 30, 2014, the Company has reserved the following shares of common stock for issuance:

Shares initially reserved under the Plan	1,680,000
Authorized increase to the Plan	2,000,000
Common stock options outstanding	(238,957)
Restricted stock awards outstanding	(1,396,160)
Remaining shares available for future issuance	2,044,883

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	2014	2013	2014
Research and development	$	$ 842,000	$	$ 3,225,000
General and administrative		1,154,000		4,279,000
Total stock-based compensation expense	$	$ 1,996,000	$	$ 7,504,000

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Stock Options Granted under the 2013 Stock-Based Incentive Plan

	Options Outstanding		
	Number of Shares	Weighted-Average Exercise Price	Weighted-average Remaining Contractual Term (in years)
Balance, December 31, 2013			
Granted	238,957	$ 10.96	
Exercised			
Forfeitures			
Balance, September 30, 2014	238,957	$ 10.96	9.49
Vested or expected to vest at September 30, 2014	238,957	$ 10.96	9.49
Exercisable at September 30, 2014	5,321	$ 13.30	1.54

The intrinsic value of our 233,636 unvested options as of September 30, 2014 was $0, based on a per share price of $5.70, the Company s closing stock price on that date, and a weighted-average exercise price of $10.90 per share.

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

The per-share weighted-average grant date fair value of the options granted to employees during the nine months ended September 30, 2014 was estimated at $6.16 per share on the date of grant using the Black-Scholes option-pricing model with the following weighted-average assumptions:

Risk-free interest rate	1.83%
Expected term of options (in years)	6.18
Expected volatility	76.56%
Dividend yield	

The weighted-average valuation assumptions were determined as follows:

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

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

original contractual term of the option due to its lack of sufficient historical data.

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

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

As of September 30, 2014, there was $1.3 million of total unrecognized compensation expense, related to unvested options granted under the Plan, which will be recognized over the weighted-average remaining period of 2.08 years.

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Restricted stock

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

A summary of the status of the Company s restricted stock awards at September 30, 2014 and of changes in restricted stock awards outstanding under the Plan for the nine months ended September 30, 2014 is as follows:

	Shares		Weighted-average Grant Date Fair Value per Share
Outstanding balance at December 31, 2013		$	
Granted	1,396,160	$	12.02
Vested restricted stock awards	(514,920)	$	12.45
Outstanding balance at September 30, 2014	881,240	$	11.77

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

As of September 30, 2014, there was $9.1 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.15 years.

7. Commitments and Contingencies

Employment Agreements

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

Legal Proceedings

The Company is not involved in any legal proceeding.

8. License and Collaboration Agreement

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

Under the terms of the agreement, the Company received an upfront payment of $10.0 million. The Company is eligible to receive regulatory milestone payments under the agreement as follows: (i) up to $60.0 million upon successful achievement of specified regulatory milestones for the first licensed product candidate; (ii) up to $42.5 million upon successful achievement of specified regulatory milestones for a defined combination product candidate; (iii) up to $25.0 million upon successful achievement of specified regulatory milestones for a second product candidate (other than the defined combination product candidate); and (iv) up to $12.5 million upon successful achievement of specified regulatory milestones for further product candidates. In addition, the Company is eligible to receive up to an aggregate of $185.0 million based on successful achievement of specified net sales thresholds of licensed products.

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

Due to the lack of standalone value for the license and research and development services, the upfront payment is being recognized ratably using the straight line method through November 2030, the expected term of the agreement. The Company recorded the $10.0 million upfront payment as deferred revenue within its consolidated balance sheet as of December 31, 2013. For the three and nine months ended September 30, 2014, the Company recognized revenue of $147,000 and $409,000, respectively, related to the $10.0 million upfront payment the Company received.

Additionally, during the three and nine months ended September 30, 2014, the Company recognized revenue of $199,000 and $685,000, respectively, related to certain development costs incurred under the Company s collaborative research and license agreement. In accordance with the accounting guidance, the Company recorded revenue on a gross basis for the reimbursement of development costs.

9. Income Taxes

In accordance with ASC Topic No. 270 Interim Reporting and ASC Topic No. 740 Income Taxes (Topic No. 740) at the end of each interim period, the Company is required to determine the best estimate of its annual effective tax rate and then apply that rate in providing for income taxes on a current year-to-date (interim period) basis. For the three months ended September 30, 2013 and 2014, the Company had tax expense of $0 and $35,000, respectively and for the nine months ended September 30, 2013 and 2014 the Company had tax expense of $0 and $84,000, respectively.

As of December 31, 2013 and September 30, 2014, the Company had a non-current deferred tax liability of $22,000 and $22,000 respectively. The deferred tax liability relates entirely to an indefinite-lived intangible that was recorded in connection with the Danish IPR&D. The Company maintains a full valuation against all deferred tax assets as management has determined that it is not more likely than not that the Company will realize these future tax benefits.

10. Related-Party Transactions

Related Party Receivables

The Company has derived all of its revenue for the three and nine months ended September 30, 2014 under its license and collaboration agreement with Shionogi who is also an investor in the Company. As of September 30, 2014, related party receivables with Shionogi were $186,000.

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 2013 Annual Report on Form 10-K filed with the Securities and Exchange Commission.

Forward Looking Statements

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. In some cases, you can identify forward-looking statements by the words may, might, will, could, would, should, expect, intend, plan, objective, an estimate, predict, project, potential, continue and ongoing, or the negative of these terms, or other comparable terminology intended to ide statements about the future. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Form 10-Q, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain, including, but not limited to, risk related to: our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; the success and timing of our non-clinical studies and clinical trials; the difficulties in obtaining and maintaining regulatory approval of our product candidates, and the labeling under any approval we may obtain; our plans and ability to develop and commercialize our product candidates; our failure to recruit or retain key scientific or management personnel or

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to retain our executive officers; the size and growth of the potential markets for our product candidates and our ability to serve those markets; regulatory developments in the United States and foreign countries; obtaining and maintaining intellectual property protection for our product candidates and our proprietary technology; the successful development of our commercialization capabilities, including sales and marketing capabilities; recently enacted and future legislation regarding the healthcare system; and the performance of third parties, including our collaboration partners, contract research organizations and third-party manufacturers. You should refer to the Risk Factors section of our most recent Annual Report on Form 10-K as filed with the SEC and which are incorporated herein by reference, for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Furthermore, such forward-looking statements speak only as of the date of this report. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Overview

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

We are a specialty pharmaceutical company developing and planning to commercialize proprietary, abuse-deterrent oral products for the treatment of pain and other indications. Using our proprietary Guardian Technology platform, we have developed a pipeline of clinical-stage, opioid-based product candidates in tablet form that are specifically designed to deter abuse by physical and chemical manipulation while also providing the ability to tailor the release of the active pharmaceutical ingredient (API).

Egalet-001

Our lead product candidate, Egalet-001, is an abuse-deterrent, extended-release, oral morphine formulation in development for the treatment of moderate to severe pain. We believe that Egalet-001, if approved, will have advantages over other currently commercially available, long-acting, morphine products due to its differentiated abuse-deterrent properties.

On August 6, 2014, we announced top-line results from two of the three bioequivalence (BE) studies of Egalet-001 initiated in the first quarter of 2014. The first study (the Fasted State Study) evaluated the area under the curve (AUC) and the maximum or peak plasma concentration (Cmax) of a 100 mg Egalet-001 tablet versus the same dose of MS CONTIN in a fasted state in 58 subjects. The results of this study demonstrated that Egalet-001 in comparison to MS CONTIN met the BE criteria on the measure of AUC. Although the Cmax ratio (122) was within the BE criteria of 80-125, the upper limit of the 90% confidence interval (127) fell just outside of the range and, therefore, formal BE was not demonstrated.

The second study (the Fed State Study) examined the effect of food on the PK profile of a 100 mg Egalet-001 tablet compared to the same dose of MS CONTIN in 52 subjects. Similar to the Fasted State Study, in this study Egalet-001 met the BE criteria in comparison to MS CONTIN on the measure of AUC but was outside the range for Cmax. Food did not increase the Cmax or the AUC of Egalet-001 in this Fed State Study when compared to other PK studies of Egalet-001 in subjects in a fasted state. In contrast, changes in the Cmax of MS CONTIN were

demonstrated when compared to other PK studies of MS CONTIN in subjects in a fasted state, consistent with previously reported studies. This suggests that our Guardian Technology will not result in a clinically relevant food effect. In both studies, Egalet-001 was well tolerated and no serious adverse events were reported.

On September 23, 2014, we announced top-line results from the third BE study which evaluated the AUC and Cmax of a 15 mg Egalet-001 tablet versus the same dose of MS CONTIN in 64 subjects in a fasted state (the 15 mg Study). Egalet-001 met the bioequivalence criteria on the measure of AUC, but was outside the range for Cmax. On the measure of Cmax, the ratio of Egalet-001 to MS CONTIN was 83.6% and was within the range necessary for bioequivalence (80 to 125%), however the 90% confidence interval was 78.99 to 88.47 percent, outside the range necessary for bioequivalence (90 % confidence interval of 80 to 125%). Egalet-001 was well tolerated and no serious adverse events were reported.

Egalet has initiated interactions with the U.S. Food and Drug Administration (FDA) to discuss the totality of the clinical data from these studies and the registration path forward for Egalet-001. Based on the clinical data generated thus far, we expect that we will need to conduct additional clinical trials to strengthen the New Drug Application (NDA) for Egalet-001. We have begun planning for a Phase 3 trial that will examine the efficacy and safety of Egalet-001 in individuals with chronic low back pain and expect to initiate this study in the first quarter of 2015.

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Egalet-002

Our second product candidate, Egalet-002, is an abuse-deterrent, extended-release, oral oxycodone formulation in development for the treatment of moderate to severe pain. We believe that Egalet-002, if approved, will have advantages over other currently commercially available, long-acting, abuse-deterrent oxycodone products due to its differentiated abuse-deterrent properties and a pharmacokinetic (PK) profile that exhibits low peak-to-trough concentration variability in drug exposure. We have conducted Phase 1 trials of Egalet-002 and have completed initial abuse-deterrence studies in accordance with the FDA draft guidance (January 2013). We expect to initiate a pivotal Phase 3 safety and efficacy trial as well as a Phase 3 long term safety study for Egalet-002 in the first quarter of 2015, initiate the category 3 abuse-deterrent studies in the fourth quarter of 2014, and submit an NDA to the FDA in mid-2016.

Collaboration and License Agreement

In November 2013, we entered into a collaboration and license agreement with Shionogi granting Shionogi an exclusive, royalty-bearing, worldwide license to develop, manufacture and commercialize abuse-deterrent hydrocodone-based product candidates using certain of our core technologies. Shionogi will be responsible for all expenses associated with the development of these product candidates and is responsible for the completion of all clinical trials necessary to support NDA filings for the product candidates. Under the terms of the agreement, Shionogi made an upfront payment to us of $10.0 million. We are eligible to receive additional payments upon the achievement of specified regulatory and sales-based milestones. These milestone payments may exceed $300.0 million in the aggregate if multiple product candidates are approved. If any products are approved for marketing, we are also eligible to receive royalties at percentage rates ranging from the mid-single digits to the low-teens on net sales of licensed products.

Strategy

Subject to the results of our ongoing and planned studies, we plan to seek U.S. regulatory approval of Egalet-001 and Egalet-002 pursuant to Section 505(b)(2), which permits companies to rely upon the FDA s previous findings of safety and effectiveness for an approved product, such as morphine and oxycodone. If either of our clinical-stage product candidates achieves regulatory approval, we intend to establish our own specialty sales force to market such product in the United States by targeting physicians specializing in pain management. To supplement our internal U.S. sales force, we intend to contract with third parties to access sales representatives who target primary care and internal medicine physicians in the United States.

Since commencing operations, as Egalet UK in July 2010, we have dedicated a significant portion of our resources to our development efforts for our clinical-stage product candidates. Prior to our IPO, we funded our operations primarily through the sale of preferred stock for net proceeds of $10.2 million, as well as $21.0 million in proceeds from the issuance of convertible debt, of which $6.0 million was later converted into shares of our preferred stock. We have also received an aggregate of $2.3 million in revenues from several research and development agreements, and in December 2013, we received an upfront payment of $10.0 million from Shionogi under the collaboration agreement. We had $15.7 million and $59.7 million in cash as of December 31, 2013 and September 30, 2014, respectively. We have no products currently available for sale.

Our net losses were $10.2 million and $34.7 million for the three and nine months ended September 30, 2014, respectively. Net losses for the three and nine months ended September 30, 2013 were $5.5 million and $11.0 million, respectively. We recognized revenues of $346,000 and $1.1 million for the three and nine months ended September 30, 2014, respectively. We did not recognize any revenues for the three and nine months ended September 30, 2013.

As of September 30, 2014, we had an accumulated deficit of $68.1 million. We expect to incur significant expenses and operating losses for the foreseeable future as we continue the development and clinical trials of, and seek regulatory approval for, our product candidates, as well as scale-up manufacturing capabilities, protect and expand our intellectual property portfolio and hire additional personnel. If we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses in establishing a sales, marketing and distribution infrastructure to sell our products in the United States.

