Insys Therapeutics, Inc.
Form 10-Q
May 05, 2016

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 March 31, 2016

OR

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

For the transition period from _____ to _____

Commission file number: 001-35902

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.)**
1333 S. Spectrum Blvd, Suite 100, Chandler, Arizona	**85286**
(Address of principal executive offices)	**(Zip Code)**

(480) 500-3127
(Registrant's telephone number, including area code)

N/A

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes 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 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. (Check one):

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

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

Yes No

As of May 1, 2016, the registrant had 71,546,491 shares of Common Stock ($0.01 par value) outstanding.

INSYS THERAPEUTICS, INC.

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GLOSSARY OF TERMS

The following glossary provides definitions for certain acronyms and terms used in our periodic filings with the United States Securities and Exchange Commission, including this Quarterly Report on Form 10-Q. These acronyms and terms are specific to our company, commonly used in our industry, or are otherwise frequently used throughout our filings, including this document.

Abbreviated Term	Defined Term
ANDA	Abbreviated New Drug Application
API	Active pharmaceutical ingredient
Aptar	AptarGroup, Inc.
ATRA	American Taxpayer Relief Act of 2012
AUC	Area under the curve
AVC	Assurance of Voluntary Compliance
BTCP	Breakthrough cancer pain
Catalent	Catalent Pharma Solutions, LLC
CBD	Synthetic cannabidiol
cGMP	Current Good Manufacturing Practices
CID	Civil Investigative Demand
CINV	Chemotherapy-induced nausea and vomiting
CMS	Centers for Medicare & Medicaid Services
CRO	Contract Research Organization
CSA	Federal Controlled Substances Act of 1970
DEA	U.S. Drug Enforcement Administration
DPT	DPT Lakewood, LLC
ERP	Enterprise Resource Planning
ESI	Express Scripts, Inc.
FDA	U.S. Food and Drug Administration
FDCA	Federal Food, Drug, and Cosmetic Act
FSS	Federal Supply Schedule
GAAP	Generally Accepted Accounting Principles
GAO	Government Accountability Office
GCP	Good Clinical Practices
GI	Gastrointestinal
GLP	Good Laboratory Practices
HHS	U.S. Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act of 1996
HITECH	Health Information Technology for Economic and Clinical Health Act of 2009
IMS	IMS Health
IND	Investigational New Drug Application
Insys Pharma	Insys Pharma, Inc.

Insys Therapeutics	Insys Therapeutics, Inc.
IPO	Initial public offering
IPR	Inter Partes Review
IRB	Institutional Review Board
JOBS Act	Jumpstart Our Business Startups Act of 2012
MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
Mylan	Mylan Pharmaceuticals, Inc.
NDA	New Drug Application
NeoPharm	NeoPharm, Inc.
NOL	Net operating loss carryforward
NRV	Net Realizable Value
NSAID	Non-steroidal anti-inflammatory drug
Orange Book	FDA's Approved Drug Products with Therapeutic Equivalence Evaluations
ODOJ	Oregon Department of Justice

PBM	Pharmacy Benefit Managers
PDEs	Prescription Drug Events
PDMA	Prescription Drug Marketing Act
PDUFA	Prescription Drug User Fee Act
PK	Pharmacokinetics
PPACA	Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010
QSR	FDA's Quality System Regulation
REMS	Risk Evaluation and Mitigation Strategy
RLD	Reference listed drug
SEC	U.S. Securities and Exchange Commission
THC	Delta-9-tetrahydrocannabinol
TIRF	Transmucosal immediate-release fentanyl
TIRF REMS	Transmucosal immediate release fentanyl risk evaluation and mitigation strategy
USAO	United States Attorney Office
USPTO	United States Patent and Trademark Office
VC	Vomiting center

Part I: FINANCIAL INFORMATION

Item 1. UNAUDITED Financial Statements

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	March 31, 2016 (unaudited)	**December 31, 2015**
Assets		
Current Assets:		
Cash and cash equivalents	$ 73,820	$ 79,515
Short-term investments	89,808	79,576
Accounts receivable, net of allowances of $4,481 and $7,180 at March 31, 2016 and December 31, 2015, respectively	20,963	48,459
Inventories	32,241	41,715
Prepaid expenses and other assets	3,918	3,973
Total current assets	220,750	253,238
Property and equipment, net	39,618	38,382
Long-term investments	36,443	43,219
Deferred income tax assets	17,046	16,331
Other assets	11,165	26
Total assets	$ 325,022	$ 351,196
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$ 25,746	$ 36,354
Accrued compensation	7,239	10,225
Accrued sales allowances	24,994	32,713
Accrued litigation award	9,567	9,567
Total current liabilities	67,546	88,859
Uncertain income tax position	7,481	8,635
Total liabilities	75,027	97,494
Commitments and contingencies		

Stockholders' Equity:		
Preferred stock (par value $0.01 per share; 10,000,000 shares authorized; 0 shares issued and outstanding as of March 31, 2016 and December 31, 2015)	-	-
Common stock (par value $0.01 per share; 100,000,000 shares authorized; 71,532,258 and 71,907,858 shares issued and outstanding as of March 31, 2016 and December 31, 2015, respectively)	715	719
Additional paid in capital	239,433	245,736
Unrealized gain (loss) on available-for-sale securities	14	(152)
Notes receivable from stockholders	(21)	(21)
Retained earnings	9,854	7,420
Total stockholders' equity	249,995	253,702
Total liabilities and stockholders' equity	$ 325,022	$ 351,196

See accompanying notes to unaudited condensed consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF INCOME AND COMPREHENSIVE INCOME

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Net revenue	$61,962	$70,770
Cost of revenue	4,638	6,375
Gross profit	57,324	64,395
Operating expenses:		
Sales and marketing	19,800	20,916
Research and development	20,535	10,602
General and administrative	14,698	13,246
Charges related to litigation award	-	8,000
Total operating expenses	55,033	52,764
Operating income	2,291	11,631
Other income:		
Interest income	225	125
Other income, net	49	-
Total other income	274	125
Income before income taxes	2,565	11,756
Income tax expense	131	3,733
Net income	2,434	8,023
Unrealized gain on available-for-sale securities	166	28
Total comprehensive income	$2,600	$8,051
Net income per common share:		
Basic	$0.03	$0.11
Diluted	$0.03	$0.11
Weighted average common shares outstanding		
Basic	71,592,089	70,916,828
Diluted	74,462,878	74,918,318

See accompanying notes to unaudited condensed consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

(unaudited)

	Common Stock Shares	Amount	Additional Paid in Capital	Unrealized Gain (Loss) on Available-For-Sale Securities	Notes Receivable from Stockholders	Retained Earnings	Total
Balance at December 31, 2015	71,907,858	$ 719	$ 245,736	$ (152)	$ (21)	$ 7,420	$ 253,702
Exercise of stock options	265,325	2	1,308	-	-	-	1,310
Excess tax benefits on stock options and awards	-	-	108	-	-	-	108
Stock based compensation - stock options and awards	-	-	5,626	-	-	-	5,626
Unrealized gain on available-for-sale securities	-	-	-	166	-	-	166
Repurchase of common stock	(640,925)	(6)	(13,345)	-	-	-	(13,351)
Net income	-	-	-	-	-	2,434	2,434
Balance at March 31, 2016	71,532,258	$ 715	$ 239,433	$ 14	$ (21)	$ 9,854	$ 249,995

See accompanying notes to unaudited condensed consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2016	**2015**
Cash flows from operating activities:		
Net income	$ 2,434	$ 8,023
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,527	1,175
Stock-based compensation	5,626	3,720
Deferred income tax benefit	(715)	(1,140)
Loss on disposal of assets	-	41
Excess tax benefits on stock options and awards	(108)	(4,069)
Changes in operating assets and liabilities:		
Accounts receivable	27,496	(7,632)
Inventories	9,474	(455)
Prepaid expenses and other assets	(11,083)	(666)
Accounts payable, accrued expenses and other current liabilities	(22,361)	17,197
Net cash provided by operating activities	12,290	16,194
Cash flows from investing activities:		
Purchase of investments	(3,289)	(6,602)

Proceeds from sales of investments	-	371
Purchases of property and equipment	(2,763)	(5,191)
Net cash used in investing activities	(6,052)	(11,422)
Cash flows from financing activities:		
Excess tax benefits on stock options and awards	108	4,069
Proceeds from exercise of stock options	1,310	3,127
Repurchase of common stock	(13,351)	-
Net cash (used in) provided by financing activities	(11,933)	7,196
Change in cash and cash equivalents	(5,695)	11,968
Cash and cash equivalents, beginning of period	79,515	58,106
Cash and cash equivalents, end of period	$ 73,820	$ 70,074
Supplemental cash flow disclosures:		
Cash paid for interest expense	$ -	$ -
Cash paid for income taxes	$ 2,500	$ -

See accompanying notes to unaudited condensed consolidated financial statements.

