

Insys Therapeutics, Inc.  
Form 10-Q  
August 06, 2015

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**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 10-Q**

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

For the quarterly period ended June 30, 2015

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)**

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

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

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

Yes      No

Indicate by a checkmark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

Yes      No

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

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

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

Yes      No

As of August 3, the registrant had 71,849,606 shares of Common Stock (\$0.01 par value) outstanding.

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**INSYS THERAPEUTICS, INC.**

**FORM 10-Q**

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**Form 10-Q****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.

| <b>Abbreviated Term</b> | <b>Defined Term</b>  |
|-------------------------|--|
| ANDA                    | Abbreviated New Drug Application   |
| API                     | Active pharmaceutical ingredient   |
| Aptar                   | AptarGroup, Inc.   |
| ASC                     | Accounting Standards Codification  |
| ATRA                    | American Taxpayer Relief Act of 2012                                       |
| 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  |
| ESI                     | Express Scripts, Inc.  |
| FASB                    | Financial Accounting Standards Board                                       |
| FDA                     | U.S. Food and Drug Administration  |
| FDCA                    | Federal Food, Drug, and Cosmetic Act                                       |
| FSS                     | Federal Supply Schedule  |
| GCP                     | Good Clinical Practices  |
| GI                      | Gastrointestinal   |
| GLP                     | Good Laboratory Practices  |
| HIPAA                   | Health Insurance Portability and Accountability Act of 1996                |
| HITECH                  | Health Information Technology for Economic and Clinical Health Act of 2009 |
| IND                     | Investigational New Drug Application                                       |
| Insys Pharma            | Insys Pharma, Inc.   |

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|             |   |
|-------------|---|
| IPO         | Initial public offering   |
| IRB         | Institutional Review Board  |
| JOBS Act    | Jumpstart Our Business Startups Act of 2012   |
| MMA         | Medicare Prescription Drug, Improvement, and Modernization Act of 2003  |
| 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   |
| PK          | Pharmacokinetics  |
| PPACA       | Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education<br>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   |
| VC          | Vomiting center   |

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**Part I: FINANCIAL INFORMATION****Item 1. UNAUDITED Financial Statements****INSYS THERAPEUTICS, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS***(In thousands, except share and per share data)*

|  | <b>June 30,<br/>2015</b> | <b>December<br/>31,<br/>(unaudited) 2014</b> |
|--|--------------------------|--|
| <b>Assets</b>  |                          |  |
| Current Assets:  |                          |  |
| Cash and cash equivalents  | \$ 74,035                | \$ 58,106                                    |
| Short-term investments   | 41,248                   | 24,757                                       |
| Accounts receivable, net of allowances of \$8,335 and \$5,816 at June 30, 2015 and December 31, 2014, respectively | 39,150                   | 26,544                                       |
| Inventories  | 35,553                   | 34,781                                       |
| Prepaid expenses and other assets  | 2,493                    | 2,243  |
| Deferred income tax assets   | 5,758                    | 4,611  |
| Total current assets   | 198,237                  | 151,042                                      |
| Property and equipment, net  | 35,479                   | 29,872                                       |
| Long-term investments  | 29,841                   | 23,262                                       |
| Deferred income tax assets   | 7,967                    | 7,602  |
| Other assets   | 3,518                    | 3,343  |
| Total assets   | \$ 275,042               | \$ 215,121                                   |
| <b>Liabilities and Stockholders' Equity (Deficit)</b>  |                          |  |
| Current Liabilities:   |                          |  |
| Accounts payable and accrued expenses  | \$ 30,626                | \$ 27,454                                    |
| Accrued compensation   | 8,719                    | 6,926  |
| Accrued sales allowances   | 17,599                   | 11,296                                       |
| Accrued litigation award   | 10,356                   | 0  |
| Total current liabilities  | 67,300                   | 45,676                                       |
| Uncertain income tax position  | 3,778                    | 3,778  |
| Total liabilities  | 71,078                   | 49,454                                       |
| 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 June 30, 2015 and December 31, 2014, respectively)                       | -          | -          |
| Common stock (par value \$0.01 per share; 100,000,000 shares authorized; 71,821,175 and 70,702,688 shares issued and outstanding as of June 30, 2015 and December 31, 2014, respectively) | 718        | 707        |
| Additional paid in capital  | 239,003    | 216,061    |
| Unrealized loss on available-for-sale securities  | (17 )      | (24 )      |
| Notes receivable from stockholders  | (21 )      | (21 )      |
| Accumulated deficit   | (35,719 )  | (51,056 )  |
| Total stockholders' equity  | 203,964    | 165,667    |
| Total liabilities and stockholders' equity  | \$ 275,042 | \$ 215,121 |