We will seek to license the development and commercial rights to our products outside the United States to a third-party organization that has an established track record of success in commercializing pain products outside the United States. We expect that this organization would be responsible for any further development and commercialization of the products in those regions.

As a publicly traded company, we will incur significant legal, accounting and other expenses that we were not required to incur as a private company. In addition, the Sarbanes-Oxley Act of 2002, as well as rules adopted by the SEC and the NASDAQ Stock Market, require public companies to implement specified corporate governance practices that were previously inapplicable to us as a

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private company. We expect these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We estimate that we will incur approximately $2.0 million to $3.0 million of incremental costs per year associated with being a publicly traded company, although it is possible that our actual incremental costs will be higher than we currently estimate.

We will seek to fund our operations primarily through public or private equity or debt financings or other sources. Any such 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.

Internal Control Over Financial Reporting

In preparing our consolidated financial statements as of and for the years ended December 31, 2012 and 2013, we and our independent registered public accounting firm identified control deficiencies in the design and operation of our internal control over financial reporting that constituted material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses identified were that we did not have sufficient financial reporting and accounting staff with appropriate training in U.S. GAAP and SEC rules and regulations with respect to financial reporting and a lack of segregation of duties. As such, our controls over financial reporting were not designed or operating effectively, and as a result there were adjustments, including with respect to revenue recognition, required in connection with closing our books and records and preparing our 2012 and 2013 consolidated financial statements. These material weaknesses identified were not remediated as of September 30, 2014.

In response to these material weaknesses, we have hired a chief financial officer, vice president of finance and administration, and senior finance manager and intend to hire additional finance and accounting personnel with appropriate training, build our financial management and reporting infrastructure, and further develop and document our accounting policies and financial reporting procedures. However, we cannot assure you that we will be successful in pursuing these measures or that these measures will significantly improve or remediate the material weaknesses described above. We also cannot assure you that we have identified all of our existing material weaknesses, or that we will not in the future have additional material weaknesses.

We have not yet remediated the material weaknesses described above, and the remediation measures that we have implemented and intend to implement may be insufficient to address our existing material weakness or to identify or prevent additional material weaknesses. See Risk Factors Risks Related to Ownership of Our Common Stock If we are unable to successfully remediate the existing material weaknesses in our internal control over financial reporting, the accuracy and timing of our financial reporting may be adversely affected included in our annual Form 10-K for the year ended December 31, 2013.

Neither we nor our independent registered public accounting firm has performed an evaluation of our internal control over financial reporting during any period in accordance with the provisions of the Sarbanes-Oxley Act. In light of the control deficiencies and the resulting material weaknesses that were identified as a result of the limited procedures performed, we believe that it is possible that, had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses and significant control deficiencies may have been identified. However, for as long as we remain an emerging growth company as defined in the Jumpstart Our Business Startup (JOBS) Act of 2012, we intend to take advantage of the exemption permitting us not to comply with the requirement that our independent registered public accounting firm provide an attestation on

the effectiveness of our internal control over financial reporting.

Critical Accounting Policies and Significant Judgments and Estimates

We believe there have been no significant changes in our critical accounting policies as discussed in our audited consolidated financial statements and the notes thereto for the year ended December 31, 2013 filed on March 31, 2014 with the SEC.

Revenue Recognition

During 2013, we entered into a collaborative research and license agreement with Shionogi. The terms of this agreement contains multiple deliverables which include (i) licenses, (ii) research and development activities and (iii) certain of our core technologies and improvements thereon. In all instances, revenue is recognized only when the price is fixed or determinable, persuasive evidence of an arrangement exists, delivery has occurred or the services have been rendered, collectability of the resulting receivable is reasonably assured, and we have fulfilled our performance obligations under the contract. We have adopted the provisions of ASU 2009-13, Multiple-Deliverable Revenue Arrangements, which amends ASC 605-25, and also adopted ASU 2010-17, Revenue

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Recognition Milestone Method. In accordance with ASU 2009-13, we consider whether the deliverables under the arrangement represent separate units of accounting. In determining the units of accounting, management evaluates certain criteria, including whether the deliverables have stand-alone value. See Note 8 License and Collaboration Agreement for further discussion of our accounting for collaborative research and license agreement.

Stock-Based Compensation

We account for all share-based compensation payments issued to employees, directors and non-employees using an option pricing model for estimating fair value. Accordingly, share-based compensation expense is measured based on the estimated fair value of the awards on the date of grant, net of forfeitures. We recognize compensation expense for the portion of the award that is ultimately expected to vest over the period during which the recipient renders the required services to us using the straight-line single option method. In accordance with authoritative accounting guidance, we re-measure the fair value of non-employee share-based awards as the awards vest, and recognize the resulting value, if any, as expense during the period the related services are rendered.