INSYS THERAPEUTICS, INC.

NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business and Basis of Presentation

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

We are a commercial-stage specialty pharmaceutical company that develops and commercializes innovative supportive care products. We have one marketed product: Subsys, a proprietary sublingual fentanyl spray for BTCP in opioid-tolerant adult patients.

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 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, 2015 included in our Annual Report on Form 10-K. The results of operations for the three months ended March 31, 2016 and 2015 are not necessarily indicative of results to be expected for the full fiscal year or any other periods.

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

On May 5, 2015, our Board of Directors approved a two-for-one stock split of our common stock that was effected through a stock dividend. The record date for the stock split was the close of business on May 26, 2015, with share

distribution occurring on June 8, 2015. As a result of the dividend, shareholders received one additional share of Insys Therapeutics, Inc. common stock, par value $0.01, for each one share they held as of the record date. All share and per share amounts have been retroactively restated for the effects of this stock split.

Certain prior period amounts have been reclassified to conform with current period presentation.

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

Recent Accounting Pronouncements

In March 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, to reduce complexity in accounting standards involving several aspects of the accounting for employee share-based payment transactions, including (1) the income tax consequences, (2) classification of awards as either equity or liabilities, and (3) classification on the statement of cash flows. The amendments will be effective for financial statements issued for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, and early adoption is permitted. Amendments related to the timing of when excess tax benefits are recognized, minimum statutory withholding requirements, forfeitures, and intrinsic value should be applied using a modified retrospective transition, amendments related to the presentation of employee taxes paid on the statement of cash flows when an employer withholds shares to meet the minimum statutory withholding requirement should be applied retrospectively, amendments requiring recognition of excess tax benefits and tax deficiencies in the income statement and the practical expedient for estimating expected term should be applied prospectively, and amendments related to the presentation of excess tax benefits on the statement of cash flows can be applied using either a prospective transition method or a retrospective transition method. An entity that elects early adoption must adopt all of the amendments in the same period. We are currently evaluating the impact of these amendments on its financial statements.

In March 2016, the FASB issued ASU No. 2016-08, Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations, to clarify the implementation guidance on principal versus agent considerations and address how an entity should assess whether it is the principal or the agent in contracts that include three or more parties. The effective date and transition requirements for these amendments are the same as the effective date and transition requirements of ASU 2014-09 (discussed below). We are currently evaluating the impact of these amendments on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases: (Topic 842), to provide guidance on recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements, specifically differentiating between different types of leases. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from all leases. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous GAAP. There continues to be a differentiation between finance leases and operating leases. However, the principal difference from previous guidance is that the lease assets and lease liabilities arising from operating leases should be recognized in the balance sheet. The accounting applied by a lessor is largely unchanged from that applied under previous GAAP. The amendments will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients that entities may elect to apply. These practical expedients relate to the identification and classification of leases that commenced before the effective date, initial direct costs for leases that commenced before the effective date, and the ability to use hindsight in evaluating lessee options to extend or terminate a lease or to purchase the underlying asset. An entity that elects to apply the practical expedients will, in effect, continue to account for leases that commence before the effective date in accordance with previous GAAP unless the lease is modified, except that lessees are required to recognize a right-of-use asset and a lease liability for all operating leases at each reporting date based on the present value of the remaining minimum rental payments that were tracked and disclosed under previous GAAP. We are currently evaluating the impact of these amendments on its financial statements.

In January 2016, the FASB issued ASU No. 2016-01, Financial Instruments—Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities, which amended the Financial Instruments topic of the Accounting Standards Codification to address certain aspects of recognition, measurement, presentation, and disclosure of financial instruments. The amendments will be effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is not permitted. These amendments should be applied by means of a cumulative-effect adjustment to the balance sheet as of the beginning of the fiscal year of adoption. The amendments related to equity securities without readily determinable fair values (including disclosure requirements) should be applied prospectively to equity investments that exist as of the date of adoption. We are is currently evaluating the impact of these amendments on its financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers, which will supersede nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step

process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. As amended by the FASB in July 2015, the standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our consolidated financial statements and have not yet determined the method by which we will adopt the standard in 2018.

In July 2015, the FASB issued guidance that requires entities to measure most inventory at the lower of cost and NRV, thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. Under the new guidance, inventory is measured at the lower of cost and NRV, which eliminates the need to determine replacement cost and evaluate whether it is above the ceiling (NRV) or below the floor (NRV less a normal profit margin). The guidance defines NRV as the “estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation.” The guidance is effective for annual periods beginning after December 15, 2016, and interim periods therein. Early application is permitted. We are currently evaluating the impact of adoption of this guidance on our financial position and results of operations.

2. Revenue Recognition

We recognize revenue from the sale of Subsys. 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 monitored by an FDA mandated REMS program known as the TIRF REMS. We sell Subsys in the United States to wholesale pharmaceutical distributors and directly to retail pharmacies, collectively our customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Subsys currently has a shelf life of 36 months from the date of manufacture. We record revenue for Subsys at the time the wholesaler receives the shipment.

We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payors and the levels of inventory within the distribution channels that may result in future discounts taken. In certain cases, such as patient assistance programs, we recognize the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, we may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. Our product sales allowances include:

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

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

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

Prompt Pay Discounts. We offer cash discounts to our customers, generally 2.0% of the sales price, as an incentive for prompt payment. We account for cash discounts by reducing accounts receivable by the full amount.

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

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

Chargebacks. We provide discounts primarily to authorized users of the 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 organizations 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 organization paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. Estimated chargebacks are recognized as a reduction of revenue in the same period the related revenue is recognized. The allowance for chargebacks is included as a reduction to accounts receivable.

3. Short-Term and Long-Term Investments

Our policy for short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Short-term and long-term investments consist of corporate and various government agency and municipal debt securities, as well as certificates of deposit that have maturity dates that are greater than 90 days. Certificates of deposit are carried at cost which approximates fair value. We classify our marketable securities as available-for-sale in accordance with FASB Accounting Standards Codification Topic 320, *Investments — Debt and Equity Securities*. Available-for-sale securities are carried at fair value with unrealized gains and losses reported in stockholders' equity. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary, results in impairment of the fair value of the investment. We did not have any realized gains or losses or decline in values judged to be other than temporary during the three months ended March 31, 2106. If we had realized gains and losses and declines in value judged to be other than temporary, we would have been required to include those changes in other income/expense in the condensed consolidated statements of income and comprehensive income. Premiums and discounts are amortized or accreted over the life of the related available-for-sale security. The cost of securities sold is calculated using the specific identification method. At March 31, 2016, our certificates of deposit as well as our marketable securities have been recorded at an estimated fair value of $1,134,000, $89,808,000 and $36,443,000 in cash and cash equivalents, short-term and long-term investments, respectively.

Investments consisted of the following at March 31, 2016 (in thousands):

	Cost	Unrealized Gains	Unrealized Losses	Other-Than-Temporary Impairment	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments

				Losses				
Cash	$53,683	$ -	$ -	$ -	$53,683	$ 53,683	$ -	$ -
Money market securities	19,003	-	-	-	19,003	19,003	-	-
Certificates of deposit	29,523	-	-	-	29,523	-	19,642	9,881
Marketable securities:								
Corporate securities	29,374	13	(16)	-	29,371	175	24,259	4,937
Federal agency securities	18,053	3	(10)	-	18,046	899	10,396	6,751
Municipal securities	50,421	36	(12)	-	50,445	60	35,511	14,874
Total marketable securities	97,848	52	(38)	-	97,862	1,134	70,166	26,562
	$200,057	**$ 52**	**$ (38)**	**$ -**	**$200,071**	**$ 73,820**	**$ 89,808**	**$ 36,443**

Investments consisted of the following at December 31, 2015 (in thousands):

	Cost	**Unrealized Gains**	**Unrealized Losses**	**Other-Than-Temporary Impairment Losses**	**Fair Value**	**Cash and Cash Equivalents**	**Short-term Investments**	**Long-term Investments**
Cash	$55,987	$ -	$ -	$ -	$55,987	$ 55,987	$ -	$ -
Money market securities	20,373	-	-	-	20,373	20,373	-	-
Certificates of deposit	26,223	-	-	-	26,223	-	16,637	9,586
Marketable securities:								
Corporate securities	27,186	-	(68)	-	27,118	1,621	19,181	6,316
Federal agency securities	18,823	-	(65)	-	18,758	-	10,129	8,629
Municipal securities	53,870	16	(35)	-	53,851	1,534	33,629	18,688
Total marketable securities	99,879	16	(168)	-	99,727	3,155	62,939	33,633
	$202,462	**$ 16**	**$ (168)**	**$ -**	**$202,310**	**$ 79,515**	**$ 79,576**	**$ 43,219**

The amortized cost and estimated fair value of the marketable securities at March 31, 2016, by maturity, are shown below (in thousands):

	March 31, 2016		December 31, 2015	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Marketable securities:				
Due in one year or less	$71,310	$71,300	$66,148	$66,094
Due after one year through 5 years	26,538	26,562	33,731	33,633
Due after 5 years through 10 years	-	-	-	-
Due after 10 years	-	-	-	-
	$97,848	**$97,862**	**$99,879**	**$99,727**

The following table shows the gross unrealized losses and the fair value of our investments, with unrealized losses that are not deemed to be other-than-temporarily impaired aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position at March 31, 2016 (in thousands):

	March 31, 2016				December 31, 2015			
	Less Than 12 Months		Greater Than 12 Months		Less Than 12 Months		Greater Than 12 Months	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Marketable securities:								
Corporate securities	$16,945	$ (16)	$ -	$ -	$25,137	$ (68)	$ -	$ -
Federal agency securities	9,408	(10)	-	-	18,759	(65)	-	-
Municipal securities	15,872	(12)	-	-	22,981	(35)	-	-
	$42,225	**$ (38)**	**$ -**	**$ -**	**$66,877**	**$ (168)**	**$ -**	**$ -**

As of March 31, 2016, we have concluded that all the unrealized losses on our marketable securities are temporary in nature. Marketable securities are reviewed quarterly for possible other-than-temporary impairment. This review includes an analysis of the facts and circumstances of each individual investment such as the severity of loss, the expectation for that security's performance and the creditworthiness of the issuer. Additionally, we do not intend to sell, and it is not probable that we will be required to sell, any of the securities before the recovery of their amortized cost basis.

4. Fair Value Measurement

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

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

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

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

At March 31, 2016, we held short-term and long-term investments, as discussed in Note 3, that are required to be measured at fair value on a recurring basis. All available-for-sale investments held by us at March 31, 2016 have been valued based on Level 2 inputs. Available-for-sale securities classified within Level 2 of the fair value hierarchy are valued utilizing reports from third-party asset managers that hold our investments, showing closing prices on the last business day of the period presented. These asset managers utilize an independent pricing source to obtain quotes for most fixed income securities, and utilize internal procedures to validate the prices obtained. In addition, we use an independent third-party to perform price testing, comparing a sample of quoted prices listed in the asset managers’ reports to quotes listed through a public quotation service.

Our investments measured at fair value on a recurring basis subject to the disclosure requirements of ASC 820 at March 31, 2016 and December 31, 2015 were as follows (in thousands):

	Fair Value Measurement at Reporting Date			
	March 31, 2016	Quoted Prices in active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities:				
Corporate securities	$29,371	$ -	$ 29,371	$ -
Federal agency securities	18,046	-	18,046	-
Municipal securities	50,445	-	50,445	-
Total assets measured at fair value	**$97,862**	**$ -**	**$ 97,862**	**$ -**

	Fair Value Measurement at Reporting Date			
	December 31, 2015	Quoted Prices in active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities:				
Corporate securities	$27,118	$ -	$ 27,118	$ -
Federal agency securities	18,758	-	18,758	-
Municipal securities	53,851	-	53,851	-
Total assets measured at fair value	**$99,727**	**$ -**	**$ 99,727**	**$ -**

5. Inventories

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

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

	March 31, 2016	**December 31, 2015**
Finished goods	$30,089	$ 28,216
Work-in-process	6,262	7,018
Raw materials and supplies	7,029	6,481
Total inventories	43,380	41,715
Less: non-current finished goods	(11,139)	-
	$32,241	$ 41,715

As of March 31, 2016 and December 31, 2015, raw materials inventories consisted of raw materials used in the manufacture of the API in our U.S.-based, state-of-the-art dronabinol manufacturing facility and component parts and packaging materials used in the manufacture of Subsys. Work-in-process consists of actual production costs, including facility overhead and tolling costs of in-process dronabinol and Subsys products. Finished goods inventories consisted of finished Subsys products. Non-current finished goods represent those inventories not expected to be sold within 12 months of the balance sheet date and are included in other assets in our condensed consolidated unaudited balance sheets. As of March 31, 2016, all work-in-process inventory is expected to be used within 12 months of the balance sheet date and, therefore, is classified as current inventory.

6. Commitments and Contingencies

Legal Matters

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

As legal and governmental proceedings are inherently unpredictable and, in part, beyond our control, unless otherwise indicated, we cannot currently reasonably predict the outcome of these legal proceedings, nor can we estimate the amount of loss, or range of loss, if any, that may result from these proceedings. A future adverse outcome in any of these proceedings could have a material adverse effect on our business, financial condition, results of operations and cash flows, and could cause the market value of our common stock to decline.

Government Proceedings

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

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

HIPPA Investigation. On September 8, 2014, we received a subpoena issued pursuant to HIPPA from the U.S. Attorney's Office for the District of Massachusetts. The subpoena requests documents regarding Subsys, including our

sales and marketing practices related to this product. We are cooperating with this investigation and have produced documents in response to the subpoena and have provided other requested information.

On or about June 23, 2015, a nurse practitioner located in Connecticut, who served on our speaker bureau in connection with our speaker programs designed to educate and promote product awareness and safety for external health care providers, pled guilty to violating the federal Anti-Kickback Statute in connection with payments of approximately $83,000 from us. On or about February 18, 2016, one of our former sales employees located in Alabama pled guilty to a conspiracy to violate the federal Anti-Kickback Statute in regards to two Alabama health care professionals who prescribed our product Subsys. Those two Alabama health care professionals served on our speaker bureau in connection with our speaker programs designed to educate and promote product awareness and safety for external health care providers. We continue to assess these matters to ensure we have an effective compliance program.

State Related Investigations. We have received CIDs from each of the Office of the Attorney General of the State of Arizona, ODOJ, the Attorney General of the Commonwealth of Massachusetts and the Office of the Attorney General of Illinois and we have also received a subpoena from the Chief Consumer Protection and Antitrust Division of the State of New Hampshire. In addition, we understand that numerous physicians practicing in New Jersey have received subpoenas from the Department of Justice of the State of New Jersey in connection with these physicians' interactions with our company. These CIDs and subpoenas request documents regarding Subsys, including our sales and marketing practices related to Subsys in the applicable state, as well as our patient services hub. We are cooperating with each of these investigations and have produced documents in response to these CIDs and related requests for information from each office.

In connection with the investigation by the ODOJ we have entered into a settlement agreement with the ODOJ referred to as an AVC, and have made monetary payments totaling approximately $1,100,000. The AVC requires us to maintain certain controls and processes around our promotional and sales activity related to Subsys in Oregon. This AVC expressly provides that we do not admit any violation of law or regulation. This settlement was reached as result of our cooperation with the ODOJ's investigation and after producing documents in response to certain CIDs and related requests for information from the ODOJ. All monetary payments in connection with this settlement were made prior to December 31, 2015.

Investigations of Physicians. In addition to the above investigations that are specifically directed at our company, we have received governmental agency requests for information, including subpoenas, from the USAO of Eastern District of Michigan, Rhode Island, Florida (Jacksonville), Connecticut, Kansas, New Hampshire, Southern District of New York, and Southern District of Alabama regarding specific physicians that we have interacted with in those states.

Opioid Litigation. Many federal and governmental agencies are focused on the abuse of opioids in the United States and agencies such as the HHS have expressed their belief that the United States is in the midst of a prescription opioid abuse epidemic. Common prescription drugs that contain opioids are drugs such as oxycodone, hydrocodone and fentanyl. Our product, Subsys, is a fentanyl-based product in the TIRF class. Certain stakeholders in the healthcare community, regulatory bodies and governmental agencies may associate us with, or determine that we are a part of, this perceived opioid abuse epidemic. Like all TIRF products, our product is part of the mandatory TIRF REMS program which is designed "to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines" and "to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors with the use of TIRF medicines." Nevertheless, from time to time, we may be included in litigation or investigations that are directed at the abuse of opioids in the United States. For example, in May 2014, Santa Clara and Orange Counties in California filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. Despite the fact that we are not named specifically in the complaint and this lawsuit was recently stayed, we have received a preservation notice letter from the Office of the County Counsel for the County of Santa Clara. From time to time, we may be included in these types of litigations as a result of the fact that we market an opioid product.

With the exception of the ODOJ investigation which we have quantified above, we believe a loss from an unfavorable outcome of these governmental proceedings is reasonably possible and an estimate of the amount or range of loss from an unfavorable outcome is not determinable at these early stages. We believe we have meritorious legal positions and will continue to represent our interests vigorously in these matters. However, responding to government investigations has and could continue to burden us with substantial legal costs in connection with defending any claims raised. Any potential resulting fines, restitution, damages and penalties, settlement payments, pleas or exclusion from federal health care programs or other administrative actions, as well as any related actions brought by shareholders or other third parties, could have a material adverse effect on our financial position, results of operations or cash flows. Additionally, these matters could also have a negative impact on our reputation and divert the attention of our management from operating our business.

Federal Securities Litigation

On or about February 2, 2016, a complaint (captioned Richard Di Donato v. Insys Therapeutics, Inc., Case 2:16-cv-00302-NVW) was filed in the Arizona District Court, against us and certain of our current and former officers. This complaint was brought as a purported class action, on behalf of purchasers of our common stock between March 3, 2015 and January 25, 2016. In general, the plaintiffs allege that the defendants violated federal securities laws by making intentionally false and misleading statements regarding our business and operations,

therefore artificially inflating the price of our common stock. The plaintiffs seek unspecified monetary damages and other relief. We intend to vigorously defend this claim.

General Litigation and Disputes

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

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

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

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

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

The trial commenced on December 1, 2014 with the evidence phase of the trial completed on January 29, 2015.

On June 8, 2015, the court issued findings of fact and conclusions of law in its final trial ruling. Specifically, the court found (i) in favor of Insys Pharma, our majority stockholder, a private trust and four of the Insys Pharma directors who were on the board in July 2008 on plaintiffs' claim for breach of fiduciary duty arising out of transactions the board approved in July 2008, (ii) found in favor of plaintiffs and against Insys Pharma, Inc., our majority stockholder, a private trust and three of the Insys Pharma directors who were on the board in June 2009 on plaintiffs' claims under Delaware law and for breach of fiduciary duties arising out of the reverse stock split the board approved in June 2009 in the amount of $7,317,450, along with pre-judgment and post-judgment interest and court costs, (iii) found in favor of two of the Insys Pharma directors who were on the Insys Pharma board as of June 2009 and against plaintiffs on plaintiffs' breach of fiduciary duty claims, (iv) found in favor of Insys Pharma and against plaintiff (Kottayil) on his claim for rescission of the patent application assignments that he entered in favor of Insys Pharma before and after his employment terminated, (v) found in favor of Insys Therapuetics, Inc. and against plaintiff on plaintiffs' claims of successor liability and fraudulent transfer, and (vi) found in favor of Kottayil and against Insys Pharma on Insys Pharma's counterclaims of breach of fiduciary duty, fraud, and negligent misrepresentation.

On October 2, 2015, the court entered a final judgment, awarding plaintiffs the amount of $7,317,450, along with pre-judgment interest from June 2, 2009, and post-judgment interest, from October 2, 2015, at the rate of 4.25% per

annum, compounded quarterly and taxable costs in the amount of $93,163. On the same date, the court denied Kottayil's request to submit an application for attorneys' fees for his defense of the Insys Pharma counterclaims, finding that the request was premature.

On October 20, 2015, plaintiffs appealed the foregoing judgment and on November 4, 2015, Insys Pharma and the other defendants against whom judgment was entered filed a notice of cross-appeal. The appeal and cross-appeal remain pending before the Court of Appeals for the State of Arizona. Plaintiffs have filed their opening brief and we have filed our answering brief and opening brief on cross-appeal. The Plaintiffs' deadline to file their combined reply in support of their appeal and answering brief for the cross-appeal is June 20, 2016.

As a result of the final ruling, we have accrued $9,567,000 at March 31, 2016 including $2,249,000 of estimated pre-and post-judgement interest. The final outcome of the appeal which could cause the estimates to vary materially from the final award.

On or around November 1, 2015 we received a notice from Dr. Kottayil's attorneys demanding indemnification for legal and other defense costs alleged to have been incurred in connection with Dr. Kottayil's defense of the Insys Pharma counterclaims in the amount of $3,630,000. We are in the process of assessing the merit of such claims as well as evaluating the basis for the costs claimed. Because of the uncertainty surrounding the ultimate outcome we have not accrued for this claim at this time; however, we believe that that it is reasonably possible that there may be a material loss associated with this claim and we currently estimate the range of the reasonably possible loss to be between $0 and the $3,630,000 claimed.

Except as it pertains to the $9,567,000 accrued for the dispute with Dr. Kottayil and the potential for damages in the Federal Securities litigation that we believe should be sufficiently covered by our director and officers insurance policies (once we have met any applicable retainage requirement under the applicable policy), we believe that the probability of unfavorable outcome or loss related to all of the above litigation matters and an estimate of the amount or range of loss, if any, from an unfavorable outcome are not determinable at this time. We believe we have meritorious legal positions and will continue to represent our interests vigorously in these matters but the range possible outcomes on these matters is very broad and we are not able to provide a reasonable estimate of our potential liability, if any, nor are we able to predict the outcome of each litigation matter. Responding to each of these litigation matters, defending any claims raised, and any resulting fines, restitution, damages and penalties, or settlement payments as well as any related actions brought by shareholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

Patent-Related Matters. On August 26, 2015, we received purported service of notice of three IPR petitions filed by a hedge fund with the Patent Trial and Appeal Board (PTAB) of the U.S. Patent and Trademark Office, challenging three of the four Orange Book-listed patents covering Subsys (US Patent Nos. 8,486,972; 8,835,459 and 8,835,460). On March 10, 2016, the PTAB declined to institute an IPR of the aforementioned three patents covering Subsys. The challenging party subsequently requested refunds of certain fees it paid the USPTO for its three petitions and, accordingly, has decided not to file requests for rehearing of these decisions and the proceedings are complete.

Wayne Automatic Fire Sprinklers. On or about January 26, 2016, Wayne Automatic Fire Sprinklers, Inc., of Wayne (“Wayne”), which installs, repairs, and monitors fire sprinkler and fire alarm systems throughout Florida and provides health insurance benefits to its employees and covered dependents through its self-funded health benefit plan filed a complaint in the Circuit Court of the Ninth Judicial Circuit in and for Orange County, Florida. Wayne is seeking injunctive relief and damages in excess of $75,000, exclusive of interest, costs and attorneys’ fees, against Insys Therapeutics, Inc., Gessler Clinic, P.A., Edward Lubin, M.D., UMR, Inc. and OptumRx, Inc., as defendants, for claims based under the Florida Racketeer Influenced and Corrupt Organization Act pursuant to section 895.03(3), Florida Statutes, the Florida Civil Remedies for Criminal Practices Act pursuant to section 772.103(3), Florida Statutes, the Florida Deceptive and Unfair Trade Practices Act under sections 501.201-501.203, Florida Statutes, common law fraud, and civil conspiracy, as well as breach of contract against UMR and OptumRx. The complaint alleges certain claims related to Subsys were erroneously paid by Wayne’s health benefit plan between January 2014 and October 2014 in connection with benefits totaling approximately $198,000 as a result of misrepresentations and failure to properly convey the nature of the indications the prescriptions were written for by the prescribing physician. We plan to vigorously defend this lawsuit.

Material Agreements

In April 2015, we entered into an amendment to our manufacturing and supply agreement with DPT, which extends our existing manufacturing and supply agreement to produce Subsys until the end of 2020. In addition to extending the term, this amendment added certain minimum purchase commitments.

On October 30, 2015, we entered into an amended and restated supply, development & exclusive licensing agreement with Aptar which, among other things, extended our exclusive supply rights to the current sublingual device, currently utilized by Subsys, as well any new device(s) jointly developed by the two companies for a period of seven years. In addition to extending the term, this amendment added certain minimum purchase commitments and requires certain tiered royalties as a percentage of net revenue to be paid by us ranging from less than one percent to the low single digits, commencing in March 2016 through the term of this agreement, from our sales of Subsys and future products that use the Aptar spray device technology.

The following table sets forth our aggregate minimum purchase commitments with DPT and Aptar under these agreements (in thousands):

Years ending December 31,	
Remainder of 2016	1,825
2017	10,450
2018	14,650
2019	18,260
2020	20,840
Thereafter	4,330
Total	$70,355

7. Stock-based Compensation

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

	Three Months Ended March 31,	
	2016	**2015**
Research and development	$2,361	$341
General and administrative	3,265	3,379
Total cost of stock-based compensation	$5,626	$3,720

As of March 31, 2016, we expected to recognize $39,839,000 of stock-based compensation for outstanding options over a weighted-average period of 2.9 years.

The following table summarizes stock option activity as of December 31, 2015 and for the three months ended March 31, 2016:

	Weighted Average	**Weighted Average Remaining**	**Aggregate Intrinsic**

	Number of Shares	Exercise Price	Contractual Term (in years)	Value (in millions)
Vested and exercisable as of December 31, 2015	3,772,736	$ 6.91		
Outstanding as of December 31, 2015	7,138,089	$ 12.33		
Granted	364,000	$ 16.69		
Cancelled	(152,835)	$ 15.98		
Exercised	(265,325)	$ 4.94		
Outstanding as of March 31, 2016	7,083,929	$ 12.75	7.6	$ 45.4
Vested and exercisable as of March 31, 2016	3,837,871	$ 7.76	6.8	$ 36.6

Cash received from option exercises under all share-based payment arrangements for the three months ended March 31, 2016 and 2015 was $1,310,000 and $3,127,000, respectively. For the three months ended March 31, 2016 and 2015, we recorded net reductions of $108,000 and $4,069,000, respectively, of our federal and state income tax liability, with an offsetting credit to additional paid-in capital, resulting from the excess tax benefits of stock options.

8. Net Income per Share

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

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

	Three Months Ended	
	March 31,	
	2016	2015
Historical net income per share - Basic Numerator:		
Net income	$2,434	$8,023
Denominator:		
Weighted average number of common shares outstanding	71,592,089	70,916,828
Basic net income per common share	$0.03	$0.11
Historical net income per share - Diluted		
Numerator:		
Net income	$2,434	$8,023
Denominator:		
Weighted average number of common shares outstanding	71,592,089	70,916,828
Effect of dilutive stock options	2,870,789	4,001,490
Weighted average number of common shares outstanding	74,462,878	74,918,318
Diluted net income per common share	$0.03	$0.11

Anti-dilutive share equivalents included 3,419,359 and 1,584,504 outstanding stock options as of March 31, 2016 and 2015, respectively.

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

We are engaged in the business of developing and selling pharmaceutical products. In 2016, we have one product line, Subsys. Our chief operating decision-maker evaluates revenues based on product lines.

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

	Net Revenue by Product Line Three Months Ended March 31,	
	2016	**2015**
Subsys	$61,962	$70,540
Dronabinol SG Capsule	**-**	230
Total net revenue	$61,962	$70,770

	Percent of Revenue by Route to Market Three Months Ended March 31,	
	2016	**2015**
Pharmaceutical wholesalers	73 %	100 %
Specialty pharmaceutical retailers	27 %	0 %
	100 %	100 %

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

Product shipments to three pharmaceutical wholesalers accounted for 21%, 19% and 16% of total shipments and product shipments to one specialty pharmaceutical retailer accounted for 27% of total shipments for the three months ended March 31, 2016. Product shipments to four pharmaceutical wholesalers accounted for 28%, 23%, 19% and 18% of total shipments for the three months ended March 31, 2015. Two pharmaceutical wholesalers' accounts receivable balances accounted for 25% and 25% of gross accounts receivable and one specialty pharmaceutical retailers' accounts receivable balance accounted for 33% of gross accounts receivable balance as of March 31, 2016. Four pharmaceutical wholesalers' accounts receivable balances accounted for 20%, 19%, 17% and 14% of gross accounts receivable as of December 31, 2015.

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, 2015 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, (the "Exchange Act"), which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects, and the factors affecting our future performance; plans and objectives of management; that ESI formulary changes relative to Subsys will not have a material impact on our net revenue; our intent to file an IND application for the treatment of epilepsy with Cannabidiol in 2016; the sufficiency of our manufacturing capacity; the beneficial attributes of our dronabinol product candidates; that sales and marketing and research and development costs will be our largest categories of expenses; that sales and marketing expenses will fluctuate on changes in Subsys net revenue; that our Subsys revenue will increase during the remainder of 2016; that cash flows from operating activities will increase; our development of different dronabinol delivery systems; the source and sufficiency of our liquidity our capital resources to fund our operations; possible capital raising transactions we may pursue; that we will hire additional sales and marketing, research and development and administrative personnel and operating costs relating thereto will increase; that our investments in our sales and research and development infrastructure will result in increased sales; accounting estimates and the impact of new or recently issued accounting pronouncements; that cash flows from operations will increase as a result of increased sales of Subsys; trends in restrictions and impediments relating to reimbursement policies imposed by pharmacy benefit managers; the impact of pending litigation and our strategy relating thereto; our exposure to interest rate

changes and market risks relating to our investments. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "should," "could," "predicts," "potential," "continue," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements. All forward-looking statements in this Form 10-Q are made based on our current expectations, forecasts, estimates and assumptions, and involve risks, uncertainties and other factors that could cause results or events to differ materially from those expressed in the forward-looking statements. In evaluating these statements, you should specifically consider various factors, uncertainties and risks that could affect our future results or operations as described from time to time in our SEC reports, including those risks outlined under "Risk Factors" in Item 1A of our Form 10-K for the year ended December 31, 2015. These factors, uncertainties and risks may cause our actual results to differ materially from any forward-looking statement set forth in this Form 10-Q. You should carefully consider these risk and uncertainties described and other information contained in the reports we file with or furnish to the SEC before making any investment decision with respect to our securities. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by this cautionary statement. Some of the important factors that could cause our actual results to differ materially from those projected in any forward-looking statements including, but are not limited to, the following:

- *the impact of ongoing regulatory review of Subsys and other product candidates that receive regulatory approval;*
- *our dependence on sales of Subsys;*
- *market acceptance, including by third-party payors, of our products;*

the unpredictability and regulation surrounding the reimbursement of Subsys;
the success of our sales and marketing strategies;
our ability to manage growth in our business;
our ability to obtain regulatory approval for Syndros, our dronabinol oral solution;
manufacturing failures;
challenges relating to our operation of a second dronabinol manufacturing facility;
our limited manufacturing capabilities and our reliance on third parties in our product supply chain;
delays in manufacturing or interruption of our sublingual spray delivery system;
competition;
our ability to achieve and maintain adequate levels of third-party payor and reimbursement coverage for sales of our products;
our reliance on wholesale pharmaceutical distributors for sales of our products through to the retail distribution channel;
our reliance on third parties for the performance of services relating to Subsys, including invoicing, storage and transportation;
our ability to develop a pipeline of product candidates;
our failure to obtain or maintain Schedule III classification for our dronabinol 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 ability to meet Section 505(b)(2) regulatory approval pathways or requirements for our product candidates;
annual DEA quotas on the amount of dronabinol allowed to be produced in the United States;
our failure to successfully acquire, develop or market additional product candidates;
our ability to retain key management and other personnel;
misconduct and improper activities by our employees, prescribing physicians and other persons involved in the marketing and distribution of our products;
our ability to utilize our net operating loss and research and development tax credit carryforwards;
the adverse impacts of strategic transactions;
our exposure to product liability claims;
our ability to comply with environmental laws relating to our use of hazardous materials;
security system failures;
natural disasters;
our significant operating expenses and need for potential additional funding;
our failure to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws;
undesirable side effects of our products and the potential for post-approval regulatory action relating to such side effects;
the impact of changes in policies and funding resulting from healthcare reform measures, including the impact on the funding, staffing and leadership of the FDA and other agencies;
heightened attention on the use of opiods, including government litigation, changes in policies, and legislation at the federal and local level;
our ability to obtain and enforce patent rights or other intellectual property rights that cover our products and product candidates;
costs of litigation and our ability to protect our intellectual property rights;
our exposure to litigation relating to infringement suits against the Company;