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)**

|   | <b>Three Months Ended<br/>June 30,</b> |             | <b>Six Months Ended June<br/>30,</b> |             |
|---|--|-------------|--------------------------------------|-------------|
|   | <b>2015</b>                            | <b>2014</b> | <b>2015</b>                          | <b>2014</b> |
| Net revenue   | \$77,633                               | \$55,696    | \$148,403                            | \$97,332    |
| Cost of revenue   | 8,305                                  | 6,555       | 14,680                               | 11,328      |
| Gross profit  | 69,328                                 | 49,141      | 133,723                              | 86,004      |
| Operating expenses:                                     |  |             |                                      |             |
| Sales and marketing                                     | 21,986                                 | 14,077      | 42,902                               | 25,695      |
| Research and development                                | 17,796                                 | 9,189       | 28,398                               | 13,197      |
| General and administrative                              | 15,284                                 | 10,689      | 28,530                               | 19,257      |
| Charges related to litigation award                     | 2,304                                  | -           | 10,304                               | -           |
| Total operating expenses                                | 57,370                                 | 33,955      | 110,134                              | 58,149      |
| Operating income  | 11,958                                 | 15,186      | 23,589                               | 27,855      |
| Other income (expense):                                 |  |             |                                      |             |
| Interest income   | 105                                    | 26          | 230                                  | 43          |
| Other income (expense), net                             | 30                                     | -           | 30                                   | 2           |
| Total other income (expense)                            | 135                                    | 26          | 260                                  | 45          |
| Income before income taxes                              | 12,093                                 | 15,212      | 23,849                               | 27,900      |
| Income tax expense                                      | 4,779                                  | 5,747       | 8,512                                | 10,777      |
| Net income  | 7,314                                  | \$9,465     | 15,337                               | \$17,123    |
| Unrealized gain (loss) on available-for-sale securities | (21)                                   | ) 13        | 7                                    | (5)         |
| Total comprehensive income                              | \$7,293                                | \$9,478     | \$15,344                             | \$17,118    |
| Net income per common share:                            |  |             |                                      |             |
| Basic   | \$0.10                                 | \$0.14      | \$0.22                               | \$0.25      |
| Diluted   | \$0.10                                 | \$0.13      | \$0.20                               | \$0.23      |
| Weighted average common shares outstanding              |  |             |                                      |             |
| Basic   | 71,517,442                             | 68,596,652  | 71,217,137                           | 67,864,742  |
| Diluted   | 75,478,649                             | 72,673,154  | 75,255,048                           | 73,095,644  |

See accompanying notes to unaudited condensed consolidated financial statements.



**INSYS THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENT OF STOCKHOLDERS' EQUITY***(In thousands, except share data)***(unaudited)**

|   | <b>Common Stock</b> |               | <b>Additional<br/>Paid in</b> | <b>Unrealized<br/>Loss on<br/>Available-For-Sale<br/>Securities</b> | <b>Notes<br/>Receivable</b> | <b>Accumulated<br/>Deficit</b> | <b>Total</b> |
|---|---------------------|---------------|-------------------------------|---|-----------------------------|--------------------------------|--------------|
|   | <b>Shares</b>       | <b>Amount</b> | <b>Capital</b>                |   | <b>Stockholder's</b>        |                                |              |
| <b>Balance at December 31, 2014</b>                       | 70,702,688          | 707           | 216,061                       | (24 )   | (21 )                       | (51,056 )                      | 165,667      |
| Exercise of stock options                                 | 1,029,598           | 10            | 6,101                         | -   | -                           | -                              | 6,111        |
| Issuance of common stock-<br>employee stock purchase plan | 88,889              | 1             | 1,478                         | -   | -                           | -                              | 1,479        |
| Excess tax benefits on stock<br>options and awards        | -                   | -             | 7,416                         | -   | -                           | -                              | 7,416        |
| Stock based compensation -<br>stock options and awards    | -                   | -             | 7,947                         | -   | -                           | -                              | 7,947        |
| Unrealized gain on<br>available-for-sale securities       | -                   | -             | -                             | 7   | -                           | -                              | 7            |
| Net income  | -                   | -             | -                             | -   | -                           | 15,337                         | 15,337       |
| <b>Balance at June 30, 2015</b>                           | 71,821,175          | \$ 718        | \$ 239,003                    | \$ (17 )  | \$ (21 )                    | \$ (35,719 )                   | 203,964      |

See accompanying notes to unaudited condensed consolidated financial statements.

**INSYS THERAPEUTICS, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS***(In thousands)***(unaudited)**

|   | <b>Six Months Ended June 30,<br/>2015</b> | <b>2014</b> |
|---|---|-------------|
| Cash flows from operating activities:   |   |             |
| Net income  | \$ 15,337                                 | \$ 17,123   |
| Adjustments to reconcile net income to net cash provided by operating activities: |   |             |
| Depreciation and amortization   | 2,457                                     | 1,107       |
| Stock-based compensation  | 7,947                                     | 8,187       |
| Deferred income tax benefit   | (1,513 )                                  | (1,622 )    |
| Loss on disposal of assets  | 41  | -           |
| Excess tax benefits on stock options and awards                                   | (7,416 )                                  | (12,399 )   |
| Changes in operating assets and liabilities:                                      |   |             |
| Accounts receivable   | (12,606 )                                 | 626         |
| Inventories   | (772 )                                    | (10,178 )   |
| Prepaid expenses and other current assets   | (424 )                                    | (1,311 )    |
| Accounts payable, accrued expenses and other current liabilities                  | 29,042                                    | 19,652      |
| Net cash provided by operating activities   | 32,093                                    | 21,185      |
| Cash flows from investing activities:   |   |             |
| Change in restricted cash   | -   | 400         |

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|   |           |           |
|---|-----------|-----------|
| Purchase of investments                         | (23,063 ) | (29,164 ) |
| Purchases of property and equipment             | (8,106 )  | (8,414 )  |
| Net cash used in investing activities           | (31,169 ) | (37,178 ) |
| Cash flows from financing activities:           |           |           |
| Proceeds from issuance of common stock          | 1,478     | 1,108     |
| Excess tax benefits on stock options and awards | 7,416     | 12,399    |
| Proceeds from exercise of stock options         | 6,111     | 3,243     |
| Net cash provided by financing activities       | 15,005    | 16,750    |
| Change in cash and cash equivalents             | 15,929    | 757       |
| