Insys Therapeutics, Inc.
Form 10-Q
November 12, 2013

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, 2013

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	**51-0327886**
(State or Other Jurisdiction of Incorporation or Organization)	**(IRS Employer Identification No.)**
444 South Ellis St, Chandler, Arizona	**85224**
(Address of Principal Executive Offices)	**(Zip Code)**

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

(Former name, former Address and Former Fiscal Year,

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 [ ] Smaller Reporting Company [X]

(Do not check if a smaller reporting company)

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

YES [ ] NO [X]

As of November 8, 2013, the registrant had 21,486,839 shares of Common Stock ($0.0002145 par value) outstanding.

INSYS THERAPEUTICS, INC.

FORM 10-Q

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Items 3 and 4 - Not applicable

FINANCIAL INFORMATION

Item 1. Financial Statements

INSYS THERAPEUTICS, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share data)

(unaudited)

	September 30, 2013	**December 31, 2012**
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 31,346	$ 361
Restricted cash and restricted cash equivalents	800	-
Accounts receivable	12,376	3,089
Inventories	11,746	7,095
Prepaid expenses and other assets	1,457	1,344
Total current assets	57,725	11,889
Property and equipment, net	8,267	6,791
Other assets	44	61
Total assets	$ 66,036	$ 18,741
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 12,221	$ 5,971
Accrued compensation	3,030	1,392
Other current liabilities	144	508
Deferred patient discount program	1,557	1,540
Deferred revenue	1,510	3,767
Line of credit	-	11,858
Notes payable to related party, including interest	-	58,383
Total current liabilities	18,462	83,419
Total liabilities	18,462	83,419

Commitments and contingencies (see Note 7)		
Stockholders' Equity (Deficit):		
Convertible preferred stock (par value $0.01 per share, 10,000,000 and 15,000,000 shares authorized as of September 30, 2013 and December 31, 2012, respectively; 0 and 14,864,607 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively)	-	149
Common stock (par value $0.0002145 per share, 50,000,000 and 25,000,000 shares authorized as of September 30, 2013 and December 31, 2012, respectively; 21,414,343 and 856,026 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively)	5	-
Additional paid in capital	160,723	64,604
Notes receivable from stockholders	(21)	(21)
Accumulated deficit	(113,133)	(129,410)
Total stockholders' equity (deficit)	47,574	(64,678)
Total liabilities and stockholders' equity (deficit)	$ 66,036	$ 18,741

See accompanying notes to unaudited condensed consolidated financial statements.

INSYS THERAPEUTICS, INC.

Condensed Consolidated Statements Of COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended		**Nine Months Ended**	
	September 30,		September 30,	
	2013	**2012**	**2013**	**2012**
Net revenue	$29,211	$4,752	$59,091	$10,317
Cost of revenue	3,096	1,948	7,454	5,567
Gross profit	26,115	2,804	51,637	4,750
Operating expenses:				
Sales and marketing	7,969	2,899	18,723	8,231
Research and development	1,737	1,119	5,348	5,647
General and administrative	4,274	2,267	9,423	5,591
Total operating expenses	13,980	6,285	33,494	19,469
Income (loss) from operations	12,135	(3,481)	18,143	(14,719)
Other income (expense), net	(24)	(90)	(22)	(596)
Interest income (expense), net	8	(679)	(937)	(1,990)
Income (loss) before income taxes	12,119	(4,250)	17,184	(17,305)
Income tax expense	532	-	907	-
Net and comprehensive income (loss)	$11,587	$(4,250)	$16,277	$(17,305)
Net income (loss) per common share:				
Basic	$0.54	$(0.46)	$1.03	$(1.86)
Diluted	$0.51	$(0.46)	$0.96	$(1.86)
Weighted average common shares outstanding:				
Basic	21,404,684	9,314,886	15,812,603	9,314,886
Diluted	22,789,138	9,314,886	16,932,372	9,314,886

See accompanying notes to unaudited condensed consolidated financial statements.

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INSYS THERAPEUTICS, INC.

Condensed Consolidated STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share amounts)

(unaudited)

	Convertible Preferred Stock		**Common Stock**		**Additional**	**Notes Receivable**		
	No. of Shares	**Amount**	**No. of Shares**	**Amount**	**Paid-In Capital**	**from Stockholders**	**Accumulated Deficit**	**Total**
Balance at January 1, 2013	14,864,607	$ 149	856,026	$ -	$ 64,604	$ (21)	$ (129,410)	$ (64,678)
Stock-based compensation expense	-	-	-	-	4,101	-	-	4,101
Issuance of common stock	-	-	4,600,000	1	32,455	-	-	32,456
Conversion of preferred to common stock	(14,864,607)	(149)	8,528,860	2	147	-	-	-
Conversion of notes payable to common stock	-	-	7,410,341	2	59,282	-	-	59,284
Exercise of stock options	-	-	19,116	-	134	-	-	134
Net income	-	-	-	-	-	-	16,277	16,277
Balance at September 30, 2013	-	$ -	21,414,343	$ 5	$ 160,723	$ (21)	$ (113,133)	$ 47,574

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,	
	2013	**2012**
Cash flows from operating activities:		
Net income (loss)	$16,277	$(17,305)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,311	1,219
Stock-based compensation	4,101	1,857
Interest expense accrued on notes payable	900	1,923
Accretion of contingent payment obligation	-	210
Changes in assets and liabilities:		
Accounts receivable	(9,287)	21
Inventories	(4,651)	(1,411)
Prepaid expenses and other assets	(95)	(26)
Accounts payable, accrued expenses, and other current liabilities	5,284	2,072
Net cash provided by (used in) operating activities	13,840	(11,440)
Cash flows from investing activities:		
Purchase of property and equipment	(2,787)	(757)
Net cash used in investing activities	(2,787)	(757)
Cash flows from financing activities:		
Restricted cash and restricted cash equivalents	(800)	-
Proceeds from issuance of common stock	32,456	-
Proceeds (repayments) under line of credit	(11,858)	10,508
Proceeds from notes payable to related party	-	2,987
Proceeds from exercise of stock options	134	9
Net cash provided by financing activities	19,932	13,504
Net increase in cash and cash equivalents	30,985	1,307
Cash and cash equivalents, beginning of period	361	11
Cash and cash equivalents, end of period	$31,346	$1,318

See accompanying notes to unaudited condensed consolidated financial statements.

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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 its subsidiaries maintain headquarters in Chandler, Arizona. We were in the development stage through December 31, 2011. The year 2012 is the first year during which we are considered an operating company and is no longer in the development stage.

We are a specialty pharmaceutical company that develops and commercializes innovative supportive care products. We launched our first two products in the United States in 2012: 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 include our accounts. All significant intercompany balances and transactions have been eliminated in the accompanying condensed consolidated financial statements.