our exposure to claims that our employees or independent contractors have wrongfully used or disclosed to the Company trade secrets of their other clients or former employers;
our compliance with the procedural, document submission, fee payment and other requirements needed to apply for patents;
control over the Company by its founder, Executive Chairman and principal stockholder;
fluctuation in the price of our common stock;

our ability to maintain and improve our financial controls and related compliance with SEC and stock exchange listing standards;
lack of, or inaccurate, published research about the Company;
the impact of future sales of our common stock or securities convertible into our common stock;
the effect of anti-takeover provisions in our charter documents and under Delaware law;
the impact of our exemptions from certain Nasdaq independence rules because of our status as a "controlled 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 file with the Securities and Exchange Commission. Any forward-looking statements in this report should be considered in light of various important factors, including the risks and uncertainties listed above, as well as others.

Overview

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

- 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 BTCP in opioid-tolerant patients. We received FDA approval for Subsys in January 2012 and commercially launched Subsys in March 2012.

- Dronabinol SG Capsule — a dronabinol soft gelatin capsule that is a generic equivalent to Marinol, an approved second-line treatment for 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 former exclusive distribution partner, Mylan Pharmaceuticals, Inc., in December 2011. We do not have any current plans to manufacture or market this product in the future.

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.

Consistent with most pharmaceutical manufacturing companies, we sell Subsys primarily to pharmaceutical wholesalers and collect sales proceeds from those wholesalers. We do not own or have any ownership stake in any

pharmaceutical wholesaler, nor do we have an option to acquire any wholesaler. For the three months ended March 31, 2016, sales to our three largest wholesale customers accounted for 56% of gross revenue. We also sell Subsys directly to specialty pharmaceutical retailers. For the three months ended March 31, 2016 direct sales to specialty pharmaceutical retailers accounted for 27% of gross revenue. We distribute Subsys through both specialty and traditional retail pharmacies. All pharmacies that fulfill Subsys prescriptions are fully independent. We do not own or have an ownership stake in any pharmacy and do not possess an option to acquire any pharmacy. Our relationships with every pharmacy that fulfills Subsys prescriptions are non-exclusive, in that each of these pharmacies may also fulfill prescriptions for other pharmaceutical manufacturers. For the three months ended March 31, 2016, more than 700 independent pharmacies have fulfilled at least one Subsys prescription.

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

We are also developing other product candidates, such as dronabinol line extensions and sublingual spray product candidates. Our most advanced potential cannabinoid line extension is Syndros. 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. In August 2015, FDA accepted for filing the NDA for Syndros. The PDUFA goal date for a decision on this NDA is July 1, 2016, which reflects a Standard Review by the FDA.

We produce the API for Syndros 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 initial launch quantities of Syndros, if approved, and support the continued development of our other dronabinol product candidates in the near-term, we have opened a second dronabinol manufacturing facility, which we anticipate will enable us to supply sufficient commercial quantities of dronabinol API for the anticipated commercialization of our proprietary dronabinol product candidates, if approved.

We have the capability to manufacture pharmaceutical CBD, an over 99.5% pure form of cannabidiol, in our Round Rock, Texas manufacturing facility. On April 23, 2015 we announced that we had commenced dosing of epilepsy patients in a Phase I PK study in pediatric subjects. We intend to file an IND application with the FDA for the treatment of epilepsy.

Factors Affecting Our Performance

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

Approved Product Sales. Our operating results will depend significantly upon our, and any of our third-party distributors', sales of approved products. During the three months ended March 31, 2016, all of our net revenues were generated from the sale of our approved product, Subsys. We will not generate any meaningful revenue from the sale of our discontinued Dronabinol SG Capsule in future periods. 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 Subsys. Moreover, our gross margins improve on a unit-by-unit basis as we sell higher dosage strengths of our products. Importantly, the proportion of prescriptions written for repeat Subsys patients has continued to increase since July 2012 from 50% of prescriptions to approximately 93% of prescriptions as of March 31, 2016. 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.

Third Party Payer Interactions and Government Programs Associated with Reimbursement. Our interaction with third-party payers is critical to the success of our business and financial condition. Our relationships with these third-party payers evolves on a regular basis and is often difficult to predict. By way of example, from time to time, third-party payers modify which drugs they choose to reimburse. For instance, on or around August 1, 2014, ESI

officially released its exclusion list of drugs, effective January 1, 2015, in connection with its national preferred formulary. Our product, Subsys, was included on this exclusion list. ESI is a large PBM that administers prescription drug benefits for employers and health plans and runs large mail-order pharmacies. While ESI, like most PBMs, has an exception process that physicians may pursue to have an off-formulary, medically necessary drug covered for patients, this decision will make it difficult for many patients covered through an ESI administered plan to have Subsys covered by insurance. The ESI formulary change did not have a material impact on our net revenue during the three months ended March 31, 2016 however, other PBMs may take similar actions and this action by ESI may have a material impact on our net revenue in the future. As we have in the past, we will continue working with other PBMs to evaluate price increases and to communicate with managed care and health-system decision-makers to ensure a balanced approach, which takes into account the clinical performance and efficacy of our products.

In addition, from time to time, our business may be affected by evolving or new governmental programs in the reimbursement landscape. For instance, CMS, which is part of the HSS, has instituted The Recovery Audit Program the mission of which is to identify and correct improper Medicare payments through the efficient detection and collection of overpayments made on claims of health care services provided to Medicare beneficiaries, and the identification of underpayments to providers so that the CMS can implement actions that will prevent future improper payments in all 50 states. We are aware that in January 2016, certain specialty pharmacies received written correspondence from Humana indicating that as a result of a CMS audit, Humana was initiating a deletion of certain PDEs related to Subsys which will result in a reversal and recovery of identified claims paid to certain pharmacies. This audit by CMS may have been part of The Recovery Audit Program or a similar initiative of CMS. Based upon information available to us, all of these claims involve Medicare Part D patients whose prescriptions were in connection with off-label indications and related to approximately $5.6 million in Subsys claims in the aggregate. Upon our inquiry for more information about these matters, Humana notified us that these deletions of certain PDEs resulting from the CMS audit also involve TIRF medications other than Subsys and Humana intends to resolve these matters with the pharmacies. We believe that some affected pharmacies may alter their processes and or protocols related to dispensing off label TIRF prescriptions to Medicare patients as a result of these and similar events.

Investments in Our Infrastructure and Growth. Our ability to increase our sales and to further penetrate our target market segments is dependent in part on our ability to invest in our infrastructure and in our sales and marketing efforts. In order to drive further growth, we may hire additional sales and marketing personnel and invest in marketing our products to our target physician prescriber base. For example, as of March 31, 2016, we had 343 full-time sales and marketing personnel. This will lead to corresponding increases in our operating expenses, although we anticipate that these investments will result in increased product sales and net revenue. In addition, we have constructed a second dronabinol manufacturing facility, which we anticipate will supply us with sufficient commercial quantities of dronabinol API for the commercialization of our proprietary dronabinol product candidates, if approved. This second facility will also increase our operating expenses.

Product Development and Related Regulatory Processes. Our operating results will also depend significantly on our research and development activities and related regulatory developments. Our research and development expenses were $20.5 million and $10.6 million for the three months ended March 31, 2016 and 2015, respectively. As of March 31, 2016, we had 80 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary cannabinoid product candidates, including Syndros, and sublingual spray product candidates. 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 DEA classifications for our product candidates, in particular those related to Syndros, could cause our research and development expenditures to increase significantly and, in turn, have a material adverse effect on our results of operations.

