Insys Therapeutics, Inc.
Form 10-Q
November 12, 2014

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

[ ] 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: 001-35902

Insys Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**51-0327886** **(IRS Employer Identification No.)**
1333 S. Spectrum Blvd, Suite 100, Chandler, Arizona **(Address of principal executive offices)**	**85286** **(Zip Code)**

(602) 910-2617
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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 [ ]

Indicate by a checkmark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Date 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 [ ]

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer [ ] Accelerated Filer [ ] Non-Accelerated Filer [ ]

		(Do not check if a smaller reporting
company)	Smaller Reporting Company [X]	

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

YES [ ] NO [X]

As of November 6, 2014, the registrant had 34,957,780 shares of Common Stock ($0.01 par value) outstanding.

INSYS THERAPEUTICS, INC.

FORM 10-Q

TABLE OF CONTENTS

Part I: FINANCIAL INFORMATION

Item 1. UNAUDITED Financial Statements

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	September 30, 2014 (unaudited)	**December 31, 2013**
Assets		
Current Assets:		
Cash and cash equivalents	$ 47,410	$ 45,382
Restricted cash	-	400
Short-term investments	15,415	-
Accounts receivable, net of allowances for doubtul accounts of $602 and $0 at September 30, 2014 and December 31, 2014, respectively	27,659	16,313
Inventories	31,441	14,528
Prepaid expenses and other assets	2,682	1,727
Deferred income tax assets	4,079	3,800
Total current assets	128,686	82,150
Property and equipment, net	24,104	10,127
Long-term investments	26,683	-
Deferred income tax assets	8,652	8,238
Other assets	26	43
Total assets	$ 188,151	$ 100,558
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 24,534	$ 12,173
Accrued compensation	7,354	3,568
Accrued sales allowances	11,300	5,340
Total current liabilities	43,188	21,081
Total liabilities	43,188	21,081

Stockholders' Equity:		
Common stock (par value $0.01 per share; 100,000,000 and 50,000,000 shares authorized; 34,824,136 and 33,184,892 shares issued and outstanding as of September 30, 2014 and December 31, 2013, respectively)	348	332
Additional paid in capital	205,061	168,199
Unrealized loss on available-for-sale securities	(20)	-
Notes receivable from stockholders	(21)	(21)
Accumulated deficit	$ (60,405)	(89,033)
Total stockholders' equity	144,963	79,477
Total liabilities and stockholders' equity	$ 188,151	$ 100,558

See accompanying notes to unaudited condensed consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Net revenue	$58,281	$29,211	$155,613	$59,091
Cost of revenue	5,390	3,096	16,718	7,454
Gross profit	52,891	26,115	138,895	51,637
Operating expenses:				
Sales and marketing	15,061	7,969	40,756	18,723
Research and development	7,018	1,737	20,215	5,348
General and administrative	10,790	4,274	30,047	9,423
Total operating expenses	32,869	13,980	91,018	33,494
Operating income	20,022	12,135	47,877	18,143
Other income (expense):				
Interest income	43	8	86	(22)
Other income (expense), net	-	(24)	2	(937)
Total other income (expense)	43	(16)	88	(959)
Income before income taxes	20,065	12,119	47,965	17,184
Income tax expense	8,560	532	19,337	907
Net income	11,505	$11,587	28,628	$16,277
Unrealized loss on available-for-sale securities	(15)	-	(20)	-
Total comprehensive income	$11,490	$11,587	$28,608	$16,277
Net income per common share:				
Basic	$0.33	$0.36	$0.84	$0.69
Diluted	$0.31	$0.34	$0.78	$0.64
Weighted average common shares outstanding				
Basic	34,616,763	32,107,026	34,160,502	23,718,905
Diluted	36,564,466	34,183,707	36,556,922	25,398,559

See accompanying notes to unaudited condensed consolidated financial statements.

2

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

(unaudited)

	Common Stock		Additional Paid in	Unrealized Loss on	Notes Receivable	Accumulated	
	Shares	Amount	Capital	Available-For-Sale Securities	From Shareholders	Deficit	Total
Balance at December 31, 2013	33,184,892	$ 332	$ 168,199	$ -	$ (21)	$ (89,033)	$ 79,477
Exercise of stock options	1,422,682	14	5,043	-	-	-	5,057
Issuance of common stock-employee stock purchase plan	216,562	2	1,106	-	-	-	1,108
Excess tax benefits on stock options and awards	-	-	19,489	-	-	-	19,489
Stock based compensation - stock options and awards	-	-	11,224	-	-	-	11,224
Unrealized loss on available-for-sale securities	-	-	-	(20)	-	-	(20)
Net income	-	-	-	-	-	28,628	28,628
Balance at September 30, 2014	34,824,136	$ 348	$ 205,061	$ (20)	$ (21)	$ (60,405)	144,963

See accompanying notes to unaudited condensed consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Nine Months Ended September 30,	
	2014	**2013**
Cash flows from operating activities:		
Net income	$ 28,628	$ 16,277
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,711	1,311
Stock-based compensation	11,224	4,101
Deferred income tax benefit	(693)	-
Excess tax benefits on stock options and awards	(19,489)	-
Interest expense accrued on notes payable	-	900
Changes in operating assets and liabilities:		
Accounts receivable	(11,346)	(9,287)
Inventories	(16,913)	(4,651)
Prepaid expenses and other current assets	(936)	(95)
Accounts payable, accrued expenses and other current liabilities	41,595	5,284
Net cash provided by operating activities	33,781	13,840
Cash flows from investing activities:		
	400	(800)

Change in restricted cash and restricted cash equivalents		
Purchase of investments	(42,120)	-
Purchases of property and equipment	(15,687)	(2,787)
Net cash used in investing activities	(57,407)	(3,587)
Cash flows from financing activities:		
Proceeds from issuance of common stock	1,108	32,456
Net repayments on line of credit	-	(11,858)
Excess tax benefits on stock options and awards	19,489	-
Proceeds from exercise of stock options	5,057	134
Net cash provided by financing activities	25,654	20,732
Change in cash and cash equivalents	2,028	30,985
Cash and cash equivalents, beginning of period	45,382	361
Cash and cash equivalents, end of period	$ 47,410	$ 31,346
Supplemental cash flow disclosures:		
Cash paid for interest expense	$ -	$ -
Cash paid for income taxes	$ 2,190	$ -

See accompanying notes to unaudited condensed consolidated financial statements.

4

INSYS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

Insys Therapeutics, Inc., which was incorporated in Delaware in June 1990, and our subsidiaries (collectively, “we,” “us,” and “our”) maintain headquarters in Chandler, Arizona.

We are a specialty pharmaceutical company that develops and commercializes innovative supportive care products. We have two marketed products: Subsys, a proprietary sublingual fentanyl spray for breakthrough cancer pain in opioid-tolerant patients and Dronabinol SG Capsule, a generic equivalent to Marinol, an approved second-line treatment for chemotherapy-induced nausea and vomiting and anorexia associated with weight loss in patients with AIDS.

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the Securities and Exchange Commission (the “SEC”). Certain information and footnote disclosures have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying condensed consolidated financial statements include normal recurring adjustments that are necessary for a fair presentation of the results for the interim periods presented. These condensed consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2013 included in our Annual Report on Form 10-K. The results of operations for the three and nine months ended September 30, 2014 are not necessarily indicative of results to be expected for the full fiscal year or any other periods.

The preparation of the condensed consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make a number of estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition (which is affected by prescriptions dispensed, wholesaler discounts, patient discount programs, rebates and chargebacks), inventories, stock-based compensation expense, and deferred tax valuation allowances. We base our estimates on historical experience and on various other assumptions that are believed by management to be reasonable under the circumstances. Actual results may differ from these estimates.

All significant intercompany balances and transactions have been eliminated in the accompanying unaudited condensed consolidated financial statements.

On February 26, 2014, our board of directors approved a three-for-two stock split of our common stock to be effected through a stock dividend. The record date for the stock split was the close of business on March 17, 2014, with share distribution occurring on March 28, 2014. As a result of the dividend, shareholders received one additional share of Insys Therapeutics, Inc. common stock, par value $0.0002145, for each two shares they held as of the record date. All share and per share amounts have been retroactively restated for the effects of this stock split.

On May 6, 2014, our shareholders approved an amendment to our certificate of incorporation to increase the authorized shares of common stock from 50,000,000 to 100,000,000 and an amendment to increase the par value for our common stock to $0.01 per share. Our condensed consolidated unaudited financial statements and notes contained herein have been retroactively restated to reflect the impact of these amendments.

Recent Accounting Pronouncements

In July 2013, the FASB issued guidance that requires a reporting entity to present an unrecognized tax benefit as a liability in the financial statements separate from deferred tax assets if a net operating loss carry forward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date to settle taxes that would result from the disallowance of the tax position or if a reporting entity does not intend to use the deferred tax asset for such purpose. This standard was effective for us beginning December 31, 2013. The adoption of this standard did not have a material impact on our financial condition or results of operations.

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. The standard is effective for annual periods beginning after December 15, 2016, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2017.