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, 2012 included in our final prospectus supplement filed with the SEC on May 2, 2013 and related to our Registration Statement on Form S-1/A (File No. 333-173154). The results of operations for the three and nine months ended September 30, 2013 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 prescriptions dispensed, wholesaler discounts,

patient discount programs, rebates and chargebacks, bad debts, inventories, deferred income taxes, stock-based compensation expenses, and contingencies and litigation. 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.

Recent Accounting Pronouncements

In July 2013, the Financial Accounting Standards Board ("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 carryforward, 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 will be effective for us beginning December 31, 2013. We are currently assessing the impact of this new guidance.

In February 2013, the FASB issued guidance that requires a reporting entity to present information about reclassification adjustments from accumulated other comprehensive income in their financial statements or footnotes. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2012. We adopted this guidance in the first interim period for the year ending December 31, 2013 and, as we had no accumulated other comprehensive income as of September 30, 2013, there was no impact on our financial position, results of operations or cash flows as of or for the period ended September 30, 2013, nor do we expect the adoption to have a material impact on our financial position, results of operations or cash flows as of the end of or for the full year.

2. Fair Value of Financial Instruments

The carrying values of our financial instruments, including, cash, accounts receivable, accounts payable and short-term debt approximate their fair value due to the short term nature of these financial instruments. We did not have financial assets or liabilities that are measured at fair value on a recurring basis as of September 30, 2013 or December 31, 2012.

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;

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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.

3. 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, collectively, our customers, subject to rights of return within a period beginning nine 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 Subsys, we currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, we defer recognition of revenue on product shipments of Subsys 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. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. We estimate patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. If this third-party data underestimates or overestimates actual patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

We will continue to recognize revenue using this methodology until we can reliably estimate product returns. We expect a change in revenue recognition could result in a material impact to revenues upon the initial change in methodology as previously deferred revenue would be immediately recognized, partially offset by an estimate of product returns. This amount of the initial accrual for returns will not be known until such time a change in methodology is made. In addition, the costs of manufacturing Subsys associated with the deferred revenue are recorded as deferred costs, which are included in inventory, until such time as the related deferred revenue is recognized.

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:

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 recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Prompt Pay Discounts. We offer cash discounts to its 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.

Stocking Allowances. We may offer discounts and extended payment terms, generally in the month of the initial commercial launch of a new product and on the first order made by certain wholesale distributors and retail pharmacies 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.

Patient Discount Programs. We offer discount card programs to patients for Subsys in which patients receive discounts on their prescriptions that are reimbursed by us 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.

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.

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.

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.

4. Inventories

Inventories, net 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. We evaluate 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 it expects 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,	**December 31,**

	2013	2012
Finished goods	$6,133	$2,221
Work-in-process	3,717	1,731
Raw materials and supplies	1,295	2,597
Deferred costs	601	546
Total inventories	$11,746	$7,095

Deferred costs represent the costs of products shipped for which recognition of revenue has been deferred.

As of September 30, 2013 and December 31, 2012, 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.

5. Line of Credit

In February 2012, we entered into a $15,000,000 revolving credit facility (the "Facility") with Bank of America, N.A. (the "Agent"), which includes a $2,000,000 letter of credit facility. Under the terms of the Facility, amounts outstanding bear interest at our election at (a) LIBOR plus 1.0% or (1.20% as of September 30, 2013) or (b) British Bankers Association Rate ("BBA") LIBOR Daily Floating Rate plus 1.0%. The Facility is secured by The Kapoor Trust Letter of Credit issued by the Agent, with the John N. Kapoor Trust ("The JNK Trust") as applicant. Dr. Kapoor is our founder, Executive Chairman and principal stockholder.

We had an outstanding balance of $11,858,000 against the line of credit as of December 31, 2012. In May 2013, the then outstanding principal balance of $11,358,000 was paid in full. The Facility was scheduled to mature in February 2014. On October 3, 2013, we terminated the Facility. See Note 12.

6. Notes Payable to a Related Party

On May 7, 2013, in connection with the closing of our initial public offering of common stock, the outstanding balance of principal and accrued interest related to several promissory and demand notes ("Kapoor Notes") of $59,282,000 was converted into 7,410,341 shares of common stock at the $8.00 per share public offering price and all of the Kapoor Notes were cancelled.

We had issued the Kapoor Notes payable in favor of a trust controlled by Dr. Kapoor, The JNK Trust, and a trust affiliated with Dr. Kapoor, the Kapoor Children 1992 Trust. Prior to completing its initial public offering on May 7, 2013, we drew on the Kapoor Notes as needed to pay its expenses. The Kapoor Notes carried interest at the prime rate plus 2.0% (5.25% as of May 7, 2013).

Interest expense relating to the Kapoor Notes was approximately $900,000 and $1,923,000 for the nine months ended September 30, 2013 and 2012, respectively.

7. Contingencies

NeoPharm Contingent Consideration

On November 8, 2010, Insys effected a merger with NeoPharm, Inc. ("NeoPharm") in a transaction accounted for as a reverse acquisition (the "NeoPharm merger"). All of the outstanding share capital of Insys was exchanged for newly-issued shares of common stock and convertible preferred stock of NeoPharm. As a result of the NeoPharm merger, Insys became a wholly-owned subsidiary of NeoPharm and changed its name to Insys Pharma, Inc. ("Insys Pharma"). NeoPharm then changed its name to Insys Therapeutics, Inc.

In connection with the NeoPharm merger, the NeoPharm board approved the distribution, immediately after the NeoPharm merger, of non-transferable contingent payment rights to its stockholders of record as of November 5, 2010. These rights entitle the pre-NeoPharm merger stockholders of NeoPharm to receive cash payments aggregating $20,000,000 (equivalent to $0.70402 per share) if, prior to the five-year anniversary of the NeoPharm merger, the FDA approves a New Drug Application for any one or more of the NeoPharm product candidates that were under development at the time of the NeoPharm merger. The distribution is payable within nine months of FDA approval. The initial fair value of this contingent payment was determined to be approximately $1,829,000 based on the assumed probability of any payment being made to the prior NeoPharm stockholders in 2015, discounted to present value at a rate of 15%, a Level 3 fair value measurement. Changes in estimated fair value representing an increase of

$210,000 during the nine months ended September 30, 2012, were recorded in other expense.

In October 2012, in connection with our analysis of impairment of in-process research and development ("IPR&D") acquired in the merger, we determined it was not probable that the contingent consideration would be paid and the related contingency reserve was reversed into other income.

Legal Matters

In September 2009, Insys Pharma and certain of its officers and directors, as well as their spouses, were named as defendants in a lawsuit in 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 one-for-1,500,000 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 states causes of action for breach of fiduciary duty 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 the Company owns 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 negligence 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. A trial has been scheduled to commence in January 2014. The Company is not able at this time to estimate the range of potential loss or any potential recovery from the counter-claims, nor is it able to predict the outcome of this litigation. If the patent assignments are successfully rescinded, the Company will not have exclusive patent rights covering its fentanyl and dronabinol product candidates, and such exclusive patent rights may not be available to the Company on acceptable terms, if at all, which would have a material adverse effect on the Company's business. If the assignments are rescinded, Dr. Kottayil could assign his interest in the fentanyl and dronabinol patent applications to a competitor and the Company would not be able to prevent generic copies of its products. The Company intends to vigorously defend against the plaintiffs' claims and pursue its counter-claims.

8. Stockholders' Equity

Authorized Share Capital

Effective May 6, 2013, our certificate of incorporation was amended and restated to provide for 50,000,000 authorized shares of common stock with a par value of $0.0002145 per share, and 10,000,000 authorized shares of undesignated preferred stock with a par value of $0.01 per share.

Initial Public Offering

On May 7, 2013, we completed its initial public offering ("IPO"), whereby we sold a total of 4,600,000 shares of common stock at $8.00 per share for net proceeds of $32,456,000 (after underwriting discounts and commissions and offering costs). This amount includes the full exercise of an over-allotment option to purchase 600,000 shares of common stock by our underwriters. Upon completion of the IPO, all outstanding shares of our convertible preferred stock were converted into 8,528,860 shares of common stock and all Kapoor Notes totaling $59,284,000 converted into 7,410,341 shares of common stock.

9. Stock-based Compensation

We currently have the following stock-based incentive plans:

2013 Employee Stock Purchase Plan

The 2013 Employee Stock Purchase Plan (the "ESPP") was adopted by our board of directors and approved by our stockholders, and became effective in connection with our initial public offering in May 2013. The ESPP authorizes the issuance of 175,000 shares of common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2014 through January 1, 2023, by the least of (a) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (b) 200,000 shares, or (c) a number determined by our board of directors that is less than (a) and (b). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended (the "Code"). As of September 30, 2013, no shares of common stock have been purchased under the ESPP.

2013 Equity Incentive Plan

The 2013 Equity Incentive Plan (the "2013 Plan") is the successor to and continuation of the 2006 Equity Incentive Plan and the Insys Pharma, Inc., Amended and Restated Equity Incentive Plan. The 2013 Plan was adopted by our board of directors and approved by our stockholders, and became effective in connection with our initial public offering in May 2013. The 2013 Plan provides for the grant of stock awards, including stock options, restricted stock, stock appreciation rights, performance units, performance shares and other stock awards, to our employees, directors and consultants. Upon the effectiveness of the 2013 Plan, 3,623,842 shares were reserved for future issuance. As of September 30, 2013, options to purchase 1,457,608 shares of common stock were outstanding.

2006 Equity Incentive Plan

The 2006 Equity Incentive Plan (the "2006 Plan") provided for the grant of stock awards, including stock options, restricted stock, stock appreciation rights, performance units, performance shares and other stock awards, to our employees, directors and consultants. The 2006 Plan was adopted in April 2006. As of September 30, 2013, options to purchase 1,102,002 shares of common stock were outstanding. The 2006 Plan has been terminated and we will not grant additional equity awards under the 2006 Plan.

Awards under the 2006 Plan generally consisted of stock options that have an exercise price equal to the fair market value of our common stock on the date of grant, a ten-year term, and generally vested ratably over four years, subject to continuous service. Stock awards granted to our non-employee directors under the 2006 Plan typically vested one year from the date of grant. Outstanding awards under the 2006 Plan vest immediately upon a change in control. Although the 2006 Plan provided for the issuance of performance units and performance shares, we did not make grants of these types of awards.

Insys Pharma, Inc. Amended and Restated Equity Incentive Plan

Insys Pharma's Amended and Restated Equity Incentive Plan (the "Plan") provided for the grant of stock options to employees, directors and consultants to acquire Insys Pharma's voting and non-voting common stock. The Plan was originally adopted by Insys Pharma in December 2002 and was amended and restated in June 2006. In connection with the NeoPharm merger in November 2010, all of the outstanding options granted under the Plan were assumed by us and were converted into options to purchase shares of our common stock at the exchange ratio set forth in the merger agreement. As of September 30, 2013, vested options to purchase an aggregate of 1,009,579 shares of our common stock under the Plan were outstanding. There were no unvested options outstanding under the Plan as of September 30, 2013. The Plan has been terminated and we will not grant additional equity awards under the Plan.

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Option awards under the Plan were generally granted with an exercise price equal to the fair market value of Insys Pharma's common stock on the date of grant. Option awards under the Plan typically had a ten-year life and vested within the first two years of the grant, subject to continuous service. Option awards granted to Insys Pharma's non-employee consultants under the Plan typically vested within two years from the date of grant. These options were marked to market at each reporting period. The expense associated with these adjustments has historically been immaterial.

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

	Three Months Ended		**Nine Months Ended**	
	September 30,		September 30,	
	2013	**2012**	**2013**	**2012**
Research and development	$247	$257	$874	$797
General and administrative	1,450	314	3,227	1,060
Total cost of stock-based compensation	$1,697	$571	$4,101	$1,857

As of September 30, 2013, we expected to recognize $20,645,000 of stock-based compensation for outstanding options over a weighted-average period of 3.2 years.

The following table summarizes stock option activity as of December 31, 2012 and for the nine months ended September 30, 2013:

	Number of Shares	**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (in years)**	**Aggregate Intrinsic Value (in millions)**
Vested and exercisable as of December 31, 2012	1,263,197	$ 2.79	7.44	$ 3.5
Outstanding as of December 31, 2012	2,162,114	$ 3.18	8.21	$ 10.2
Granted	1,459,700	$ 14.05		
Cancelled	(33,509)	$ 4.21		

Exercised	(19,116)	$ 4.97		
Outstanding as of September 30, 2013	3,569,189	7.61	7.09	$ 97.8
Vested and exercisable as of September 30, 2013	1,628,138	3.40	7.09	$ 51.5

10. Net Income (Loss) per Share

Basic net income (loss) per common share is computed by dividing the net income (loss) allocable to the common stockholders by the weighted average number of common shares outstanding during the period. The diluted income (loss) 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 (loss) per share for the three and nine months ended September 30, 2013 and September 30, 2012, including share and per share amounts, includes the effects of the conversion of convertible preferred stock into 8,528,860 shares of common stock as if the conversion had occurred at the beginning of the respective periods.

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2013	**2012**	**2013**	**2012**
Historical net income (loss) per share-Basic:				
Numerator:				
Net income (loss)	$11,587	$(4,250)	$16,277	$(17,305)
Denominator:				
Weighted average number of common shares outstanding	21,404,684	9,314,886	15,812,603	9,314,886
Basic net income (loss) per common share	$0.54	$(0.46)	$1.03	$(1.86)
Historical net income (loss) per share-Diluted:				
Numerator:				
Net income (loss)	$11,587	$(4,250)	$16,277	$(17,305)
Denominator:				
Weighted average number of common shares outstanding	21,404,684	9,314,886	15,812,603	9,314,886
Effect of dilutive stock options	1,384,454	--	1,119,769	--
	22,789,138	9,314,886	16,932,372	9,314,886
Diluted net income (loss) per common share	$0.51	$(0.46)	$0.96	$(1.86)

As we incurred a net loss for the three and nine months ended September 30, 2012, basic and diluted per share amounts are the same, since the effect of potential common share equivalents is anti-dilutive. Anti-dilutive share equivalents included 3,278 and 1,775,157 outstanding stock options as of September 30, 2013 and 2012, respectively.

11. 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 (dollars in thousands):

Net Revenue by Product Line			
Three Months Ended		**Nine Months Ended**	
September 30,		September 30,	
2013	**2012**	**2013**	**2012**

Subsys	$28,355	$2,572	$56,552	$3,764
Dronabinol SG Capsule	856	2,180	2,539	6,553
Total net revenue	$29,211	$4,752	$59,091	$10,317

	% of Revenue by Route to Market			
	Three Months Ended		**Nine Months Ended**	
	September 30,		September 30,	
	2013	**2012**	**2013**	**2012**
Pharmaceutical wholesalers	97 %	54 %	96 %	36 %
Generic pharmaceutical distributor	3 %	46 %	4 %	64 %
	100 %	100 %	100 %	100 %

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

Product shipments to four pharmaceutical wholesalers accounted for 30%, 20%, 20% and 18% of shipments for the nine months ended September 30, 2013. Product shipments to one generic pharmaceutical distributor accounted for 42% and product shipment to three pharmaceutical wholesalers accounted for 20%, 19% and 13% of shipments for the nine months ended September 30, 2012. Four pharmaceutical wholesalers' accounts receivable balances accounted for 40%, 22%, 17% and 10% of accounts receivable as of September 30, 2013. Three pharmaceutical wholesalers' accounts receivable balances accounted for 34%, 22% and 21% of accounts receivable as of December 31, 2012.

12. Subsequent Events

In October 2013, we terminated our $15,000,000 revolving credit facility with Bank of America, N.A. and we entered into a $15,000,000 revolving credit facility (the "New Facility") with JPMorgan Chase Bank, N.A., which includes a $500,000 letter of credit facility. Under the terms of the New Facility, amounts outstanding bear interest at LIBOR plus 1.5% and the New Facility is subject to a 0.35% non-usage fee. Advances are subject to a borrowing base such that the maximum advances that may be outstanding under the New Facility is 80% of the book value of eligible accounts receivable. The New Facility matures on September 30, 2014. On the effective date of the New Facility, no amounts were outstanding and $11.2 million was available to borrow, taking into account the applicable borrowing base limitations.

The New Facility contains covenants that limit our ability to, among other things, incur additional indebtedness, create or permit to exist liens, pay dividends or make other distributions relating to our common stock (including the repurchase of outstanding common stock). In addition, we are required to meet certain financial covenants, including (i) minimum cash liquidity (as defined in the New Facility) equal to or greater than funded indebtedness and (ii) net income of at least $1.00 for any period of four consecutive fiscal quarters commencing with the quarter ending December 31, 2013.

In October 2013, we made a progress payment to a manufacturer of capital equipment in the amount of $1,104,000. The manufacturer had invoiced us prior to September 30, 2013, however, we did not relect this invoice in property and equipment as of September 30, 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, 2012 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed with the Securities and Exchange Commission ("SEC") on May 2, 2013 relating to our Registration Statement on Form S-1/A (File No. 333-173154) for our initial public offering.

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; our plans to build a second dronabinol manufacturing facility and the estimated costs and benefits relating thereto; estimated costs to complete development and obtain approvals for our Dronabinol Oral Solution product candidate and the timing related to actions in connection therewith; that net revenue from sales of Subsys will increase during the remainder of 2013; that net revenue from sales of Dronabinol SG Capsule will fluctuate on a quarterly basis; 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 we will hire additional sales and marketing, research and development and administrative personnel and that costs relating thereto will increase; the impact of new or recently issued accounting pronouncements; that we will not incur substantial interest charges during the remainder of 2013; that cash flows from operations will increase as a result of increased sales of Subsys and Dronabinol; the sufficiency and sources of our capital resources; the impact of a change in our deferred revenue recognition policy; the estimated amortization period for stock-based compensation; 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 probability of making payments relating to the NeoPharm contingent payment rights; our planned uses of our IPO proceeds; the impact of changing interest rates; the exposure of our cash to default and illiquidity risks; 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," "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. 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 history of net losses and negative cash flows and our ability to become profitable;*

our dependence on sales of Subsys and Dronabinol;
market acceptance, including by third-party payors, of our products;
the success of our marketing strategies;
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;
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 failure to obtain or maintain Schedule III classification for our dronabinol products;
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 manage growth in our business;
our ability to retain key management and other personnel;
employee misconduct and improper activities;
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;
changes in accounting standards;
natural disasters;
our significant operating losses and need for potential additional funding;
our level of indebtedness and our ability to raise additional capital;
restrictions on our business imposed by our credit facility;
market fluctuation and economic conditions;
the regulatory impact on our existing Subsys and Dronabinol 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;
our compliance with complex regulations;
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 failure to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws;

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;
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;
fluctuation in the price of our common stock;
lack of, or inaccurate, published research about the Company;
lack of a viable public market for our common stock;
the impact of future sales of our common stock or securities convertible into our common stock;
the impact of our abbreviated disclosures as allowed by the JOBS Act because of our status as an "emerging growth company"; and
our intention to not pay dividends in the foreseeable future.

Additionally, there may be other risks that are otherwise described from time to time in the reports that we filed 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 wells 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. We 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.

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 plan to build 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.

In addition, we are developing other product candidates, such as dronabinol line extensions and sublingual spray product candidates. Our most advanced potential dronabinol 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. As a result, there is a possibility the NDA may not be submitted during the fourth quarter of 2013.

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. 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, 2012 and 2013, all of our net revenues were generated from the sale of our two approved products, Subsys and Dronabinol SG Capsule. 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 90% and Dronabinol SG Capsule gross margin was approximately 35% for the nine months ended September 30, 2013. 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 over 75% of prescriptions as of September 2013. 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. In addition, we currently defer 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 estimate patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. If this third-party data underestimates or overestimates actual patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

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, in 2013, we added 45 sales professionals to enhance our commercial infrastructure. 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 plan to build 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. We expect the capital expenditures associated with the completion of our planned second dronabinol manufacturing facility will be approximately $11.0 million to $13.0 million. 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 $5.3 million and $5.6 million for the nine months ended September 30, 2013 and 2012, respectively. As of September 30, 2013, we had 25 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, 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 $2.7 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 (“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.

Recent Developments

In October 2012, Mylan Pharmaceuticals, Inc. (“Mylan”), our exclusive distributor of Dronabinol SG Capsule product, rejected a large batch of 10mg Dronabinol SG Capsule product. We believe this rejection was wrongful as the Dronabinol SG Capsule product rejected had both the appropriate Certificate of Analysis and Certificate of Conformance. We have filed a lawsuit seeking judicial determination that the rejection was wrongful, termination of our distributor agreement with Mylan, and damages. We continue to negotiate resolution of this issue with Mylan. As a result of the dispute with Mylan, the distribution channel with Mylan is clogged with unsold product and Mylan has, since the October 2012 rejection, purchased and sold less Dronabinol SG Capsule product, both in terms of volume and price, than we anticipated. We are hopeful for a settlement of the dispute with Mylan (whether through a negotiated settlement or favorable judicial determination and termination of the distribution contract). As reflected in our results for the three and nine months ended September 30, 2013 (and discussed under the heading “—Results of Operations”), our sales revenue for Dronabinol SG Capsule decreased significantly during 2013. If the dispute with Mylan is not favorably resolved, or not favorably resolved in the near future, our sales of Dronabinol SG Capsule could continue to fluctuate significantly and be adversely affected which could have a material adverse effect on our results of operations and financial position.

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. We currently defer 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 estimate patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. If this third-party data underestimates or overestimates actual patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

As a result of this policy, the deferred revenue balance was $1.5 million and $3.8 million at September 30, 2013 and December 31, 2012, respectively, for Subsys product shipments, which is net of estimated pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs. We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we

can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred, partially offset by an estimate of product returns.

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.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue for Subsys consists primarily of materials, third-party manufacturing costs, freight and 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.

The cost of revenue associated with the deferred product revenues are recorded as deferred costs, which are included in inventories until such time as the deferred revenue is recognized. Deferred cost of revenue was $601,000 and $546,000 as of September 30, 2013 and December 31, 2012, respectively.

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, 2013, we had 108 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 2013 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 (“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, 2013, we had 25 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, 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, 2013, we had 17 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.

Other Income (Expense), Net

In connection with the NeoPharm merger, the NeoPharm board approved the distribution, immediately after the merger, of non-transferable contingent payment rights to its stockholders of record as of November 5, 2010. These rights entitle the pre-merger stockholders of NeoPharm to receive cash payments aggregating $20.0 million (equivalent to $0.70402 per share) if, prior to the five year anniversary of the NeoPharm merger, the FDA approves an NDA for any one or more of the NeoPharm product candidates that were under development at the time of the merger. The distribution is payable within nine months of FDA approval. The initial fair value of this contingent payment was determined to be approximately $1.8 million based on the assumed probability of any payment being made to the prior NeoPharm stockholders in 2015, discounted to present value at a rate of 15%, a Level 3 fair value measurement. Changes in estimated fair value representing an increase of $210,000 during the nine months ended September 30, 2012 were recorded in other expense.

Interest Income (Expense), Net

Interest income (expense), net 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 and $1.3 million related to accrued interest on these notes during the nine months ended September 30, 2013 and 2012, respectively. Upon completion of our IPO in May 2013, all outstanding principal and accrued interest on the Kapoor Notes converted into 7,410,341 shares of common stock and all of the Kapoor Notes were cancelled.

During the year ended December 31, 2012, we entered into a $15.0 million revolving credit facility with Bank of America. The outstanding principal balance under this facility was $11.4 million as of May 7, 2013 and we recorded interest expense of $51,000 during the nine months ended September 30, 2013 in connection with borrowings under this credit facility. This balance was paid off on May 10, 2013 with proceeds from the IPO.

From May 7, 2013 through September 30, 2013, we recorded interest income of approximately $13,000 that was earned from the excess cash held as a result of our IPO.

Income Tax Benefit, Net Operating Loss Carryforwards

In each period since our inception, we have recorded a valuation allowance for the full amount of our net deferred tax assets, as the realization of our deferred tax assets is uncertain. As a result, we have not recorded any federal or state income tax benefit in our consolidated statements of comprehensive income (loss).

As of September 30, 2013, we had approximately $276 million of federal net operating loss carry forwards (“NOLs”), which utilization of $269 million is subject to a significant Section 382 limitation as noted below, and we had approximately $278 million of state NOLs. For federal tax purposes, the NOLs began expiring in 2011 and will continue expiring through 2032 to the extent they are not utilized. For state tax purposes, the NOLs will generally begin expiring in 2016 if not utilized.

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. Prior to the NeoPharm merger, NeoPharm had completed a partial analysis of ownership changes under Section 382 of the Code to determine if a change in control had occurred. Based on this partial analysis, no change in control was identified. A complete formal analysis of ownership change would have to be performed in order to obtain certainty that a change in control had not occurred prior to the merger, which could further limit the utilization of our pre-merger NOLs.

Based on the above, we have estimated the amount of pre-NeoPharm merger federal NOLs that are available to offset post-NeoPharm merger income are limited to approximately $158,000 per year for 20 years, or cumulatively $3.0 million as of September 30, 2013. Post-NeoPharm merger, federal NOLs of approximately $7.3 million as of September 30, 2013 are not subject to this annual limitation and begin expiring in 2032.

The issuance of common stock in connection with our IPO completed on May 7, 2013, together with the issuance of common stock in other transactions involving our common stock, may have resulted in an additional ownership change, which could further limit the amount of the NOLs we may use to offset future taxable income, if any. In addition, any future equity financing transactions, private placements and other transactions that occur within the specified three-year period may trigger additional ownership changes, which could further limit our use of such NOLs. Any such limitations, whether as the result of the IPO, prior or future offerings of our common stock or sales of common stock by our existing stockholders, could have an adverse effect on our consolidated results of operations in future years.

Significant Accounting Polices and Estimates

There were no changes in our significant accounting policies and estimates during the nine months ended September 30, 2013 from those set forth in “Significant Accounting Policies and Estimates” in our final prospectus filed with the SEC on May 2, 2013 relating to our Registration Statement on Form S-1/A (File No. 333-173154) for our IPO.

Results of Operations

Comparison of three months ended September 30, 2013 to three months ended September 30, 2012

The following table presents certain selected consolidated financial data for the three months ended September 30, 2013 and 2012 expressed as a percentage of net revenue:

	Three Months Ended September 30,	
	2013	**2012**
Net revenue	100.0%	100.0%
Cost of revenue	10.6 %	41.0 %
Gross profit	89.4 %	59.0 %
Operating expenses:		
Sales and marketing	27.3 %	61.0 %
Research and development	5.9 %	23.5 %
General and administrative	14.6 %	47.7 %
Total operating expenses	47.9 %	132.3%
Income (loss) from operations	41.5 %	-73.3 %
Other income (expense), net	-0.1 %	-1.9 %
Interest income (expense), net	0.0 %	-14.3 %
Income (loss) before income taxes	41.5 %	-89.4 %
Income tax expense	1.8 %	0.0 %
Net income (loss)	39.7 %	-89.4 %

Net Revenue. Net revenue increased $24.5 million, or 515%, to $29.2 million for the three months ended September 30, 2013, compared to $4.8 for the three months ended September 30, 2012. The increase in net revenue was primarily attributable to the $25.8 million, or 1002%, increase in net sales of Subsys to $28.4 million for the three months ended September 30, 2013 compared to $2.6 million for the three months ended September 30, 2012, as Subsys was initially marketed in March 2012. Provisions for wholesaler discounts, patient discounts and rebates increased to $2.8 million, $2.5 million and $2.0 million, respectively, or 20% on a combined basis of gross revenue for the three months ended September 30, 2013, compared to $0.4 million, $1.0 million and $0.1 million, respectively, or 37% on a combined

basis of gross revenue for the three months ended September 30, 2012. The decrease in revenue provisions as a percentage of gross revenue was primarily attributable to decreased provisions for patient discounts compared to gross revenue. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2013 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix. The increase in sales of Subsys was partially offset by a decrease in sales of Dronabinol SG Capsule of $1.3 million to $0.9 million for the three months ended September 30, 2013, compared to $2.2 million for the three months ended September 30, 2012. The decrease in sales of Dronabinol SG Capsule was due primarily to a dispute with our exclusive distributor of Dronabinol SG Capsule and the resulting impact of reduced product supply and lower selling prices since 2012. As Dronabinol SG Capsule is marketed by Mylan, we expect net revenue from sales of Dronabinol SG Capsule to continue to fluctuate on a quarterly basis.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $1.2 million to $3.1 million for the three months ended September 30, 2013 compared to $1.9 million for the three months ended September 30, 2012. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the three months ended September 30, 2013. Gross profit increased $23.3 million to $26.1 million for the three months ended September 30, 2013 compared to $2.8 million for the three months ended September 30, 2012. Gross margin for the three months ended September 30, 2013 was approximately 89% compared to approximately 59% for the three months ended September 30, 2012. The increase in gross margin was due primarily to a higher mix of sales of Subsys, which yields higher gross margins than sales of Dronabinol SG Capsule. Subsys gross margin was approximately 91% and 82% for the three months ended September 30, 2013 and 2012, respectively. Dronabinol SG Capsule gross margin was approximately 32% for the three months ended September 30, 2013 and 2012, respectively.

Sales and Marketing Expense. Sales and marketing expense increased $5.1 million to $8.0 million for the three months ended September 30, 2013 compared to $2.9 million for the three months ended September 30, 2012. 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 March 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 $0.6 million to $1.7 million for the three months ended September 30, 2013 compared to $1.1 million for the three months ended September 30, 2012. The increase in research and development expense was due primarily to an increase in research and development personnel during the three months ended September 30, 2013.

General and Administrative Expense. General and administrative expense increased $2.0 million to $4.3 million for the three months ended September 30, 2013 compared to $2.3 million for the three months ended September 30, 2012. The increase in general and administrative expense was due primarily to costs incurred in connection with increases in administrative infrastructure to support the growth of Subsys sales combined with increased cost of being a public company during 2013.

Other Income (Expense), Net. Other expense was $24,000 for the three months ended September 30, 2013, compared to $90,000 for the three months ended September 30, 2012. During the three months ended September 30, 2012, changes in the estimated fair value of the NeoPharm contingent consideration of $70,000 were recorded as other expense. As a result of the reassessment of the probability of payment of the NeoPharm contingent consideration in October 2012, no further changes to the estimated fair value of contingent consideration were recorded during the three months ended September 30, 2013.

Interest Income (Expense), Net. Interest income was $8,000 for the three months ended September 30, 2013, compared to interest expense of $0.7 million for the three months ended September 30, 2012. The decrease in interest expense was primarily a result of the conversion of the Kapoor Notes to common stock and the repayment of the $15.0 million line of credit in May 2013. We do not expect to record significant interest expense for the remainder of 2013. Interest income for the three months ended September 30, 2013 was due primarily to interest earned on excess cash from our May 2013 IPO.

Income Tax Expense. 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. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. While we have pre-tax book income for the nine months ended September 30, 2013, such positive evidence does not outweigh the negative evidence of our historical losses. Each period we will continue to evaluate both the positive and negative evidence and will reduce the valuation allowance in the period the positive evidence outweighs the negative evidence.

Comparison of nine months ended September 30, 2013 to nine months ended September 30, 2012

The following table presents certain selected consolidated financial data for the nine months ended September 30, 2013 and 2012 expressed as a percentage of net revenue:

	Nine Months Ended September 30,	
	2013	**2012**
Net revenue	100.0%	100.0%
Cost of revenue	12.6%	54.0%
Gross profit	87.4%	46.0%
Operating expenses:		
Sales and marketing	31.7%	79.8%
Research and development	9.1%	54.7%
General and administrative	15.9%	54.2%
Total operating expenses	56.7%	188.7%
Income (loss) from operations	30.7%	-142.7%
Other income (expense), net	0.0%	-5.8%
Interest income (expense), net	-1.6%	-19.3%
Income (loss) before income taxes	29.1%	-167.7%
Income tax expense	1.5%	0.0%
Net income (loss)	27.5%	-167.7%

Net Revenue. Net revenue increased $48.8 million, or 473%, to $59.1 million for the nine months ended September 30, 2013, compared to $10.3 million for the nine months ended September 30, 2012. The increase in net revenue was primarily attributable to the $52.8 million, or 1402%, increase in net sales of Subsys to $56.6 million for the nine months ended September 30, 2013 compared to $3.8 million for the nine months ended September 30, 2012, as Subsys was initially marketed in March 2012. Provisions for wholesaler discounts, patient discounts and rebates increased to $5.8 million, $6.4 million and $4.0 million, respectively, or 22% on a combined basis of gross revenue for the nine months ended September 30, 2013, compared to $0.6 million, $2.0 million and $0.1 million, respectively, or 43% on a combined basis of gross revenue for the nine months ended September 30, 2012. The decrease in revenue provisions as a percentage of gross revenue was primarily attributable to decreased provisions for patient discounts compared to gross revenue. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2013 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix. The increase in sales of Subsys was partially offset by a decrease in sales of Dronabinol SG Capsule of $4.0 million to $2.5 million for the nine months ended September 30, 2013, compared to $6.6 million for the nine months ended September 30, 2012. The decrease in sales of Dronabinol SG Capsule was due primarily to a dispute with our exclusive distributor of Dronabinol SG Capsule and the resulting impact of reduced product supply

and lower selling prices since 2012. As Dronabinol SG Capsule is marketed by Mylan, we expect net revenue from sales of Dronabinol SG Capsule to continue to fluctuate on a quarterly basis.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $1.9 million to $7.5 million for the nine months ended September 30, 2013 compared to $5.6 million for the nine months ended September 30, 2012. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the nine months ended September 30, 2013. Gross profit increased $46.9 million to $51.6 million for the nine months ended September 30, 2013 compared to $4.8 million for the nine months ended September 30, 2012. Gross margin for the nine months ended September 30, 2013 was approximately 87% compared to approximately 46% for the nine months ended September 30, 2012. The increase in gross margin was due primarily to a higher mix of sales of Subsys, which yields higher gross margins than sales of Dronabinol SG Capsule. Subsys gross margin was approximately 90% and 75% for the nine months ended September 30, 2013 and 2012, respectively. Dronabinol SG Capsule gross margin was approximately 35% and 30% for the nine months ended September 30, 2013 and 2012, respectively.