Basis of Presentation

Net Revenue

During the year ended December 31, 2012, we began recognizing net revenue from sales of Subsys made by us. 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 record revenue for Subsys at the time the wholesaler receives the shipment.

Cost of Revenue, Gross Profit and Gross Margin

Cost of revenue consists primarily of materials, third-party manufacturing costs, freight in, indirect personnel costs, and other overhead costs based on units dispensed through patient prescriptions. Also included in cost of revenue are charges for reserves for excess, dated or obsolete commercial inventories and production manufacturing variances.

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

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries, commissions, benefits, consulting fees, costs of obtaining prescription and market data, and market research studies related to Subsys. As of March 31, 2016, we had 343 full-time sales and marketing personnel. We expect the number of our sales and marketing personnel to increase as we seek to continue to increase our existing product sales and as any subsequently approved products are commercialized. We expect our sales and marketing expenses, along with our research and development expenses, to be our largest categories of operating expenses for the foreseeable future. In addition, because we use an incentive-based compensation model for our sales professionals, we expect our sales and marketing expenses to fluctuate from period to period based on changes in Subsys net revenue. Specifically, we expect our sales and marketing expenses to increase in the near future to the extent that expected increases in Subsys net revenue are realized.

Research and Development Expenses

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

- external research and development expenses incurred under agreements with third-party 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, dronabinol and cannabidiol programs. As of March 31, 2016, we had 80 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.

The following table provides a breakdown of our research and development expenses during the three months ended March 31, 2016 and 2015 (in millions):

	Three Months Ended March 31,	
	2016	**2015**
Cannabidiol	$3.7	$4.1
Buprenorphine/Naloxone	0.5	1.1
LEP-ETU and IL-13	1.1	0.7
Buprenorphine	2.7	0.5
Ondansetron	0.2	0.2
Dronabinol	0.5	0.1
Fentanyl	2.0	0.1
Sildenafil	0.2	-
Naloxone	0.5	-
Other	0.5	0.5
Internal research and development costs	8.6	3.3
Total research and development expenses	$20.5	$10.6

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, legal, business development and internal support functions. In addition, general and administrative expenses include facility costs not otherwise included in research and development expenses, and professional fees for legal, consulting and accounting services. As of March 31, 2016, we had 47 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.

Charges Related to Litigation Award

Charges related to litigation award expenses for the three months ended March 31, 2015 represent a legal accrual of $8.0 million related to our dispute with Dr. Kottayil. There was no similar expense for the three months ended March 31, 2016. See Note 6 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion of our ongoing dispute with Dr. Kottayil.

Income Tax Expense

We account for income taxes based upon an asset and liability approach. Deferred tax assets and liabilities represent the future tax consequences of the differences between the financial statement carrying amounts of assets and liabilities versus the tax basis of assets and liabilities. Under this method, deferred tax assets are recognized for deductible temporary differences, and operating loss and tax credit carryforwards. Deferred tax liabilities are recognized for taxable temporary differences. Deferred tax assets are reduced by a valuation allowance when, in our opinion, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The impact of tax rate changes on deferred tax assets and liabilities is recognized in the year that the change is enacted. We also account for the uncertainty in income taxes by utilizing a comprehensive model for the recognition, measurement, presentation, and disclosure in financial statements of any uncertain tax positions that have been taken or are expected to be taken on an income tax return.

Significant Accounting Polices and Estimates

There were no changes in our significant accounting policies and estimates during the three months ended March 31, 2016 from those set forth in “Management’s Discussion and Analysis of Financial Condition and Results of Operations - Significant Accounting Policies and Estimates” in our Annual Report on Form 10-K for the year ended December 31, 2015.

Results of Operations

Comparison of Three Months Ended March 31, 2016 to Three Months Ended March 31, 2015

The following table presents certain selected consolidated financial data for the three months ended March 31, 2016 and 2015 expressed as a percentage of net revenue:

	Three Months Ended March 31,	
	2016	**2015**
Net revenue	100.0%	100.0%
Cost of revenue	7.5	9.0
Gross profit	92.5	91.0
Operating expenses:		
Sales and marketing	32.0	29.6
Research and development	33.1	15.0
General and administrative	23.7	18.7
Charges related to litigation award	-	11.3
Total operating expenses	88.8	74.6
Operating income	3.7	16.4
Other income (expense):		
Interest income	0.4	0.2
Other income (expense), net	0.1	-
Total other income (expense)	0.5	0.2
Income before income taxes	4.1	16.6
Income tax expense	0.2	5.3
Net income	3.9 %	11.3 %

Net Revenue. Net revenue decreased $8.8 million, or 12%, to $62.0 million for the three months ended March 31, 2016, compared to $70.8 million for the three months ended March 31, 2015. The decrease in net revenue was attributable to a decrease in net revenue of Subsys. The decrease in Subsys net revenue was primarily a result of a 32% decrease in shipments to pharmaceutical wholesalers for the three months ended March 31, 2016 as compared to the three months ended March 31, 2015, partially offset by a 20% increase in net sales price, which was impacted by price increases in January 2015, July 2015, and January 2016, combined with changes in mix of prescribed dosages and changes in provisions for wholesaler discounts, patient discounts, rebates and returns. Provisions for wholesaler discounts, patient discounts, rebates, and returns decreased to $6.4 million, $16.1 million, $7.2 million and ($0.5) million, respectively, or 32.0% on a combined basis of gross revenue from the sale of Subsys for the three months

ended March 31, 2016, compared to $8.0 million, $17.0 million, $8.4 million and $0.6 million, respectively, or 32.4% on a combined basis of gross revenue from the sale of Subsys for the three months ended March 31, 2015. The decrease in product sales allowances was primarily attributable to decreased sales, lower volumes of patient assistance, and lower rebate rates due to recent price increases. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2016 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

There was no net revenue from the sales of Dronabinol SG Capsule during the three month period ended March 31, 2016, compared to $0.2 million during the three month period ended March 31, 2015. We will not generate any meaningful revenue from the sale of Dronabinol SG Capsule in future periods.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue decreased $1.8 million to $4.6 million for the three months ended March 31, 2016 compared to $6.4 million for the three months ended March 31, 2015. The decrease in cost of revenue was primarily attributable to the decrease in sales of Subsys during the three months ended March 31, 2016. Gross profit decreased $7.1 million to $57.3 million for the three months ended March 31, 2016 compared to $64.4 million for the three months ended March 31, 2015 due primarily to the decrease in sales of Subsys. Gross margin for the three months ended March 31, 2016 was approximately 93% compared to approximately 91% for the three months ended March 31, 2015.

Sales and Marketing Expense. Sales and marketing expense decreased $1.1 million to $19.8 million for the three months ended March 31, 2016 compared to $20.9 million for the three months ended March 31, 2015. The decrease in sales and marketing expense was due primarily to the decrease in sales of Subsys.

Research and Development Expense. Research and development expense increased $9.9 million to $20.5 million for the three months ended March 31, 2016, compared to $10.6 million for the three months ended March 31, 2015. The increase in research and development expense was due primarily to an increase in research and development personnel and to clinical and development expenses incurred during 2016 related to growing our product pipeline.

General and Administrative Expense. General and administrative expense increased $1.5 million to $14.7 million for the three months ended March 31, 2016 compared to $13.2 million for the three months ended March 31, 2015. The increase in general and administrative expense was due primarily to an increase in general and administrative personnel and to legal expense incurred in connection with various ongoing government investigation and subpoena related matters.

Charges Related to Litigation Award. Charges related to litigation award for the three months ended March 31, 2015 represents an $8.0 million legal expense accrual associated with our dispute with Dr. Kottayil. There was no similar expense for the three months ended March 31, 2016. See Note 6 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion on our ongoing dispute with Dr. Kottayil.

Income Tax Expense. Provision for income taxes was $0.1 million for the three months ended March 31, 2016, representing an effective tax rate of 5.1%, as compared to $3.7 million for the three months ended March 31, 2015, representing and effective tax rate of 31.8%. The decrease in the effective rate for the period ended March 31, 2016 compared with the same period in the previous year is due principally to increased benefit of tax credits. As of March 31, 2016, we had approximately $1.1 million of federal and $268 million of state net operating loss carry forwards.