2. Revenue Recognition

We recognize revenue from the sale of Subsys and Dronabinol SG Capsule. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

Subsys

Subsys was commercially launched in March 2012, and is available through a U.S. Food and Drug Administration ("FDA") mandated Risk Evaluation and Mitigation program known as the Transmucosal Immediate Release Fentanyl program ("TIRF REMS"). We sell Subsys in the United States to wholesale pharmaceutical distributors, and on a very limited basis directly to retail pharmacies, or collectively our customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Subsys currently has a shelf life of 36 months from the date of manufacture. Given the limited sales history of prescriptions of Subsys, prior to the fourth quarter of 2013 we were not able to reliably estimate expected returns of the product at the time of shipment. Accordingly, we initially deferred the recognition of revenue and related product costs of Subsys product shipments until the product was dispensed through patient prescriptions. The quantity of prescription units dispensed was estimated using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. Beginning in the fourth quarter of 2013, we were able to reasonably estimate product returns of Subsys. Therefore, we began recognizing revenue for Subsys sales at the time of shipment.

We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the

levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. Our product sales allowances include:

Product Returns. We allow customers to return product for credit within six months before and up to 12 months following its product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after its product expiration date, there may be a significant period of time between when the product is shipped and when we issue credits on returned product. Accordingly, we may have to adjust these estimates, which could have an effect on product sales and earnings in the period of adjustments. The allowance for product returns is included in accrued sales allowances.

Wholesaler Discounts. We offer discounts to certain wholesale distributors based on contractually determined rates. We accrue the discount as a reduction of receivables due from the wholesalers upon shipment to the respective wholesale distributors and retail pharmacies and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. We offer cash discounts to our customers, generally 2.0% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the full amount and recognize the discount as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. We offer discount card programs to patients for Subsys in which patients receive discounts on their prescriptions that are reimbursed to the retailer. We estimate the total amount that will be redeemed based on a percentage of actual redemption applied to inventory in the distribution and retail channel and recognize the discount as a reduction of revenue in the same period the related revenue is recognized. The allowance for patient discount programs is included in accrued sales allowances.

Rebates. We participate in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, we pay a rebate to the third-party administrator of the program, generally two to three months after the quarter in which prescriptions subject to the rebate are filled. We estimate and accrue these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized. The allowance for rebates is included in accrued sales allowances.

Chargebacks. We provide discounts primarily to authorized users of the Federal Supply Schedule ("FSS") of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the entity paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized. The allowance for chargebacks is included as a reduction to accounts receivable.

Dronabinol SG Capsule

Dronabinol SG Capsule was commercially launched in December 2011, and we sell Dronabinol SG Capsule exclusively to Mylan Pharmaceuticals, Inc. ("Mylan") in the United States under a supply and distribution agreement. Pursuant to the terms of the Mylan agreement, we manufacture Dronabinol SG Capsule under the Mylan label. Mylan distributes Dronabinol SG Capsule and on a monthly basis pays us an amount equal to the value of Dronabinol SG Capsule it sold to wholesale pharmaceutical distributors, less contractually defined deductions for chargebacks, rebates, sales discounts, distribution and storage fees, and royalties. Under the terms of the supply and distribution agreement with Mylan, we are obligated to pay Mylan a royalty of between 10% and 20% on Mylan's net product sales, and a single digit percentage fee on such sales for distribution and storage services. We bear no risk of product return upon acceptance by Mylan. As Mylan has control over the amount it charges to wholesale pharmaceutical distributors for Dronabinol SG Capsule and the discounts offered to the distributors, the sales price is not fixed and determinable at the date we ship such products to Mylan. Accordingly, we recognize revenue upon Mylan's sale of products to wholesale distributors, which is the point at which the sales price is fixed and determinable. The allowance for chargebacks is included in accrued expense. See Note 7 for a discussion on our ongoing dispute with Mylan.

3. Short-Term and Long-Term Investments

Our policy for short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Short-term and long-term investments consist of corporate and various government agency and municipal debt securities, as well as certificates of deposit that have maturity dates that are greater than 90 days. Certificates of deposit are carried at cost which approximates fair value. We classify our marketable securities as available-for-sale in accordance with FASB Accounting Standards Codification Topic 320, *Investments — Debt and Equity Securities*. Available-for-sale securities are carried at fair value with unrealized gains and losses reported in stockholders' equity. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary, results in impairment of the fair value of the investment. We did not have any realized gains or losses or decline in values judged to be other than temporary during the nine months ended September 30, 2014. If we had realized gains and losses and declines in value judged to be other than temporary, we would have been required to include those changes in other expense in the condensed consolidated statements of income and comprehensive income. Premiums and discounts are amortized or accreted over the life of the related available-for-sale security. The cost of securities sold is calculated using the specific identification method. At September 30, 2014, our certificates of deposit as well as our marketable securities have been recorded at an estimated fair value of $15,415,000 and $26,683,000 in short-term and long-term investments, respectively.

Investments consisted of the following at September 30, 2014 (in thousands):

	Cost	Unrealized Gains	Unrealized Losses	Other-Than-Temporary Impairment Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
Cash	$27,284	$ -	$ -	$ -	$27,284	$ 27,284	$ -	$ -
Money market funds	20,126	-	-	-	20,126	20,126	-	-
Certificates of deposit	10,629	-	-	-	10,629		2,196	8,433
Marketable securities:								
Corporate securities	11,390	-	(23)	-	11,367	-	6,149	5,218
Federal agency securities	10,015	3	(12)	-	10,006	-	-	10,006
Municipal securities	10,084	12	-	-	10,096	-	7,070	3,026
Total marketable securities	31,489	15	(35)	-	31,469	-	13,219	18,250
	$89,528	**$ 15**	**$ (35)**	**$ -**	**$89,508**	**$ 47,410**	**$ 15,415**	**$ 26,683**

We did not have marketable securities at December 31, 2013.

The amortized cost and estimated fair value of the marketable securities at September 30, 2014, by maturity, are shown below (in thousands):

	September 30, 2014	
	Cost	Fair Value
Marketable securities:		
Due in one year or less	$15,412	$15,415
Due after one year through 5 years	26,706	26,683
Due after 5 years through 10 years	-	-
Due after 10 years	-	-
	$42,118	**$42,098**

The following table shows the gross unrealized losses and the fair value of our investments, with unrealized losses that are not deemed to be other-than-temporarily impaired aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at September 30, 2014 (in thousands):

	September 30, 2014			
	Less Than 12 Months		**Greater Than 12 Months**	
	Fair Value	**Unrealized Loss**	**Fair Value**	**Unrealized Loss**
Marketable securities:				
Corporate securities	$10,862	$ (23)	$ -	$ -
Federal agency securities	6,988	(12)	-	-
Municipal securities	444	-	-	-
	$18,294	**$ (35)**	**$ -**	**$ -**

As of September 30, 2014, we have concluded that the unrealized losses on our marketable securities are temporary in nature. Marketable securities are reviewed quarterly for possible other-than-temporary impairment. This review includes an analysis of the facts and circumstances of each individual investment such as the severity of loss, the expectation for that security's performance and the creditworthiness of the issuer. Additionally, we do not intend to sell, and it is not probable that we will be required to sell, any of the securities before the recovery of their amortized cost basis.

4. Fair Value Measurement

FASB Accounting Standards Codification ("ASC") No. 820, "Fair Value Measurement" defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. It also establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

At September 30, 2014, we held short-term and long-term investments, as discussed in Note 3, that are required to be measured at fair value on a recurring basis. All available-for-sale investments held by us at September 30, 2014 have been valued based on Level 2 inputs. Available-for-sale securities classified within Level 2 of the fair value hierarchy are valued utilizing reports from third-party asset managers that hold our investments, showing closing prices on the last business day of the period presented. These asset managers utilize an independent pricing source to obtain quotes for most fixed income securities, and utilize internal procedures to validate the prices obtained. In addition, we use an independent third-party to perform price testing, comparing a sample of quoted prices listed in the asset managers' reports to quotes listed through a public quotation service.

Our investments measured at fair value on a recurring basis subject to the disclosure requirements of ASC 820, *Fair Value Measurements and Disclosures*, at September 30, 2014 were as follows (in thousands):

	Fair Value Measurement at Reporting Date		
September 30, 2014	**Quoted Prices in active Markets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**

Marketable securities:						
Corporate securities	$11,367	$	-	$ 11,367	$	-
Federal agency securities	10,006		-	10,006		-
Municipal securities	10,096		-	10,096		-
Total assets measured at fair value	**$31,469**	**$**	**-**	**$ 31,469**	**$**	**-**

We did not have any marketable securities at December 31, 2013.

5. Inventories

Inventories are stated at lower of cost or market. Cost, which includes amounts related to materials and costs incurred by our contract manufacturers, is determined on a first-in, first-out basis. Inventories are reviewed periodically for potential excess, dated or obsolete status. Management evaluates the carrying value of inventories on a regular basis, taking into account such factors as historical and anticipated future sales compared to quantities on hand, the price we expect to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

The components of inventories, net of allowances, are as follows (in thousands):

	September 30, 2014	December 31, 2013
Finished goods	$ 22,461	$ 8,084
Work-in-process	4,672	3,886
Raw materials and supplies	4,308	2,558
Total inventories	$ 31,441	$ 14,528

As of September 30, 2014 and December 31, 2013, raw materials inventories consisted of raw materials used in the manufacture of the active pharmaceutical ingredient (“API”) in our U.S.-based, state-of-the-art dronabinol manufacturing facility and component parts used in the manufacture of Subsys. Work-in-process consisted of actual production costs, including facility overhead and tolling costs of in-process Dronabinol SG Capsule and Subsys products. Finished goods inventories consisted of finished Dronabinol SG Capsule and Subsys products.

6. Line of Credit

On September 30, 2014, our $15,000,000 revolving credit facility (the “Facility”), which we entered into in October 2013 with JPMorgan Chase Bank, N.A. matured. As of December 31, 2013, no amounts were outstanding under the Facility. The Facility was secured by all of our assets.

7. Contingencies

Legal Matters

Other than the matters that we have disclosed below, we from time to time become involved in various ordinary course legal and administrative proceedings, which include intellectual property, commercial, governmental and regulatory investigations, employee related issues and private litigation, which we do not believe are either individually or collectively material.

As legal and governmental proceedings are inherently unpredictable and, in part, beyond our control, unless otherwise indicated, we cannot reasonably predict the outcome of these legal proceedings, nor can we estimate the amount of

loss, or range of loss, if any, that may result from these proceedings. An adverse outcome in any of these proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows, and could cause the market value of our common shares to decline.

Government Proceedings

Like other companies in the pharmaceutical industry, we are subject to extensive regulation by national, state and local government agencies in the United States. As a result, interaction with government agencies occurs in the normal course of our operations. The following is a brief description of pending governmental investigations which we believe are potentially material at this time. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from any government investigation or proceeding whether we deem them to be material or not.

Department of Health and Human Services Investigation. We received a subpoena, dated December 9, 2013, from the Office of Inspector General of the Department of Health and Human Services, or HHS, in connection with an investigation of potential violations involving HHS programs. The subpoena was issued in connection with an investigation by the U.S. Attorney's Office for the Central District of California. The subpoena requests documents regarding our business, including the commercialization of Subsys. We are cooperating with this investigation and have produced documents in response to the subpoena and have provided other requested information.

Health Insurance Portability and Accountability Act Investigation. On September 8, 2014, we received a subpoena issued pursuant to the Health Insurance Portability and Accountability Act of 1996, as amended, from the U.S. Attorney's Office for the District of Massachusetts. The subpoena requests documents regarding Subsys, including our sales and marketing practices related to this product. We are cooperating with this investigation and have produced documents in response to the subpoena and have provided other requested information.

We believe that the probability of unfavorable outcome or loss related to these governmental proceedings and an estimate of the amount or range of loss, if any, from an unfavorable outcome are not determinable at this time. We believe we have meritorious legal positions and will continue to represent our interests vigorously in these matters. However, responding to government investigations, defending any claims raised, and any resulting fines, restitution, damages and penalties, settlement payments or administrative actions, as well as any related actions brought by shareholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

Federal Securities Litigation.

Between May 15 and May 19, 2014, two complaints (captioned Larson v. Insys Therapeutics, Inc., Case No. 14-cv-01043-GMS) and (Li vs. Insys Therapeutics, Inc., Case No 14-cv-01077-DGC) were filed in the U.S. District Court for the District of Arizona, or Arizona District Court, against us and certain of our current officers. The complaints were brought as purported class actions, on behalf of purchasers of our common stock. In general, the plaintiffs allege that the defendants violated federal securities laws by making intentionally false and misleading statements regarding our business and operations, therefore artificially inflating the price of our common stock. The plaintiffs seek unspecified monetary damages and other relief. On July 14, 2014, several purported shareholders filed motions to consolidate the two cases, appoint a lead plaintiff, and appoint lead counsel. On August 29, 2014, the Arizona District Court issued an order consolidating the action, appointing Hongwei Li as lead plaintiff, and appointing the lead counsel. Lead plaintiffs complaint was filed on October 27, 2014. Our response to the consolidated complaint is due on December 11, 2014.

General Litigation and Disputes

Kottayil vs. Insys Pharma, Inc. On September 29, 2009, Insys Pharma, Inc., our wholly owned subsidiary, and certain of our officers and the five directors who comprised the Insys Pharma board of directors as of June 2009, as well as their spouses, were named as defendants in a lawsuit in the Superior Court of the State of Arizona, Maricopa County, or the Arizona Superior Court, brought by Santosh Kottayil, Ph.D., certain of his family members and a trust of which Dr. Kottayil is the trustee. Dr. Kottayil formerly served as President, Chief Scientific Officer and a director of Insys Pharma, among other positions. The complaint brought a cause of action for statutory and common law appraisal of Dr. Kottayil's Insys Pharma common stock. The cause of action for appraisal relates to a reverse stock split that Insys Pharma effected in June 2009, which resulted in Dr. Kottayil's ownership position becoming a fractional share of Insys Pharma common stock. Following the reverse stock split, Insys Pharma cancelled all resulting fractional shares, including the fractional share held by Dr. Kottayil, and offered a cash payment in lieu of the fractional shares. The complaint also brought causes of action for breach of fiduciary duty, fraud and negligent misrepresentation in the defendants' dealings with Dr. Kottayil on the subject of his compensation and stock ownership in Insys Pharma. In January 2010, the plaintiffs added claims seeking to rescind Dr. Kottayil's assignment to Insys Pharma of his interest in all of the fentanyl and dronabinol patent applications previously assigned to Insys Pharma and to recover the benefits of those interests. Dr. Kottayil is seeking, among other relief, the fair value of his Insys Pharma common stock as of June 2, 2009, compensatory and punitive damages, and rescission of all assignments to Insys Pharma of his

interest in the patent applications, as well as attorneys' fees, costs and interest.

In February 2010, Insys Pharma and the other defendants answered and filed counter-claims to Dr. Kottayil's amended complaint. The counter-claims include actions for breach of fiduciary duty, fraud and negligent misrepresentations and omissions with respect to the time during which Dr. Kottayil was employed at Insys Pharma. The counter-claims, among other relief, seek compensatory and punitive damages.

Discovery on all of the foregoing claims was completed and a trial was scheduled to commence on January 27, 2014; however, on January 22, 2014, the court vacated the trial and granted plaintiffs leave to file an amended complaint to add Insys Therapeutics, Inc. as a defendant.

On January 29, 2014, the plaintiffs filed a second amended complaint in the Arizona Superior Court in which Insys Therapeutics, Inc. was also named as defendant in this lawsuit. This amended complaint filed by plaintiffs re-alleges substantially the same claims set forth in the prior complaint, except that plaintiffs now allege that they are entitled to rescissory damages, plaintiffs have also added our majority stockholder, a private trust, as a defendant to the breach of fiduciary duty claim and plaintiffs have revised their fraud claim against the Insys Pharma director defendants.

On February 25, 2014, we filed a Motion to Dismiss the Kottayil Plantiffs' claims for a statutory and common law appraisal. The motion was denied on May 2, 2014.

The court has set the case for trial commencing on December 1, 2014.

Insys Therapeutics, Inc. vs. Mylan Pharmaceuticals. On or around May 30, 2013, we filed a lawsuit against Mylan Pharmaceuticals, or Mylan, seeking a declaration that the parties' Supply and Distribution Agreement dated May 20, 2011, or the Distribution Agreement, had been terminated because of Mylan's material breach of the Distribution Agreement. Mylan removed the action to the United States District Court for the District of Arizona, or the District Court, as Case No. 2:13-cv-01112-DGC, and moved to compel arbitration and sought a preliminary injunction. The District Court compelled arbitration and issued a preliminary injunction requiring that the Distribution Agreement continue in full force and effect pending the outcome of arbitration. The District Court then dismissed the lawsuit.

On May 31, 2013, Mylan filed a demand with the American Arbitration Association, Case No. 55 122 00119 13. Mylan's demand alleged that we were in breach of the Distribution Agreement. On July 10, 2013, we filed a response to Mylan's demand, denying we were in breach of the Distribution Agreement, and asserting counterclaims based on Mylan's material breach of the Distribution Agreement and the duty of good faith and fair dealing.

On September 23, 2014, the three member arbitration panel held a preliminary hearing wherein it decided that the arbitration proceeding would be bifurcated. The first phase of the proceeding will determine whether there has been a material breach of the Agreement. If either party is successful in establishing its claims during this first phase then there will be a second phase of the arbitration to determine damages. The panel has set an arbitration hearing in early November 2014, in connection with the first phase of the arbitration. We anticipate that the first phase of the arbitration will resolve: (1) whether Mylan materially breached the Distribution Agreement by failing to accept delivery of a conforming shipment of product in October 2012, January 2014 and March 2014; (2) whether Mylan has materially breached the parties Distribution Agreement by failing to use commercially reasonable efforts to market and sell the product; and (3) whether the Distribution Agreement has been terminated because of the parties dispute over floor pricing.

On January 21, 2014, Mylan filed a second new lawsuit against us with the District Court, as Case No. 2:14-cv-00119-GMS, asserting a claim for declaratory judgment and seeking a temporary restraining order and preliminary injunction relating to our notice of termination of the Distribution Agreement with respect to the parties' failure to agree on floor pricing. On January 24, 2014, Insys responded in opposition to the application for temporary restraining order and preliminary injunction, or Application. A hearing was initially set for April 3, 2014. After stipulation of the parties to postpone the hearing, the Court denied all pending motions as moot on April 2, 2014. The Application was dismissed by the Court with prejudice on June 2, 2014. After the Application was dismissed, Mylan filed a Motion to Enforce a draft settlement agreement between the parties. We responded in opposition and the District Court denied Mylan's motion on September 12, 2014. We have moved for sanctions against Mylan for filing the motion to enforce and we intend to seek damages and attorneys' fees as part of this arbitration.

We believe that the probability of unfavorable outcome or loss related to all of the above litigation matters and an estimate of the amount or range of loss, if any, from an unfavorable outcome are not determinable at this time. We believe we have meritorious legal positions and will continue to represent our interests vigorously in these matters but the range possible outcomes on these matters is very broad and we are not able to provide a reasonable estimate of our potential liability, if any, nor are we able to predict the outcome of each litigation matter. For instance, in the Kottayil

matter, if the patent assignments are successfully rescinded, we may not have exclusive patent rights covering our fentanyl and dronabinol product candidates, and such patent rights may not be available to us on acceptable terms, if at all, which would have a material adverse effect on our business. Responding to each of these litigation matters, defending any claims raised, and any resulting fines, restitution, damages and penalties, or settlement payments as well as any related actions brought by shareholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

8. Stock-based Compensation

Amounts recognized in the condensed consolidated statements of income and comprehensive income with respect to our stock-based compensation plans were as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	**2013**	**2014**	**2013**
Research and development	$432	$247	$4,294	$874
General and administrative	2,605	1,450	6,930	3,227
Total cost of stock-based compensation	$3,037	$1,697	$11,224	$4,101

As previously disclosed on a Form 8-K filed by us on April 1, 2014, we entered into a Separation and Consulting Agreement with a former officer. In accordance with the terms of the Separation and Consulting Agreement, during the second quarter of 2014, we recorded $3,142,000 in stock-based compensation to research and development expense related to the acceleration of vesting of 167,461 shares subject to outstanding stock options granted to the former officer.

As of September 30, 2014, we expected to recognize $36,181,000 of stock-based compensation for outstanding options over a weighted-average period of 3.1 years.

The following table summarizes stock option activity as of December 31, 2013 (which reflects the aforementioned stock split) and for the nine months ended September 30, 2014:

	Number of Shares	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual**	**Aggregate Intrinsic Value (in millions)**

			Term (in years)	
Vested and exercisable as of December 31, 2013	1,810,653	$ 2.80		
Outstanding as of December 31, 2013	4,496,667	$ 5.79		
Granted	1,485,411	$ 28.25		
Cancelled	(374,448)	$ 11.21		
Exercised	(1,422,682)	$ 3.55		
Outstanding as of September 30, 2014	4,184,948	$ 14.04	8.5	$ 103.5
Vested and exercisable as of September 30, 2014	1,371,523	$ 6.44	7.4	$ 44.4

Cash received from option exercises under all share-based payment arrangements for the nine months ended September 30, 2014 and 2013 was $5,057,000 and $134,000, respectively. For the nine months ended September 30, 2014, we recorded net reductions of $19,489,000 of our federal and state income tax liability, with an offsetting credit to additional paid-in capital, resulting from the excess tax benefits of stock options.

9. Net Income per Share

Basic net income per common share is computed by dividing the net income allocable to the common stockholders by the weighted average number of common shares outstanding during the period. The diluted income per share further includes any common shares available to be issued upon exercise of outstanding stock options if such inclusion would be dilutive.

The net income per share for the nine months ended September 30, 2013, including share and per share amounts, includes the effects of the conversion of convertible preferred stock into 12,793,290 shares of common stock (8,528,860 on a pre-split basis) as if the conversion had occurred at the beginning of the respective period.

The following table sets forth the computation of basic and diluted net income per common share (dollars in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Historical net income per share - Basic				
Numerator:				
Net income	$11,505	$11,587	$28,628	$16,277
Denominator:				
Weighted average number of common shares outstanding	34,616,763	32,107,026	34,160,502	23,718,905
Basic net income per common share	$0.33	$0.36	$0.84	$0.69
Historical net income per share - Diluted				
Numerator:				
Net income	$11,505	$11,587	$28,628	$16,277
Denominator:				
Weighted average number of common shares outstanding	34,616,763	32,107,026	34,160,502	23,718,905
Effect of dilutive stock options	1,947,703	2,076,681	2,396,420	1,679,654
Weighted average number of common shares outstanding	36,564,466	34,183,707	36,556,922	25,398,559
Diluted net income per common share	$0.31	$0.34	$0.78	$0.64

Anti-dilutive share equivalents included 1,462,265 and 4,917 outstanding stock options as of September 30, 2014 and 2013, respectively.

10. Product Lines, Concentration of Credit Risk and Significant Customers

We are engaged in the business of developing and selling pharmaceutical products. We have two product lines, consisting of Subsys and Dronabinol SG Capsule. Our chief operating decision-maker evaluates revenues based on product lines.

The following tables summarize our net revenue by product line, as well as the percentages of revenue by route to market (in thousands):

Net Revenue by Product Line

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Subsys	$58,203	$28,355	$153,431	$56,552
Dronabinol SG Capsule	78	856	2,182	2,539
Total net revenue	$58,281	$29,211	$155,613	$59,091

	Percent of Revenue by Route to Market			
	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Pharmaceutical wholesalers	100%	97%	99%	96%
Generic pharmaceutical distributors	0%	3%	1%	4%
	100%	100%	100%	100%

All our products are sold in the United States of America.

Product shipments to four pharmaceutical wholesalers accounted for 39%, 21%, 15% and 14% of shipments for the nine months ended September 30, 2014. Product shipments to four pharmaceutical wholesalers accounted for 30%, 20%, 20% and 18% of net revenue for the nine months ended September 30, 2013. Four pharmaceutical wholesalers' accounts receivable balances accounted for 39%, 22%, 17% and 10% of gross accounts receivable as of September 30, 2014. Four pharmaceutical wholesalers' accounts receivable balances accounted for 40%, 22%, 17% and 14% of gross accounts receivable as of December 31, 2013.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2013 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, ("the Exchange Act"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management; the amount of estimated costs and the benefits of our planned second dronabinol manufacturing facility; estimated costs to complete development and obtain approvals for our Dronabinol Oral Solution product candidate and the timing related to actions in connection therewith; our intent to file and IND application for the treatment of epilepsy with Cannabidiol; the sufficiency of our manufacturing capacity; the beneficial attributes of our dronabinol product candidates; our expectation that gross margins will fluctuate; that sales and marketing and research and development costs will be our largest categories of expenses; that sales and marketing expenses will fluctuate based on changes in Subsys net revenue; that our Subsys revenue will increase during the remainder of 2014 and the reasons therefore; that cash flows from operating activities will increase; our development of different dronabinol delivery systems; the source and sufficiency of our liquidity our capital resources to fund our operations; possible capital raising transactions we may pursue; that we will hire additional sales and marketing, research and development and administrative personnel, that costs relating thereto will increase and the anticipated benefits resulting therefrom; accounting estimates and the impact of new or recently issued accounting pronouncements; that cash flows from operations, will increase as a result of increased sales of Subsys; that we will incur substantial costs as we transition to a public company; certain anticipated strategies and outcomes of our litigation with Mylan; trends in restrictions and impediments relating to reimbursement policies imposed by pharmacy benefit managers; the impact on our 2014 results of an announcement by a pharmacy benefit manager to exclude Subsys from its preferred formulary; the impact of pending litigation and our strategy relating thereto; that we will not recognize revenue in the near term from current research and development initiatives; the potential impact of Section 382 limitations on our NOLs; and the magnitude and impact of ownership changes, including pre-merger changes relating to NeoPharm, under Section 382 of the Internal Revenue Code. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "should," "could," "predicts," "potential," "continue," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any

obligation to update any forward-looking statements. All forward-looking statements in this Form 10-Q are made based on our current expectations, forecasts, estimates and assumptions, and involve risks, uncertainties and other factors that could cause results or events to differ materially from those expressed in the forward-looking statements. In evaluating these statements, you should specifically consider various factors, uncertainties and risks that could affect our future results or operations as described from time to time in our SEC reports, including those risks outlined under "Risk Factors" in Item 1A of our Form 10-K for the year ended December 31, 2013. These factors, uncertainties and risks may cause our actual results to differ materially from any forward-looking statement set forth in this Form 10-Q. You should carefully consider these risk and uncertainties described and other information contained in the reports we file with or furnish to the SEC before making any investment decision with respect to our securities. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by this cautionary statement. Some of the important factors that could cause our actual results to differ materially from those projected in any forward-looking statements including, but are not limited to, the following:

- *our dependence on sales of Subsys and Dronabinol SG Capsule;*
- *market acceptance, including by third-party payors, of our products;*
- *the success of our marketing strategies;*
- *our early stage of commercialization and history of net losses;*
- *our ability to manage growth in our business;*
- *our ability to obtain regulatory approval for Dronabinol Oral Solution;*

manufacturing failures;
challenges relating to our construction and operation of a second dronabinol manufacturing facility;
our limited manufacturing capabilities and our reliance on third parties in our product supply chain;
delays in manufacturing or interruption of our sublingual spray delivery system;
competition;
our ability to achieve and maintain adequate levels of third-party payor and reimbursement coverage for sales of our products;
our reliance on wholesale pharmaceutical distributors for sales of our products through to the retail distribution channel;
our reliance on third parties for the performance of services relating to Subsys, including invoicing, storage and transportation;
our ability to develop a pipeline of product candidates;
our failure to obtain or maintain Schedule III classification for our dronabinol products;
failure of our clinical trials to demonstrate acceptable levels of safety and efficacy;
expenses, delays, changes and terminations that could adversely affect the design and implementation of our clinical trials;
reliance on third parties to conduct and oversee our clinical trials;
acceptance by the FDA our data from our clinical trials conducted outside the United States;
risks and uncertainties associated with starting materials sourced from India;
our ability to meet Section 505(b)(2) regulatory approval pathways or requirements for our product candidates;
annual DEA quotas on the amount of dronabinol allowed to be produced in the United States;
our failure to successfully acquire, develop or market additional product candidates;
our ability to retain key management and other personnel;
misconduct and improper activities by our employees, prescribing physicians and other persons involved in the marketing and distribution of our products;
our ability to utilize our net operating loss and research and development tax credit carryforwards;
the adverse impacts of strategic transactions;
our exposure to product liability claims;
our ability to comply with environmental laws relating to our use of hazardous materials;
accounting estimates;
security system failures;
natural disasters;
our significant operating losses and need for potential additional funding;
restrictions on our business imposed by our credit facility;
market fluctuation and economic conditions;
our failure to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws;
the regulatory impact on our existing Subsys and Dronabinol SG Capsule products as well as our future product candidates;
undesirable side effects of our products and the potential for post-approval regulatory action relating to such side effects;
the impact of changes in policies and funding resulting from healthcare reform measures, including the impact on the funding, staffing and leadership of the FDA and other agencies;
our ability to obtain and enforce patent rights or other intellectual property rights that cover our products and product candidates;
the potential for rescission of invention assignments existing in favor of the Company from its employees, including the potential for rescission of invention rights resulting from a current lawsuit between Insys Pharma and Santosh Kottayil;

costs of litigation and our ability to protect our intellectual property rights;
our exposure to litigation relating to infringement suits against the Company;
our exposure to claims that our employees or independent contractors have wrongfully used or disclosed to the Company trade secrets of their other clients or former employers;
our compliance with the procedural, document submission, fee payment and other requirements needed to apply for patents;
control over the Company by its founder, Executive Chairman and principal stockholder;
fluctuation in the price of our common stock;
lack of, or inaccurate, published research about the Company;
the impact of future sales of our common stock or securities convertible into our common stock;
the effect of anti-takeover provisions in our charter documents and under Delaware law;
the impact of our abbreviated disclosures as allowed by the JOBS Act because of our status as an "emerging growth company";
our intention to not pay dividends in the foreseeable future;
our failure to remediate significant deficiencies or material weaknesses in our internal control over financial reporting and related compliance with SEC and stock exchange listing standards;
the costs and management distraction resulting from being a public company; and
the unpredictability and regulation surrounding the reimbursement of Subsys.

Additionally, there may be other risks that are otherwise described from time to time in the reports that we file with the Securities and Exchange Commission. Any forward-looking statements in this report should be considered in light of various important factors, including the risks and uncertainties listed above, as well as others.

Overview

We are a commercial-stage specialty pharmaceutical company that develops and commercializes innovative supportive care products. We have two marketed products:

- Subsys — a proprietary, single-use product that delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue, offered in 100, 200, 400, 600, 800, 1,200 and 1,600 mcg dosages. Subsys is approved for the treatment of breakthrough cancer pain ("BTCP") in opioid-tolerant patients. We received FDA approval for Subsys in January 2012 and commercially launched Subsys in March 2012.

- Dronabinol SG Capsule — a dronabinol soft gelatin capsule that is a generic equivalent to Marinol, an approved second-line treatment for chemotherapy-induced nausea and vomiting ("CINV") and anorexia associated with weight loss in patients with AIDS, offered in 2.5, 5.0 and 10.0 milligram dosages. We received FDA approval for Dronabinol SG Capsule in August 2011. We commercially launched Dronabinol SG Capsule through our exclusive distribution partner, Mylan Pharmaceuticals, Inc., in December 2011.

We market Subsys through our U.S.-based field sales force focused on supportive care physicians. We utilize an incentive-based sales model that employs a pay structure where a significant component of the compensation paid to sales representatives is in the form of potential bonuses based on sales performance.

Our sales of, and revenue from, Subsys depend in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers. All third-party payers are sensitive to the cost of drugs and consistently implement efforts to control these costs, which efforts include, but are not limited to, establishing excluded or preferred drug lists. Subsys has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, particularly pharmacy benefit managers ("PBMs") and private health insurers. We provide administrative reimbursement support assistance, in large part through our insurance reimbursement support hub, which provides administrative support assistance to help patients work with their insurance companies.

On or around August 1, 2014, Express Scripts, Inc. ("ESI") officially released its exclusion list of drugs, effective January 1, 2015, in connection with its national preferred formulary. Our product, Subsys, was included on this exclusion list. ESI is a large PBM that administers prescription drug benefits for employers and health plans and runs large mail-order pharmacies. While ESI, like most PBMs, has an exception process that physicians may pursue to have an off-formulary, medically necessary drug covered for patients, this decision will make it difficult for many patients covered through an ESI administered plan to have Subsys covered by insurance. This change in ESI formulary status will not take effect until 2015 and therefore we do not expect this ESI announcement to impact our 2014 revenue or results of operations. As we have in the past, we will continue working with other PBMs to evaluate price increases and to communicate with managed care and health-system decision-makers to ensure a

balanced approach, which takes into account the clinical performance and efficacy of our products.

We produce the Active Pharmaceutical Ingredient ("API") for Dronabinol SG Capsule at our U.S.-based, state-of-the-art dronabinol manufacturing facility. While we believe that this facility has the capacity to supply sufficient commercial quantities of dronabinol API for our Dronabinol SG Capsule, initial launch quantities of Dronabinol Oral Solution, if approved, and support the continued development of our other dronabinol product candidates in the near-term, we have commenced construction of a second dronabinol manufacturing facility, which we anticipate will enable us to supply sufficient commercial quantities of dronabinol API for our continued commercialization of Dronabinol SG Capsule and for the commercialization of our proprietary dronabinol product candidates, if approved. In May 2011, we entered into a supply and distribution agreement with Mylan, pursuant to which we engaged Mylan to exclusively distribute Dronabinol SG Capsule within the United States. See Note 7 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

In addition, we are developing other product candidates, such as dronabinol line extensions and sublingual spray product candidates. Our most advanced potential cannabinoid line extension is Dronabinol Oral Solution. This product candidate has demonstrated more rapidly detectable blood levels and a more reliable absorption profile than Marinol in our clinical studies. We believe these attributes may ultimately increase patient compliance because of more rapid onset of action and less dose-to-dose variability, which we believe will allow us to further penetrate and potentially expand the market for the medical use of dronabinol. We completed a pre-NDA meeting with the FDA and a pivotal bioequivalence study for Dronabinol Oral Solution in 2012 and we completed the clinical dossier for this product candidate during the third quarter of 2013. We are currently engaged in an ongoing dialogue with the U.S. FDA and U.S. Drug Enforcement Agency ("DEA") regarding the potential scheduling classification for this product candidate. On October 15, 2014, we announced that we received a Refusal to File Letter from the FDA for our proprietary Dronabinol Oral Solution. The letter indicates that the FDA refused to file the NDA because the NDA contained an inadequate or incomplete pediatric study plan. We are currently working with the FDA to resubmit the application as quickly as possible.

We have the capability to manufacture pharmaceutical Cannabidiol ("CBD"), a synthetically produced and over 99% pure form of cannabidiol, in our Round Rock, Texas manufacturing facility. We believe we are the only U.S.-based company with the capacity to produce pharmaceutical CBD in large quantities. We intend to file an IND application with the FDA during 2014 for the treatment of epilepsy.

Factors Affecting Our Performance

We believe that our performance and future success are dependent upon a number of factors, including our approved product sales, investments in our infrastructure and growth, and our ability to successfully develop product candidates and complete related regulatory processes. In addition, our ability to ensure that our products, policies and practices adhere to the extensive national, state and local regulations applicable to our industry is critical to our success, particularly as our operations and product opportunities continue to grow at a rapid pace. While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must successfully address.

Approved Product Sales. Our operating results will depend significantly upon our, and any of our third-party distributors', sales of approved products. During the nine months ended September 30, 2014 and 2013, all of our net revenues were generated from the sale of our two approved products, Subsys and Dronabinol SG Capsule, with sales of Subsys accounting for almost 100% of our 2014 year-to-date revenues. Our results will depend on prescription volume generally, which we believe will be driven primarily by achievement of broad market acceptance and coverage by third-party payors and effectiveness of the marketing and selling efforts with respect to our products. In addition, our results will also depend on our mix of sales between Subsys and Dronabinol SG Capsule as well as the amounts of dosage strengths sold. Subsys gross margins are substantially higher than those of Dronabinol SG Capsule. For example, though we expect gross margins to fluctuate from period to period, Subsys gross margin was approximately 91% and Dronabinol SG Capsule gross margin was negative for the nine months ended September 30, 2014. Moreover, our gross margins improve on a unit-by-unit basis as we sell higher dosage strengths of our products. Importantly, the proportion of prescriptions written for repeat Subsys patients has continued to increase since July 2012 from 50% of prescriptions to approximately 80% of prescriptions as of September 30, 2014. Generally, repeat Subsys patients receive significantly higher doses of Subsys on average than first-time patients as patients are titrated from a starter dose of Subsys to their effective dose in accordance with the TIRF REMS protocol.