Sales and Marketing Expense. Sales and marketing expense increased $10.5 million to $18.7 million for the nine months ended September 30, 2013 compared to $8.2 million for the nine months ended September 30, 2012. 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 March 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 decreased $0.3 million to $5.3 million for the nine months ended September 30, 2013 compared to $5.6 million for the nine months ended September 30, 2012. The decrease in research and development expense was due primarily to the completion of development of Subsys during the nine months ended September 30, 2012, combined with a decline in spending during 2013 on the in-process research and development programs acquired from NeoPharm.

General and Administrative Expense. General and administrative expense increased $3.8 million to $9.4 million for the nine months ended September 30, 2013 compared to $5.6 million for the nine months ended September 30, 2012. The increase in general and administrative expense was due primarily to costs incurred in connection with increases in administrative infrastructure to support the growth of Subsys sales combined with increased costs of being a public company during 2013.

Other Income (Expense), Net. Other expense was $22,000 for the nine months ended September 30, 2013, compared to $596,000 for the nine months ended September 30, 2012. During the nine months ended September 30, 2012, changes in the estimated fair value of the NeoPharm contingent consideration of $210,000 were recorded as other expense. As a result of the reassessment of the probability of payment of the NeoPharm contingent consideration in October 2012, no further changes to the estimated fair value of contingent consideration were recorded during the nine months ended September 30, 2013. Also included in other expense for the nine months ended September 30, 2012 was $0.3 million of costs and termination fees associated with the termination of a lease.

Interest Income (Expense), Net. Interest expense decreased to $0.9 million for the nine months ended September 30, 2013 from $2.0 million for the nine months ended September 30, 2012. The $1.1 million decrease was primarily a result of the conversion of the Kapoor Notes to common stock and the repayment of the $15.0 million line of credit in May 2013. We do not expect to record significant interest expense for the remainder of 2013.

From May 7, 2013 through September 30, 2013, we recorded interest income of approximately $13,000 that was earned from the excess cash held as a result of our IPO.

Income Tax Expense. 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. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. While we have pre-tax book income for the nine months ended September 30, 2013, such positive evidence does not outweigh the negative evidence of our historical losses. Each period we will continue to evaluate both the positive and negative evidence and will reduce the valuation allowance in the period the positive evidence outweighs the negative evidence.

Liquidity and Capital Resources

Sources of Liquidity

We incurred losses from our inception through December 31, 2012. As of September 30, 2013, we had an accumulated deficit of $113.1 million. Previously 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 4,600,000 shares of our common stock at a price of $8.00 per share, 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 8,528,860 shares of common stock.

As of May 7, 2013, we had $59.3 million in debt, including accrued interest of $10.7 million, under the promissory notes payable to The John N. Kapoor Trust and the Kapoor Children 1992 Trust, and $0.7 million in cash and cash equivalents. Upon the closing of our IPO on May 7, 2013, all principal indebtedness and accrued interest under these notes and other notes issued by us to trusts controlled by or affiliated with Dr. Kapoor converted into 7,410,341 shares of our common stock at the $8.00 per share offering price.

During 2012, we entered into a $15.0 million revolving credit facility with Bank of America. On May 10, 2013, the outstanding principal balance of $11.4 million was paid in full using proceeds from the IPO, and on October 3, 2013 this credit facility was terminated.

In October 2013, we entered into a $15.0 million revolving credit facility with JPMorgan Chase Bank, N.A., which includes a $500,000 letter of credit facility. Under the terms of the credit facility, amounts outstanding bear interest at LIBOR plus 1.5% and the credit facility is subject to a 0.35% non-usage fee. Advances are subject to a borrowing base such that the maximum advances that may be outstanding under is limited to 80% of the book value of eligible accounts receivable. The credit facility matures on September 30, 2014. On the effective date of the credit facility, no amounts were outstanding and $11.2 million was available to borrow, taking into account the applicable borrowing base limitations.

Cash Flows

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

	Nine Months Ended September 30,	
	2013	**2012**
Net cash provided by (used in) operating activities	$13.8	$(11.4)
Net cash used in investing activities	(2.8)	(0.8)
Net cash provided by financing activities	19.9	13.5
Net increase in cash and cash equivalents	30.9	1.3
Cash and cash equivalents, beginning of period	0.4	0.0
Cash and cash equivalents, end of period	$31.3	$1.3

Cash Flows From Operating Activities. Net cash provided by operating activities was $13.8 million for the nine months ended September 30, 2013 and net cash used in operating activities was $11.4 million for the nine months ended September 30, 2012. The net cash provided during the nine months ended September 30, 2013 primarily reflects the net income for the period driven primarily by growth in Subsys net sales, increased in part by depreciation and amortization, stock-based compensation expense and non-cash interest expense and is also impacted by changes in working capital.

Cash Flows From Investing Activities. Net cash used in investing activities was $2.8 million and $0.8 million for the nine months ended September 30, 2013 and 2012, respectively and represents the purchase of equipment and leasehold improvements.

Cash Flows From Financing Activities. Net cash provided by financing activities was $20.7 million and $13.5 million for the nine months ended September 30, 2013 and 2012, respectively. During the nine months ended September 30, 2013, we received $32.4 million in net proceeds in connection with an IPO. We used $11.9 million of these proceeds to make a payment against the line of credit with Bank of America. Net cash provided by financing activities for the nine months ended September 30, 2012 was primarily attributable to borrowings against the credit facility in the amount of $10.5 million combined with increased borrowings under promissory notes payable to The John N. Kapoor Trust and The Kapoor Children 1992 Trust of $3.0 million.

We invoice wholesalers upon shipment of Subsys. To date, our wholesalers have typically paid us 30 to 60 days from their applicable invoice dates. Accordingly, we have typically received cash payments on sales of Subsys in advance of recognition of revenues from such sales.

Our cash flows for the rest of 2013 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 inflows 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 May 7, 2013 IPO 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.

As of October 19, 2013, we had $11.2 million of undrawn funds available under our revolving credit facility with JPMorgan Chase Bank.

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;

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- the effects of competing technological and market developments;
- costs associated with litigation;
- 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, 2013, we expect to continue to fund our operations primarily from operating activities as well as from the net proceeds from offerings of our equity securities and through our revolving credit facility with JPMorgan Chase Bank. We cannot be sure that our existing cash and cash equivalents will be adequate, or 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, 2013, 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.