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

Significant Factors, Assumptions and Methodologies Used in Determining Fair Value

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

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

We use the simplified method as prescribed by the SEC SAB No. 107, Share-Based Payment, to calculate the expected term of stock option grants to employees as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term of stock options granted to employees. We utilize a dividend yield of zero based on the fact that we have never paid cash dividends and have no current intention to pay cash dividends. The risk-free interest rate used for each grant is based on the U.S. Treasury yield curve in effect at the time of grant for instruments with a similar expected life. The weighted-average assumptions used to estimate the fair value of stock options using the Black-Scholes option pricing model were as follows for the nine months ended September 30, 2014:

Risk-free interest rate	1.83%
Expected term of options (in years)	6.18
Expected volatility	76.56%
Dividend yield	

We are also required to estimate forfeitures at the time of grant, and revise those estimates in subsequent periods if actual forfeitures differ from our estimates. To the extent that actual forfeitures differ from our estimates, the difference is recorded as a cumulative adjustment in the period the estimates were revised. There were no forfeitures through September 30, 2014.

Restricted stock

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

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.

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As of September 30, 2014, there was $9.1 million of total unrecognized compensation expense, related to restricted stock under the Plan, which will be recognized over the weighted-average remaining period of 1.15 years.

Basic and Diluted Net Loss Per Share

We compute basic net loss per share by dividing net loss applicable to common stockholders by the weighted-average number of shares of common stock outstanding during the period, excluding the dilutive effects of preferred shares. We compute diluted net loss per share by dividing the net loss applicable to common stockholders by the sum of the weighted-average number of shares of common stock outstanding during the period plus the potential dilutive effects of preferred shares outstanding during the period calculated in accordance with the treasury stock method, but such items are excluded if their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between our basic and diluted net loss per share for the three and nine months ended September 30, 2013 and 2014.

Results of Operations

Comparison of the Three Months Ended September 30, 2013 and 2014

	Three Months Ended September 30,		
	2013	**2014**	**Change**
Revenues	$	$ 346,000	$ 346,000
Operating expenses:			
General and administrative	1,252,000	4,194,000	2,942,000
Research and development	1,057,000	6,346,000	5,289,000
Total operating expenses	2,309,000	10,540,000	8,231,000
Loss from operations	(2,309,000)	(10,194,000)	(7,885,000)
Interest (expense) income	(3,076,000)	5,000	3,081,000
Gain (loss) on foreign currency exchange	(124,000)	46,000	170,000
Loss from operations before income taxes	(5,509,000)	(10,143,000)	(4,634,000)
Provision for income taxes		(35,000)	(35,000)
Net loss	$ (5,509,000)	$ (10,178,000)	$ (4,669,000)

Revenues

Revenues increased from $0 for the three months ended September 30, 2013 to $346,000 for the three months ended September 30, 2014, as a result of the amortization of deferred revenue and certain research and development services performed under our collaborative agreement with Shionogi.

General and administrative expenses

General and administrative expenses increased by $2.9 million, or 235.0%, from $1.3 million for the three months ended September 30, 2013 to $4.2 million for the three months ended September 30, 2014. This was primarily attributable to the increase in employee compensation and stock compensation expense of $1.8 million related to the hiring of personnel and the adoption of a stock compensation plan and professional fees of $700,000 related to the establishment of our U.S. office.

Research and development expenses

Research and development expenses increased by $5.2 million, or 500.4%, from $1.1 million for the three months ended September 30, 2013 to $6.3 million for the three months ended September 30, 2014. This increase was driven primarily by an increase in our development costs for Egalet-001 of $3.4 million and an increase in employee compensation and stock-based compensation expense of $900,000 due to the adoption of a stock compensation plan.

Interest (expense) income

Interest expense was $3.1 million for the three months ended September 30, 2013, compared to interest income of $5,000 for the three months ended September 30, 2014. This change was primarily attributable to the $3.1 million in interest expense recognized in

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2013 related to the accretion of the beneficial conversion feature that was recorded in connection with our April 2013 convertible debt issuance and the accretion of the premium that was recorded in connection with our August 2013 convertible debt issuance.