Investments in Our Infrastructure and Growth. Our ability to increase our sales and to further penetrate our target market segments is dependent in part on our ability to invest in our infrastructure and in our sales and marketing efforts. In order to drive further growth, we may hire additional sales and marketing personnel and invest in marketing our products to our target physician prescriber base. For example, as of September 30, 2014, we had 249 full-time sales and marketing personnel. This will lead to corresponding increases in our operating expenses, although we anticipate that these investments will result in increased product sales and net revenue. In addition, we have commenced construction on a second dronabinol manufacturing facility, which we anticipate will supply us with sufficient commercial quantities of dronabinol API for our continued commercialization of Dronabinol SG Capsule and for the commercialization of our proprietary dronabinol product candidates, if approved. Capital expenditures associated with the completion of our planned second dronabinol manufacturing facility were approximately $16.3 million as of September 30, 2014. We expect that this facility will be operational in the fourth quarter of 2014. This second facility will also increase our operating expenses. We have incurred and will continue to incur substantial operating costs in connection with our transition to operating as a public company, including increasing headcount and salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors' and officers' insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

Product Development and Related Regulatory Processes. Our operating results will also depend significantly on our research and development activities and related regulatory developments. Our research and development expenses were $20.2 million and $5.3 million for the nine months ended September 30, 2014 and 2013, respectively. As of September 30, 2014, we had 46 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary cannabinoid product candidates, including Dronabinol Oral Solution, and sublingual spray product candidates. For example, we estimate that our research and development expenses to complete the development of, and obtain FDA approval for, Dronabinol Oral Solution will be approximately $2.8 million. We do not expect to realize net revenues from all of these research and development initiatives in the near term and may never realize net revenues from these investments. Due to the risks inherent in conducting preclinical studies and clinical trials, the regulatory approval process and the costs of preparing, filing and prosecuting patent applications, our development completion dates and costs will vary significantly for each product candidate and are very difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals or acceptable U.S. Drug Enforcement Administration, or DEA, classifications for our product candidates, in particular those related to Dronabinol Oral Solution, could cause our research and development expenditures to increase significantly and, in turn, have a material adverse effect on our results of operations.

Basis of Presentation

Net Revenue

During the year ended December 31, 2012, we began recognizing net revenue from sales of Subsys made by us, and from Dronabinol SG Capsule under our supply and distribution agreement with Mylan. We sell Subsys in packages of various sized single-dose units in dosage strengths of 100, 200, 400, 600, 800, 1,200 and 1,600 mcg, to wholesale pharmaceutical distributors and retail pharmacies, collectively, our customers, on a wholesale basis. Sales to our customers are subject to specified rights of return. From product launch in March 2012 to September 30, 2013, because we did not have sufficient historical information to estimate returns, we deferred recognition of revenue on product shipments of Subsys to our customers until the right of return no longer exists, which occurs at the earlier of the time Subsys units are sold to healthcare facilities or dispensed through patient prescriptions, or expiration of the right of return. We estimated patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. In the fourth quarter of 2013, in response to our ability to estimate returns, we changed the timing of our revenue recognition for Subsys and began recognizing revenue upon shipment to our customers.

We sell Dronabinol SG Capsule exclusively to Mylan in dosage strengths of 2.5, 5.0 and 10.0 milligrams under the Mylan label. Mylan distributes Dronabinol SG Capsule and on a monthly basis pays us an amount equal to the value of Dronabinol SG Capsule it sold to wholesale pharmaceutical distributors and retail pharmacies, less contractually defined deductions for chargebacks, rebates, sales discounts, distribution and storage fees, and royalties. We are obligated to pay Mylan a royalty between 10% and 20% on Mylan’s net product sales, and a single digit percentage fee on such sales for distribution and storage services. We bear no risk of product return upon acceptance by Mylan. As Mylan has control over the amount it charges to wholesale pharmaceutical distributors for Dronabinol SG Capsule and the discounts offered to the distributors, the sales price is not fixed and determinable at the date we ship such product to Mylan. Accordingly, we recognize revenue on the sale of Dronabinol SG Capsule upon Mylan’s sale of product to wholesale distributors, which is the point at which the sales price is fixed and determinable. See Note 7 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue for Subsys consists primarily of materials, third-party manufacturing costs, freight in, indirect personnel costs, and other overhead costs based on units dispensed through patient prescriptions. Cost of revenue for Dronabinol SG Capsule primarily consists of materials, manufacturing costs and third-party assembly and packaging costs based on units sold by Mylan to wholesale distributors. We manufacture the API for Dronabinol SG Capsule at our U.S.-based, dronabinol manufacturing facility. Also included in cost of revenue are charges for reserves for excess, dated or obsolete commercial inventories and production manufacturing variances.

Gross profit is net revenue less cost of revenue. Gross margin is gross profit expressed as a percentage of net revenue.

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries, commissions, benefits, consulting fees, costs of obtaining prescription and market data, and market research studies related to Subsys. As of September 30, 2014, we had 249 full-time sales and marketing personnel. We expect the number of our sales and marketing personnel to increase as we seek to continue to increase our existing product sales and as any subsequently approved products are commercialized. We expect our sales and marketing expenses, along with our research and development expenses, to be our largest categories of operating expenses for the foreseeable future. In addition, because we use an incentive-based compensation model for our sales professionals, we expect our sales and marketing expenses to fluctuate from period to period based on changes in Subsys net revenue. Specifically, we expect our sales and marketing expenses to increase in the near future to the extent that expected increases in Subsys net revenue are realized.

Research and Development Expenses

Research and development expenses consist of costs associated with our preclinical studies and clinical trials, and other expenses related to our drug development efforts. Our research and development expenses consist primarily of:

- external research and development expenses incurred under agreements with third-party Contract Research Organizations, or CROs, and investigative sites, third-party manufacturers and consultants;
- employee-related expenses, which include salaries, benefits and stock-based compensation for the personnel involved in our preclinical and clinical drug development activities; and
- facilities, depreciation and other allocated expenses, equipment and laboratory supplies.

To date, our research and development efforts have been focused primarily on our fentanyl and dronabinol programs. As of September 30, 2014, we had 46 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary dronabinol product candidates, including Dronabinol Oral Solution. We determine which research and development projects to pursue, as well as the level of

funding available for each project, based on the scientific and preclinical and clinical results of each product candidate and related regulatory action. We expect our research and development expenses, along with our sales and marketing expenses, to be our largest categories of operating expenses for the foreseeable future.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, legal, business development and internal support functions. In addition, general and administrative expenses include facility costs not otherwise included in research and development expenses, and professional fees for legal, consulting and accounting services. As of September 30, 2014, we had 25 full-time general and administrative personnel. We expect general and administrative expense to increase as a result of increasing related headcount, expanding our operating activities and the costs we will incur operating as a public company. We expect these increases to include salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors' and officers' insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

Interest Expense

Interest expense has consisted primarily of the interest accrued on outstanding promissory notes payable to The John N. Kapoor Trust and the Kapoor Children 1992 Trust. These trusts are controlled by or are affiliated with our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor. These promissory notes carried interest rates equal to the applicable prime rate plus 2.0%, which was 5.25% as of May 7, 2013. We recorded interest expense of $0.9 million related to accrued interest on these notes during the nine months ended September 30, 2013. Upon completion of our IPO in May 2013, all outstanding principal and accrued interest on the Kapoor Notes converted into 11,115,511 shares of common stock (7,410,341 on a pre-split basis) and all of the Kapoor Notes were cancelled.

Income Tax Benefit, Net Operating Loss Carryforwards

In each period prior to December 31, 2013, we have recorded a valuation allowance for the full amount of our net deferred tax assets, as the realization of our deferred tax assets was uncertain. During the fourth quarter of 2013, we determined it was more likely than not that we would be able to utilize all our federal net operating loss carryforwards based on our profitability in 2013 and our expectations of future profitability. Accordingly, we reversed the deferred tax asset valuation allowance associated with our federal NOLs and other deferred tax assets in the amount of $18.6 million for the year ended December 31, 2013 and recorded an overall income tax benefit of $8.8 million for the year ended December 31, 2013.

As of September 30, 2014, we had approximately $1.6 million of federal net operating loss carry forwards ("NOLs"), all of which are subject to a significant Section 382 limitation as noted below. In addition, we have excess tax deductions in the current year of $38.4 million related to stock compensation deductions that are not yet benefited in the financial statements as of September 30, 2014. For federal tax purposes, the Section 382 NOL carryforward is limited on an annual basis and begins expiring in 2034.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of NOLs that can be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period as determined under the Code, which we refer to as an ownership change. Any such annual limitation may significantly reduce the utilization of these NOLs before they expire. Our ability to utilize federal NOLs created prior to the NeoPharm merger is significantly limited.

Based on the above, we have estimated the amount of pre-NeoPharm merger federal NOLs that are available to offset post-NeoPharm merger income at approximately $1.6 million as of September 30, 2014.

For state tax purposes, we had approximately $275 million of state NOLs at September 30, 2014. Approximately $270.6 million of these NOLs relate only to Illinois. Based on projections and our limited activity in Illinois, we estimate that approximately $267.0 million of these Illinois NOLs will not be utilized. For this reason, we recorded a valuation allowance for the estimated tax benefit relating to this amount, or $20.7 million. Generally, the state NOL carryforwards begin expiring in 2027 if not utilized. The Illinois NOLs begin expiring in 2014 if not utilized. Also, as stated above, we have excess tax deductions in the current year of $38.4 million related to stock compensation deductions that are not yet benefited in the financial statements as of the September 30, 2014

Significant Accounting Polices and Estimates

There were no changes in our significant accounting policies and estimates during the nine months ended September 30, 2014 from those set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Significant Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2013.