Contractual Obligations and Commitments

The following table summarizes our outstanding contractual obligations as of September 30, 2013 (in millions, except years):

	Payments Due by Period				
	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
Operating leases	$0.1	$ 3.0	$ 6.2	—	$9.3
Line of credit[1]	—	—	—	—	—
Manufacturing agreement expenses[2]	21.5	—	—	—	21.5
Capital equipment[3]	2.5	—	—	—	2.5
Total	$24.1	$ 3.0	$ 6.2	$ —	$33.3

(1) The $15.0 million credit facility with Bank of America, which has a balance of $0 as of September 30, 2013, was terminated in October 2013 and was replaced with a $15.0 million credit facility with JPMorgan Chase Bank.

(2) Estimated minimum purchase obligations based on amounts reasonably likely to be paid in future periods to contract manufacturers for Subsys and Dronabinol SG Capsule.

(3) Remaining unpaid obligations for dronabinol manufacturing equipment.

In connection with the NeoPharm merger, each of the pre-merger stockholders of NeoPharm was distributed a contingent payment right, or CPR, for each share of NeoPharm common stock then-held by such stockholder. Each CPR entitles the holder to receive a pro rata share of up to an aggregate of $20.0 million, payable in cash, if, within five years of the merger, one of the NeoPharm product candidates that was in development prior to the merger receives FDA approval. We believe the probability of making this payment is low.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Due to the short-term duration of our investment portfolio, which was created on May 7, 2013 in connection with the net proceeds from our IPO, and the low risk profile of our investments, an immediate 10.0% change in interest rates should not have a material effect on the fair market value of our portfolio. Accordingly, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a sudden change in market interest rates on our investment portfolio.

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We do not believe that our cash and cash equivalents have significant risk of default or illiquidity. While we believe our cash and cash equivalents and certificates of deposit do not contain excessive risk, we cannot provide absolute assurance that in the future our investments will not be subject to adverse changes in market value. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are in excess of federally insured limits.

Inflation generally affects us by increasing our cost of labor and clinical trial costs. Inflation has not had a material effect on our results of operations for the nine months ended September 30, 2013 or 2012.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act), have concluded that, based on such evaluation, as of September 30, 2013 our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the three month period ended September 30, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

There have been no material changes to legal proceedings from those disclosed under the heading “Legal Proceedings” in our final prospectus filed with the SEC on May 2, 2013 relating to our Registration Statement on Form S-1/A (File No. 333-173154) for our IPO.

ITEM 1A. RISK FACTORS

There have been no material changes from the risk factors disclosed in Part II, Item 1A, of our Form 10-Q filed June 5, 2013.

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

Use of Proceeds from Registered Securities

We commenced our IPO pursuant to a registration statement on Form S-1 (File No. 333-173154) that was declared effective by the SEC on May 2, 2013 and registered an aggregate of 4,600,000 shares of our common stock for sale to the public at price of $8.00 per share and an aggregate offering price of approximately $36.8 million. On May 7, 2013, we completed the IPO. Wells Fargo Securities and JMP Securities acted as joint book-running managers for the offering, and Oppenheimer served as co-manager for the offering.

The underwriting discounts and commissions connected with the offering totaled approximately $2.6 million. We incurred additional costs of approximately $1.8 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $4.4 million. Thus, net offering proceeds to us, after deducting underwriting discounts and commissions and offering costs, were $32.5 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents, money market funds and government agency securities. Through August 6, 2013, we have used approximately $11.4 million of the net proceeds from our IPO to repay the outstanding principal balance on our line of credit with Bank of America. We have also used approximately $2.0 million to fund a downpayment on manufacturing equipment for our planned second dronabinol manufacturing facility. We intend to invest the remaining funds in the future in some combination of short—and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. We plan to use the net proceeds from our IPO to fund capital expenditures and lease expenses for the a second dronabinol manufacturing facility in Austin, Texas and to fund clinical and research and development costs, including fees for a new drug application for dronabinol oral solution and for working capital and other general corporate purposes. Our expected use of net proceeds from our IPO represents our current intentions based upon our present plans and business condition. We cannot predict with certainty all of the particular uses for our current funds, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of these funds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of our research, preclinical and clinical development programs, and the amount and timing of additional revenues. As a result, our management will have broad discretion in the application of these funds, and investors will be relying on our judgment regarding the application of the net proceeds of the offering.

ITEM 5. OTHER INFORMATION

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On October 1, 2013 and November 7, 2013, the Compensation Committee of the Board of Directors of the Company revised the compensation of the Company’s CEO and President as follows:

(1) Base Salary - $400,000;

(2) Bonus (target) - $600,000 contingent upon satisfactory performance in the fourth quarter of 2013; and

(3) Long Term Incentive Compensation – 50% of total compensation to be entirely comprised of stock options.

The base salary and bonus target above are retroactive to May 2, 2013. The long-term incentive compensation is effective as of January 1, 2014.

ITEM 6. EXHIBITS

The Exhibit Index immediately following the Signatures to this Form 10-Q are 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, 2013 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)	Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
3.4(4)	Certificate of Amendment of Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
3.5(5)	Certificate of Amendment of Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
3.6(6)	Agreement and Plan of Merger among the Registrant, Insys Therapeutics, Inc. and ITNI Merger Sub Inc. dated October 29, 2010.
4.1(7)	Form of Common Stock Certificate of Insys Therapeutics, Inc.
10.1(8)	Lease Agreement
10.2(9)	Credit Agreement, dated as of October 17, 2013 between Insys Therapeutics, Inc. and JPMorgan Chase Bank, N.A.
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, as amended.
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, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
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.

* In accordance with Rule 406T of Regulation S-T, the XBRL related information in Exhibit 101 to this Quarterly Report on Form 10-Q is furnished and shall not be deemed to be "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of the section, and shall not be part of any registration statement or other document filed under the Securities Act or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

(1) Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on May 8, 2013, 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 Exhibit 3.5 to the Registrant's Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC on March 30, 2011, as amended, and incorporated herein by reference.

(4) Previously filed as Exhibit 3.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC on March 30, 2011, as amended, and incorporated herein by reference.

(5) Previously filed as Exhibit 3.7 to the Registrant's Registration Statement on Form S-1/A (File No. 333-173154), originally filed with the SEC on April 16, 2013, as amended, and incorporated herein by reference.

(6) Previously filed as Exhibit 2.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC on March 30, 2011, and incorporated herein by reference.

(7) Previously filed as Exhibit 4.1 to the Registrant's Registration Statement on Form S-1/A (File No. 333-173154), originally filed with the SEC on June 9, 2011, as amended, and incorporated herein by reference.

(8) Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on September 3, 2013 and incorporated herein by reference.

(9) Previously filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on October 23, 2013 and incorporated herein by reference.