We had unrecognized tax benefits of approximately $10.5 million as of March 31, 2016, primarily associated with tax positions taken in prior year. No significant penalties and $0.3 million of interest are included in income taxes and accounted for on the balance sheet related to unrecognized tax positions.

Liquidity and Capital Resources

Sources of Liquidity

Current operations are financed principally with existing cash on hand and cash flows from operations.

Cash Flows

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

	Three Months Ended March 31,	
	2016	**2015**
Net cash provided by operating activities	$12.3	$16.2
Net cash used in investing activities	(6.1)	(11.4)
Net cash (used in) provided by financing activities	(11.9)	7.2
Net increase (decrease) in cash and cash equivalents	(5.7)	12.0
Cash and cash equivalents, beginning of period	79.5	58.1
Cash and cash equivalents, end of period	$73.8	$70.1

Cash Flows From Operating Activities. Net cash provided by operating activities was $12.3 million and $16.2 million for the three months ended March 31, 2016 and 2015, respectively. The net cash provided during the three months ended March 31, 2016 primarily reflects the net income for the period driven by Subsys net sales, adjusted in part by depreciation and amortization, stock-based compensation expense and is also impacted by changes in working capital.

Cash Flows From Investing Activities. Net cash used in investing activities was $6.1 million and $11.4 million for the three months ended March 31, 2016 and 2015, respectively, and consists primarily of the purchase of investments and property and equipment.

Cash Flows From Financing Activities. Net cash used in financing activities was $11.9 million for the three months ended March 31, 2016, as compared to net cash provided by financing activities of $7.2 million for the three months ended March 31, 2015. During the three months ended March 31, 2016, we expended approximately $13.4 million to repurchase shares of our common stock, partially offset by excess tax benefits on stock options and awards of $0.1 million and proceeds from the exercise of stock options of $1.3 million. During the three months ended March 31, 2015, we recorded excess tax benefits on stock options and awards of $4.1 million, and received proceeds from the exercise of stock options of $3.1 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.

Our cash flows for 2016 and beyond will depend on a variety of factors, including sales of Subsys and any additional approved products, regulatory approvals, investments in manufacturing and production such as our second dronabinol manufacturing facility, capital equipment, and research and development. We expect our net cash flows from operating activities to increase as we expect to increase sales of Subsys, 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 our cash from operations and our pre-existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months.

Because of the numerous risks and uncertainties associated with commercialization of Subsys and the development of our other 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 Syndros and any other product candidates that we may develop, in-license or acquire;
- regulatory approvals, DEA classifications and other regulatory related events;
- personnel, facilities, equipment and other similar requirements;
- costs of operating as a public company;
- the effects of competing technological and market developments;
- costs associated with litigation and government investigations;

costs and judgements 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 three months ended March 31, 2016 and we expect to continue to fund our operations primarily from operating activities, we cannot guarantee that we will generate sufficient operating cash flows to fund our planned activities. We cannot be sure that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. If we raise additional funds by issuing equity or convertible securities, substantial dilution to existing stockholders will likely result. If we raise additional funds by incurring new debt obligations, the terms of the debt will likely require significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2016, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

At March 31, 2016, $19.0 million of our cash equivalent investments was in money market securities that are reflected as cash equivalents because all maturities are within 90 days. Included in money market securities are commercial paper, Federal agency discount notes and money market funds. We believe our interest rate risk with respect to these investments is limited due to the short-term duration of these arrangements and the yields earned, which approximate current interest rates.

Our policy for our short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Our investment portfolio, consisting of fixed income securities that we hold on an available-for-sale basis, was approximately $127.4 million as of March 31, 2016, and $126.0 million as of December 31, 2015. These securities, like all fixed income instruments, are subject to interest rate risk and would likely decline in value if market interest rates increase. We have the ability to hold our fixed income investments until maturity and, therefore, we would not expect to recognize any material adverse impact in income or cash flows if market interest rates increase.

The following table provides information about our available-for-sale securities that are sensitive to changes in interest rates. We have aggregated our available-for-sale securities for presentation purposes since they are all very similar in nature (dollar amounts in millions):

Interest Rate Sensitivity

Principal Amount by Expected Maturity as of March 31, 2016

	Financial instruments mature during year ended December 31,					
	Remainder of 2016	**2017**	**2018**	**2019**	**2020**	**Thereafter**
CD's and Available-for-sale securities	$73.1	$37.9	$13.9	$2.4	$ -	$ -
Weighted-average yield rate	0.30%	0.23%	0.11%	0.03%	-	-

We have not entered into derivative financial instruments. We do not have operations outside of the U.S. and, accordingly, we have not been susceptible to significant risk from changes in foreign currencies.

During the normal course of business we could be subjected to a variety of market risks, examples of which include, but are not limited to, interest rate movements and foreign currency fluctuations, as we discussed above, and collectability of accounts receivable. We continuously assess these risks and have established policies and procedures to protect against the adverse effects of these and other potential exposures. Although we do not anticipate any material losses in these risk areas, no assurance can be made that material losses will not be incurred in these areas in the future.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, and in light of the unremediated material weakness in the design and operation of our internal control over financial reporting relating specifically to the lack of effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock options awards in accordance with GAAP, as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2015, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were not effective. To address this material weakness, we have taken steps to address the underlying causes of the material weakness as described further below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting.” Accordingly, we believe that the condensed consolidated financial statements included in this Quarterly Report on Form 10-Q do fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented.

Change in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, other than that disclosed below under “Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting,” that occurred during the quarterly period ended March 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

Remediation Efforts to Address Material Weakness in Internal Control over Financial Reporting

We are currently in the process of remediating the material weakness in our internal control over financial reporting as described above and are taking numerous steps that we believe will address the underlying causes of the material weakness. We are in the process of completing the formal documentation of our policies and procedures relating to our internal control over financial reporting and will begin testing of these formalized controls in the near future. The identified material weakness in internal control will not be considered fully remediated until sufficient time has elapsed to provide evidence that the new controls have been implemented and are operating effectively. We continue to work on implementing and testing these controls in order to make this final determination. Other than the remediation steps described above, there was no change in our internal control over financial reporting that occurred during the period covered by this Quarterly Report on Form 10-Q 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

The information contained in Note 6 to the Unaudited Condensed Consolidated Financial Statements is incorporated herein by reference.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2015, as well as other factors discussed herein under “Forward-Looking Statements” in Item 2 Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our business, financial condition and results of operations could be adversely affected by any of the risks and uncertainties described therein. There have been no material changes from the risk factors disclosed in Part I, Item 1A, in our Annual Report on Form 10-K.

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

Share Repurchase Program

On November 5, 2015, we announced a stock repurchase program which authorizes up to $50 million in repurchases of common stock. This program was effective immediately and has no planned expiration date. The following table provides information regarding repurchases of our common stock during the three months ended March 31, 2016:

	Total Number of Shares Purchased	Average Price Paid per Share ($)	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value of Shares that May Yet Be Purchased Under the Program ($)
January 1 - 31, 2016	411,500	$ 23.04	411,500	$ 24,062,406
February 1 - 29, 2016	94,200	15.91	94,200	22,563,715
March 1 - 31, 2016	135,225	17.55	135,225	20,189,884
Total	640,925	$ 20.83	640,925	$ 20,189,884

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable.

ITEM 4. MINE SAFETY DISCLOSURE

Not applicable.

ITEM 5. OTHER INFORMATION

Not applicable.

ITEM 6. EXHIBITS

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

INSYS THERAPEUTICS, INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INSYS THERAPEUTICS, INC.

Dated: May 4, 2016	By:	/s/ Dr. John N. Kapoor Dr. John N. Kapoor 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	Amended and Restated Certificate of Incorporation of Insys Therapeutics, Inc. (1)
3.2	Amended and Restated Bylaws of Insys Therapeutics, Inc. (2)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock (3)
4.1	Form of Common Stock Certificate of Registrant (4)
4.2	Rights Agreement, dated August 15, 2014 between Insys Therapeutics, Inc. and Computershare Trust Company, N.A. (5)
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith)
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934 (filed herewith)
32	Certifications of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.

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

(2)

Previously filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on November 10, 2014, and incorporated herein by reference.

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

(4) Previously filed as 4.1 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2014 and incorporated herein by reference.

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