Results of Operations

Comparison of Three Months Ended September 30, 2014 to Three Months Ended September 30, 2013

The following table presents certain selected consolidated financial data for the three months ended September 30, 2014 and 2013 expressed as a percentage of net revenue:

	Three Months Ended September 30,	
	2014	**2013**
Net revenue	100.0%	100.0%
Cost of revenue	9.2	10.6
Gross profit	90.8	89.4
Operating expenses:		
Sales and marketing	25.8	27.3
Research and development	12.0	5.9
General and administrative	18.5	14.6
Total operating expenses	56.4	47.9
Operating income	34.4	41.5
Other income (expense):		
Interest income	0.1	0.0
Other income (expense), net	-	(0.0)
Total other income (expense)	0.1	(0.0)
Income before income taxes	34.4	41.5
Income tax expense	14.7	1.8
Net income	19.7 %	39.7 %

Net Revenue. Net revenue increased $29.1 million, or 100%, to $58.3 million for the three months ended September 30, 2014, compared to $29.2 million for the three months ended September 30, 2013. The increase in net revenue was attributable to the $29.8 million, or 105%, increase in net revenue of Subsys to $58.2 million for the three months ended September 30, 2014 compared to $28.4 million for the three months ended September 30, 2013. The increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages as Subsys was a relatively new product during the three months ended September 30, 2013 and also price increases in January

2014 and April 2014. Provisions for wholesaler discounts, patient discounts, rebates and returns increased to $6.3 million, $12.3 million, $7.3 million and $0.2 million, respectively, from the sale of Subsys for the three months ended September 30, 2014, compared to $2.8 million, $2.5 million $2.0 million and $0, respectively, from the sale of Subsys for the three months ended September 30, 2013. The increase in revenue provisions was primarily attributable to increased provisions patient discounts. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2014 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

During the third quarter of 2014, Dronabinol SG Capsule net revenue was $0.1 million as compared with $0.9 million during Q3 2013. We expect that the Dronabinol SG Capsule revenues will continue to be an insignificant portion of our consolidated net revenues prospectively. See Note 7 for a discussion on our ongoing dispute with Mylan.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $2.3 million to $5.4 million for the three months ended September 30, 2014 compared to $3.1 million for the three months ended September 30, 2013. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the three months ended September 30, 2014. Gross profit increased $26.8 million to $52.9 million for the three months ended September 30, 2014 compared to $26.1 million for the three months ended September 30, 2013 due primarily to the increase in sales of Subsys. Gross margin for the three months ended September 30, 2014 was approximately 91% compared to approximately 89% for the three months ended September 30, 2013.

Sales and Marketing Expense. Sales and marketing expense increased $7.1 million to $15.1 million for the three months ended September 30, 2014 compared to $8.0 million for the three months ended September 30, 2013. The increase in sales and marketing expense was due primarily to variable sales compensation expense and incremental product marketing expense associated with the increase in sales of Subsys. As Dronabinol SG Capsule is marketed by Mylan, we did not incur any sales and marketing expense related to Dronabinol SG Capsule.

Research and Development Expense. Research and development expense increased $5.3 million to $7.0 million for the three months ended September 30, 2014 compared to $1.7 million for the three months ended September 30, 2013. The increase in research and development expense was due primarily to an increase in clinical expenses, product development, and an increase in research and development personnel during 2014 in response to our growing product pipeline.

General and Administrative Expense. General and administrative expense increased $6.5 million to $10.8 million for the three months ended September 30, 2014 compared to $4.3 million for the three months ended September 30, 2013. The increase in general and administrative expense was due primarily to increases in legal expense incurred in connection with various ongoing litigation and subpoena related matters, stock-based compensation costs, and administrative infrastructure to support the growth of Subsys sales combined with increased cost of being a public company during 2014.

Income Tax Expense. Provision for income taxes was $8.6 million for the three months ended September 30, 2014. Income tax expense was $0.5 million for the three months ended September 30, 2013 and represents estimated alternative minimum tax and state tax liability. As of September 30, 2014, we had approximately $1.6 million of federal and $275.0 million of state net operating loss carry forwards.

We had unrecognized tax benefits of approximately $0.3 million as of September 30, 2014, primarily associated with tax positions taken in prior year. No significant penalties or interest are included in income taxes or accounted for on the balance sheet related to unrecognized tax positions.

Comparison of Nine Months Ended September 30, 2014 to Nine Months Ended September 30, 2013

The following table presents certain selected consolidated financial data for the nine months ended September 30, 2014 and 2013 expressed as a percentage of net revenue:

	Nine Months Ended September 30,	
	2014	**2013**
Net revenue	100.0%	100.0%
Cost of revenue	10.7	12.6
Gross profit	89.3	87.4
Operating expenses:		
Sales and marketing	26.2	31.7
Research and development	13.0	9.1
General and administrative	19.3	15.9
Total operating expenses	58.5	56.7
Operating income	30.8	30.7
Other income (expense):		
Interest income	0.1	0.0
Other income (expense), net	-	(1.6)
Total other income (expense)	0.1	(1.6)
Income before income taxes	30.8	29.1
Income tax expense	12.4	1.5
Net income	18.4%	27.5%

Net Revenue. Net revenue increased $96.5 million, or 163%, to $155.6 million for the nine months ended September 30, 2014, compared to $59.1 million for the nine months ended September 30, 2013. The increase in net revenue was attributable to the $96.8 million, or 171%, increase in net revenue of Subsys to $153.4 million for the nine months ended September 30, 2014 compared to $56.6 million for the nine months ended September 30, 2013. The increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages as Subsys was a relatively new product during the nine months ended September 30, 2013 and also price increases in January 2014 and April 2014. Provisions for wholesaler discounts, patient discounts, rebates and returns increased to $15.5 million, $22.0 million, $17.0 million and $1.7 million, respectively, from the sale of Subsys for the nine months ended September 30, 2014, compared to $5.8 million, $6.4 million, $4.0 million, and $0 million, respectively, from the sale of Subsys for the nine months ended September 30, 2013. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2014 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

During July 2014, we were noticed by Mylan that certain Dronabinol SG Capsule inventories were approaching their product expiry date, and therefore, the inventory was not saleable to Mylan customers. As a result of this notice, we recorded $0.7 million in revenue related to the recognition of non-refundable deposits for amounts paid by Mylan for this inventory, and a corresponding $1.4 million charge to cost of goods sold into it operating results for the second quarter of 2014. During Q3 2014, Dronabinol SG Capsule net revenues were $0.1 million. We expect that the Dronabinol SG Capsule revenues will continue to be an insignificant portion of our consolidated net revenues prospectively. See Note 7 for a discussion on our ongoing dispute with Mylan.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $9.2 million to $16.7 million for the nine months ended September 30, 2014 compared to $7.5 million for the nine months ended September 30, 2013. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the nine months ended September 30, 2014. Gross profit increased $87.3 million to $138.9 million for the nine months ended September 30, 2014 compared to $51.6 million for the nine months ended September 30, 2013. Gross margin for the nine months ended September 30, 2014 was approximately 89% compared to approximately 87% for the nine months ended September 30, 2013.

Sales and Marketing Expense. Sales and marketing expense increased $22.1 million to $40.8 million for the nine months ended September 30, 2014 compared to $18.7 million for the nine months ended September 30, 2013. The increase in sales and marketing expense was due primarily to variable sales compensation expense and incremental product marketing expense associated with the increase in sales of Subsys, as Subsys was initially marketed in 2012. As Dronabinol SG Capsule is marketed by Mylan, we did not incur any sales and marketing expense related to Dronabinol SG Capsule.

Research and Development Expense. Research and development expense increased $14.9 million to $20.2 million for the nine months ended September 30, 2014 compared to $5.3 million for the nine months ended September 30, 2013. The increase in research and development expense was due primarily to a $3.1 million stock-compensation expense recorded in connection with the acceleration of vesting of stock options of a former employee, an increase in clinical expenses, product development, and an increase in research and development personnel during 2014 in response to our growing product pipeline.

General and Administrative Expense. General and administrative expense increased $20.6 million to $30.0 million for the nine months ended September 30, 2014 compared to $9.4 million for the nine months ended September 30, 2013. The increase in general and administrative expense was due primarily to increases in legal expense incurred in connection with various ongoing litigation and subpoena related matters, stock-based compensation costs, and administrative infrastructure to support the growth of Subsys sales combined with increased cost of being a public company during 2014.

Other Income/Expense. We incurred no interest expense for the nine months ended September 30, 2014, compared to interest expense of $0.9 million for the nine months ended September 30, 2013. The decrease in interest expense was primarily a result of the conversion of the Kapoor Notes to common stock and the repayment of our previous $15.0 million line of credit in May 2013.

Income Tax Expense. Provision for income taxes was $19.3 million for the nine months ended September 30, 2014, representing an effective tax rate of 40.3%. Income tax expense was $0.9 million for the nine months ended September 30, 2013 and represents estimated alternative minimum tax and state tax liability. As of September 30, 2014, we had approximately $1.6 million of federal and $275.0 million of state net operating loss carry forwards.

We had unrecognized tax benefits of approximately $0.3 million as of September 30, 2014, primarily associated with tax positions taken in prior year. No significant penalties or interest are included in income taxes or accounted for on the balance sheet related to unrecognized tax positions.