Loss on Foreign Currency Exchange

We recognized a loss on foreign currency exchange of $124,000 during the three months ended September 30, 2013 compared to a gain of $46,000 during the three months ended September 30, 2014. This difference is primarily attributable the change in the average rates of currency in which we transacted during 2013 when compared to 2014.

Provision for Income Taxes

We had a provision for income taxes of $0 and $35,000 for the three months ended September 30, 2013 and 2014, respectively. During the three months ended September 30, 2014, tax expense increased primarily due to amortization of the indefinite-lived intangible and for state income taxes resulting from imputed interest income on inter-company loan agreements.

Comparison of the Nine Months Ended September 30, 2013 and 2014

	Nine Months Ended September 30,		
	2013	**2014**	**Change**
Revenues	$	$ 1,094,000	$ 1,094,000
Operating expenses:			
General and administrative	3,223,000	12,190,000	8,967,000
Research and development	3,220,000	16,487,000	13,267,000
Total operating expenses	6,443,000	28,677,000	22,234,000
Loss from operations	(6,443,000)	(27,583,000)	(21,140,000)
Interest expense	(4,443,000)	(7,084,000)	(2,641,000)
Gain (loss) on foreign currency exchange	(113,000)	3,000	116,000
Loss from operations before income taxes	(10,999,000)	(34,664,000)	(23,655,000)
Provision for income taxes		(84,000)	(84,000)
Net loss	$ (10,999,000)	$ (34,748,000)	$ (23,749,000)

Revenues

Revenues increased from zero for the nine months ended September 30, 2013 to $1.1 million for the nine months ended September 30, 2014, as a result of the amortization of deferred revenue and certain research and development services performed under our collaborative agreement with Shionogi.

General and administrative expenses

General and administrative expenses increased by $9.0 million, or 278.2%, from $3.2 million for the nine months ended September 30, 2013 to $12.2 million for the nine months ended September 30, 2014. This was primarily attributable to the increase in stock-based compensation expense, employee compensation expense, and professional fees of $4.3 million, $2.2 million and $1.8 million, respectively, related to the establishment of our U.S. office and hiring of personnel, as well as the adoption of a stock compensation plan and costs associated with being a publicly traded company.

Research and development expenses

Research and development expenses increased by $13.3 million, or 412.0%, from $3.2 million for the nine months ended September 30, 2013 to $16.5 million for the nine months ended September 30, 2014. This increase was driven primarily by an increase in our development costs for Egalet-001 and Egalet-002 of $7.4 million and $737,000, respectively, and an increase in employee compensation and stock-based compensation expense of $3.8 million due to the adoption of a stock compensation plan.

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Interest expense

Interest expense increased from $4.4 million for the nine months ended September 30, 2013 to $7.1 million for the nine months ended September 30, 2014. This change was primarily attributable to the recognition of the unamortized premium upon conversion of our related party senior convertible debt in connection with our IPO in February 2014.

Loss on foreign currency exchange

We recognized a loss on foreign currency exchange of $113,000 during the nine months ended September 30, 2013 compared to a gain of $3,000 during the nine months ended September 30, 2014. This difference is primarily attributable the change in the average rates of currency in which we transacted during 2013 when compared to 2014.

Provision for income taxes

We had a provision for income taxes of $0 and $84,000 for the nine months ended September 30, 2013 and 2014, respectively. During the nine months ended September 30, 2014, tax expense increased primarily due to amortization of the indefinite-lived intangible and for state income taxes resulting from imputed interest income on inter-company loan agreements.

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 $10.2 million and $34.7 million for the nine months ended September 30, 2013 and 2014, respectively. Our operating activities used $7.5 million and $19.0 million of cash during the nine months ended September 30, 2013 and 2014, respectively. At September 30, 2014, we had an accumulated deficit of $68.1 million, a working capital surplus of $56.2 million and cash of $59.7 million.

From our inception through September 30, 2014, we have received gross proceeds of $31.2 million from the issuance of preferred stock and convertible debt. We have also financed our operations with the $2.3 million in payments received through September 30, 2014 from our collaborative research and development agreements along with an upfront payment of $10.0 million from Shionogi under a collaboration agreement. We are potentially eligible to earn a significant amount of milestone payments and royalties under our agreement with Shionogi. Our ability to earn these payments and their timing is dependent upon the outcome of ours and Shionogi s activities and is uncertain at this time.

On February 11, 2014, 4,200,000 shares of our common stock were sold on an IPO price of $12.00 per share, for aggregate gross proceeds of $50.4 million. On March 7, 2014, in connection with the exercise by the underwriters of a portion of the over-allotment option granted to them in connection with the IPO, 630,000 additional shares of our common stock were sold at the IPO price of $12.00 per share, for aggregate gross

proceeds of approximately $7.6 million. In addition, as part of the IPO, we converted all of our convertible preferred stock and related party senior convertible debt into 5,329,451 and 2,585,745 shares of common stock, respectively. Also, Shionogi, our collaboration partner, purchased 1,250,000 shares of our common stock in a separate private placement concurrent with the completion of the IPO at a price per share equal to $12.00 per share, for aggregate gross proceeds of $15.0 million. In addition, the 2013 related party senior convertible debt holders automatically exercised 600,000 warrants for shares of common stock at an exercise price of $0.0083 per share.

Cash Flows

The following table summarizes our cash flows for the nine months ended September 30, 2013 and 2014:

	Nine Months Ended September 30,	
	2013	**2014**
Net cash (used in) provided by:		
Operating activities	$ (7,474,000)	$ (18,974,000)
Investing activities	(729,000)	(2,816,000)
Financing activities	14,902,000	66,982,000
Effect of foreign currency translation on cash	360,000	(1,167,000)
Net increase (decrease) in cash and cash equivalents	$ 7,059,000	$ 44,025,000

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Cash Flows from Operating Activities

Net cash used in operating activities was $7.5 million for the nine months ended September 30, 2013 and consisted primarily of a net loss of $11.0 million and net cash outflows of $1.1 million from changes in operating assets and liabilities offset by non-cash depreciation, amortization, and interest expenses of $4.6 million. The net cash outflow from changes in operating assets and liabilities were primarily due to a decrease in prepaid expenses of $1.1 million.

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

Cash Flows from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2013 and 2014 was $729,000 and $2.8 million, respectively. This cash flow from investing activities consisted of purchases of property and equipment as well as deposits on future related purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2013 was $14.9 million, made up entirely of proceeds from the issuance of convertible debt net of lender fees.

Net cash provided by financing activities was $67.0 million for the nine months ended September 30, 2014 and consisted of $53.0 million in proceeds from the completion of our IPO in February of 2014. There were additional proceeds of $14.0 million from the issuance of common stock in connection with our concurrent private placement with Shionogi.

Operating and Capital Expenditure Requirements

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

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

We believe that our existing capital resources, together with the net proceeds from our IPO and the concurrent private placement with Shionogi, will be sufficient to fund our operations through the end of September 30, 2015. However, our future operating and capital requirements will depend on many factors, including:

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

- the results of our clinical trials;

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- the costs, timing and outcome of regulatory review;

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

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

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

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

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

Please see Risk Factors section of our most recent annual report filed with the SEC on March 31, 2014 for additional risks associated with our substantial capital requirements.

Commitments

Purchase Commitments

During the three and nine month period ended September 30, 2014, there have been no material changes to our contractual obligations outside the ordinary course of business from those specified in our 2013 Annual Report.

Employment Agreements

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

Legal Proceedings

We are not involved in any legal proceeding.

Off-Balance Sheet Arrangements

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

JOBS Act

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

As a smaller reporting company as defined by Item 10 of Regulation S-K, we are not required to provide the information required by Item 3.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as

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amended (the Exchange Act), as of the end of the period covered by this quarterly report on Form 10-Q. The purpose of this evaluation is to provide reasonable assurance that the information required to be disclosed by us in reports filed under the Exchange Act, is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and that information required to be disclosed by us in the reports we file or submit under the Exchange Act, is accumulated and communicated to our management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure. Based on management s evaluation, the chief executive officer and chief financial officer concluded that, as of the end of the period covered by this report, the Company s disclosure controls and procedures were not effective as a result of the material weaknesses that existed in the Company s internal control over financial reporting as previously described in our 2013 Annual Report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. However, as explained in greater detail under Item 9A in our Annual Report on Form 10-K for the year ended December 31, 2013, we undertook a range of remedial procedures prior to March 31, 2014, the filing date of that report, to address the material weaknesses in our internal control over financial reporting identified as of December 31, 2013. Our efforts to improve our internal controls are ongoing and focused on expanding our organizational capabilities to improve our internal control environment, and on implementing process changes to strengthen our internal control and monitoring activities. Therefore, while there were no changes in our internal control over financial reporting in the period ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, we continued monitoring the operation of these remedial measures through the date of this report. For a more comprehensive discussion of the material weaknesses in internal control over financial reporting identified by management as of December 31, 2013, and the remedial measures undertaken to address these material weaknesses, investors are encouraged to review Item 9A, Controls and Procedures, in our Annual Report on Form 10-K for the year ended December 31, 2013.

PART II

ITEM 1. LEGAL PROCEEDINGS

None.

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, 2013, and is updated for the following:

If the FDA does not conclude that Egalet-001 is sufficiently bioequivalent, or has comparable bioavailability for approval, or if the FDA does not allow us to pursue the Section 505(b)(2) approval pathway as anticipated for our product candidates, the approval pathway for these product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and the FDA may not approve these product candidates.

A key element of our strategy is to seek FDA approval for Egalet-001 and Egalet-002 through the Section 505(b)(2) regulatory pathway. Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA), permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. Such reliance is typically predicated on a showing of bioequivalence or comparable bioavailability to an approved drug and/or utilizing other preclinical or clinical data from a Reference Labeled Drug in addition to demonstrating efficacy and safety of a product candidate.

If the FDA does not allow us to pursue the Section 505(b)(2) approval pathway as anticipated, or if we cannot demonstrate bioequivalence or comparable bioavailability for Egalet-001, to gain product approvals, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. For example, if the totality of the pharmacokinetic data for Egalet-001 does not provide an option to pursue a BE regulatory approach, the FDA may be less likely to approve our NDA with respect to Egalet-001 without a Phase 3 safety and efficacy trial. Moreover, an additional Phase 3 trial with the resultant delay in an NDA submission could result in new competitive products reaching the market more quickly than our product candidates, which could hurt

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our competitive position and our business prospects. Even if we are allowed to pursue the Section 505(b)(2) approval pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization on a timely basis, if at all.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA s interpretation of Section 505(b)(2) is successfully challenged, the FDA may change its policies and practices with respect to Section 505(b)(2) regulatory approvals, which could delay, make it more difficult for us to obtain approval for or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). Even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

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

Recent Sales of Unregistered Securities

In February 2014, concurrent with the completion of our IPO described below, Shionogi purchased 1,250,000 shares of our common stock for $12.00 per shares in a private placement, resulting in total net proceeds of approximately $14.0 million. The sale of these shares was not registered under the Securities Act of 1933, as amended, in reliance on the exemptions set forth under Section 4(2) thereof and Rule 506 of Regulation D thereunder.

Use of Proceeds

Our IPO of common stock was effected through a Registration Statement on Form S-1 (File No. 333-191759) that was declared effective by the SEC on February 5, 2014, which registered an aggregate of 4,830,000 shares of our common stock. On February 11, 2014, 4,200,000 shares of common stock were sold on our behalf at an IPO price of $12.00 per share, for aggregate gross proceeds of $50.4 million, managed by Stifel, Nicolaus & Company, Incorporated, JMP Securities LLC, Canaccord Genuity Inc., and Janney Montgomery Scott LLC. On March 7, 2014, in connection with the exercise by the underwriters of our IPO of the over-allotment option granted to them in connection with the IPO, 630,000 additional shares of common stock were sold on our behalf at the IPO price of $12.00 per share, for aggregate gross proceeds of approximately $7.6 million.

The underwriting discounts and commissions in connection with the offering totaled approximately $5.1 million. We incurred additional costs of approximately $2.4 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $7.5 million. Thus, the net offering proceeds to us, after deducting underwriting discounts, commissions and offering costs, were approximately $51.5 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

From the effective date of our Registration Statement on Form S-1 (File No. 333-191759) through September 30, 2014, we have used the proceeds from our IPO as described in our final prospectus, filed with the SEC on February 7, 2014 pursuant to Rule 424(b) and invested the funds received in cash equivalents and other short-term and long-term investments in accordance with our investment policy.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

ITEM 5. OTHER INFORMATION

None.

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ITEM 6. EXHIBITS

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

Exhibit Number	Description
10.1+	Employment agreement, dated as of July 31, 2014, by and between Egalet Corporation and Jeffrey M. Dayno, M.D. (incorporated by reference to Exhibit 10.1 to the Company s Current Report on Form 8-K filed with the SEC on July 28, 2014).
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2	Certification of the Principal Financial and Accounting Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of the Principal Financial and Accounting Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document (furnished herewith).
101.SCH	XBRL Taxonomy Extension Schema Document (furnished herewith).
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (furnished herewith).
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (furnished herewith).
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (furnished herewith).
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (furnished herewith).

+ Indicates management contract or compensatory plan.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: November 14, 2014

EGALET CORPORATION

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

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+ Indicates management contract or compensatory plan.