25

Liquidity and Capital Resources

Sources of Liquidity

We incurred losses from our inception through December 31, 2012. Although we began generating positive operating cash flows in connection with the commercial launch of Subsys during the first quarter of 2013, and continued to do so through the current quarter, as of September 30, 2014, we have an accumulated deficit of $60.4 million. Prior to our initial public offering, or IPO, we financed our operations primarily through the issuance of promissory notes to The John N. Kapoor Trust and the Kapoor Children 1992 Trust, which are controlled by or affiliated with our founder, Executive Chairman and principal stockholder.

On May 7, 2013, we completed our IPO, pursuant to which we sold 6,900,000 shares of our common stock (4,600,000 on a pre-split basis) at a price of $5.33 per share ($8.00 on a pre-split basis), which included the underwriters' exercise of their over-allotment option. As a result of the IPO, we raised a total of $32.5 million in net proceeds after deducting underwriting discounts and commissions of $2.6 million and offering expenses of $1.8 million. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the completion of the IPO. These costs have been recorded as a reduction of the proceeds received in arriving at the amount recorded in additional paid-in capital. Upon completion of the IPO, all outstanding shares of our preferred stock were converted into 12,793,290 shares of common stock (8,528,860 on a pre-split basis).

On September 30, 2014, our $15,000,000 revolving credit facility (the "Facility"), which we entered into in October 2013 with JPMorgan Chase Bank, N.A. matured. As of December 31, 2013, no amounts were outstanding under the Facility.

Cash Flows

The following table shows a summary of our cash flows for the periods indicated (in millions):

	Nine Months Ended September 30,	
	2014	**2013**
Net cash provided by operating activities	$33.8	$13.8

Net cash used in investing activities	(57.4)	(3.6)
Net cash provided by financing activities	25.6	20.7
Net increase in cash and cash equivalents	2.0	30.9
Cash and cash equivalents, beginning of period	45.4	0.4
Cash and cash equivalents, end of period	$47.4	$31.3

Cash Flows From Operating Activities. Net cash provided by operating activities was $33.8 million and $13.8 million for the nine months ended September 30, 2014 and 2013, respectively. The net cash provided during the nine months ended September 30, 2014 primarily reflects the net income for the period driven primarily by growth in Subsys net sales, adjusted in part by depreciation and amortization, stock-based compensation expense and is also impacted by changes in working capital.

Cash Flows From Investing Activities. Net cash used in investing activities was $57.4 million and $3.6 million for the nine months ended September 30, 2014 and 2013, respectively, and consists primarily of the purchase of investments and property and equipment.

Cash Flows From Financing Activities. Net cash provided by financing activities was $25.7 million for the nine months ended September 30, 2014, as compared to $20.7 million for the nine months ended September 30, 2013. During the nine months ended September 30, 2014, we recorded excess tax benefits on stock options and awards of $19.5 million, proceeds from the exercise of stock options of $5.1 million and proceeds from shares issued under an employee stock purchase plan of $1.1 million. During the nine months ended September 30, 2013, we received $32.4 million in net proceeds in connection with an IPO and we used $11.9 million of these proceeds to make a payment against a previous line of credit.

We invoice wholesalers upon shipment of Subsys. To date, our wholesalers have typically paid us 30 to 60 days from their applicable invoice dates.

Our cash flows for 2014 and beyond will depend on a variety of factors, including sales of Subsys and Dronabinol SG Capsule and any additional approved products, regulatory approvals, investments in manufacturing and production such as our planned second dronabinol manufacturing facility, capital equipment, and research and development. We expect our net cash flows from operating activities to increase as we expect to increase sales of Subsys and Dronabinol SG Capsule, partially offset by anticipated expansion in sales and marketing, research and development, manufacturing, and general and administrative expenses as a public company.

Funding Requirements

We believe that the net proceeds from the IPO, cash from operations and our pre-existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months.

Because of the numerous risks and uncertainties associated with commercialization of Subsys and Dronabinol SG Capsule and the development of our product candidates, we are unable to predict the amounts of increased capital outlays and operating expenditures associated with our current anticipated product introduction, clinical trials and preclinical studies. The timing and amounts of our funding requirements will depend on numerous factors, including but not limited to:

- the levels and mix of our product sales;
- the rates of progress, costs and outcomes of our clinical trials and other product development programs, including for Dronabinol Oral Solution and any other product candidates that we may develop, in-license or acquire;
- regulatory approvals, DEA classifications and other regulatory related events;
- personnel, facilities, equipment and other similar requirements;
- costs of operating as a public company;
- the effects of competing technological and market developments;
- costs associated with litigation and government investigations;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- our ability to acquire or in-license products and product candidates, technologies or businesses; and
- terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

Although we generated cash from operating activities during the nine months ended September 30, 2014 and we expect to continue to fund our operations primarily from operating activities, we cannot guarantee that we will generate sufficient operating cash flows to fund our planned activities. We cannot be sure that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. If we raise additional funds by issuing equity or convertible

securities, substantial dilution to existing stockholders will likely result. If we raise additional funds by incurring new debt obligations, the terms of the debt will likely require significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Off-Balance Sheet Arrangements

During the nine months ended September 30, 2014, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarterly period ended September 30, 2014 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We believe that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within any company have been detected.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The information contained in Note 7 to the Unaudited Condensed Consolidated Financial Statements is incorporated herein by reference.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2013, as well as other factors discussed herein under "Forward-Looking Statements" in Item 2 Management's Discussion and Analysis of Financial Condition and Results of Operations." Our business, financial condition and results of operations could be adversely affected by any of the risks and uncertainties described therein. Other than the risk factor set forth below, there have been no material changes from the risk factors disclosed in Part I, Item 1A, in our Annual Report on Form 10-K.

The unpredictably and regulation surrounding reimbursement on Subsys may affect our financial condition and results of operations.

Our sales of, and revenue from, Subsys depend in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers. All third-party payers are sensitive to the cost of drugs and consistently implement efforts to control these costs, which efforts include, but are not limited to, establishing excluded or preferred drug lists. Subsys has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, particularly pharmacy benefit managers ("PBMs") and private health insurers. Our product, Subsys, has been included on an exclusion list for at least one PBM and may in the future be included on other PBM exclusion lists. These PBMs, which administer prescription drug benefits for employers and health plans and runs large mail-order pharmacies, have significant influence in the insurance industry. While most PBMs have an exception process that physicians may pursue to have an off-formulary, medically necessary drug covered for patients, being placed on an exclusion list makes it difficult for many patients covered through a PBM administered plan to have Subsys covered by insurance. In the future, we may not be able to work with other PBMs to evaluate price increases and to communicate with managed care and health-system decision-makers to ensure a balanced approach which takes into account the clinical performance and efficacy of our products. Moreover, in the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that third party payers may pay to reimburse the cost of drugs, particularly

for state and federal government programs such as Medicare and Medicaid, as well as managed care providers and private insurance plans. We believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of Subsys. Our ability to generate revenue is affected by the availability of third-party reimbursement for Subsys and our results of operations will be negatively affected if we fail to manage adequate reimbursement levels for Subsys from such third-party payers.

In addition, our business operations include administrative reimbursement support assistance for patients, in large part through our insurance reimbursement support hub, to help patients work with their insurance companies. The reimbursement support assistance provided by us, including our insurance reimbursement support hub, is subject to extensive and complex federal and state laws and varied third party payers standards, procedures, processes and conditions. Our compliance with applicable laws, regulations and standards is expensive and time consuming and substantial governmental resources exist to enforce and prosecute these applicable laws, regulations and standards and companies that violate such laws, regulations and standards may face substantial penalties. The potential sanctions include significant civil, criminal and administrative penalties, damages and fines and exclusion from participation in federal health care programs. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge or penalty under one or more of these laws. Such a challenge, irrespective of the underlying merits of the challenge or the ultimate outcome of the matter, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

ITEM 6. EXHIBITS

The Exhibit Index immediately following the Signatures to this Form 10-Q is hereby incorporated by reference into this Form 10-Q.

INSYS THERAPEUTICS, INC.

SIGNATURES

Pursuant to the requirements 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.

INSYS THERAPEUTICS, INC.

Dated: November 12, 2014 By: /s/ Michael L. Babich
Michael L. Babich
President and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Darryl S. Baker
Darryl S. Baker
Chief Financial Officer
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation of Insys Therapeutics, Inc.
3.2(2)	Amended and Restated Bylaws of Insys Therapeutics, Inc.
3.3(3)	Certificate of Designation of Series A Junior Participating Preferred Stock (3).
4.1(4)	Rights Agreement, dated August 15, 2014 between the Insys Therapeutics, Inc. and Computershare Trust Company, N.A.
10.1	Employment Offer Statement effective January 31, 2014 by and between Insys Therapeutics, Inc. and Franc Del Fosse.
10.2(5)	Separation and Consulting Agreement dated October 31, 2014 between Insys Therapeutics, Inc. and Christopher Homrich.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, (filed herewith).
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, (filed herewith).
32	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

(1) Previously filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014, and incorporated herein by reference.

(2) Previously filed as Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 8, 2013, and incorporated herein by reference.

(3) Previously filed as 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 18, 2014 and incorporated here by reference.

(4) Previously filed as 4.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on August 18, 2014 and incorporated here by reference

(5) Previously filed as Exhibit 10.2 to Registrant's Current Report on Form 8-K, filed with the SEC on October 31, 2014 and incorporated here by reference.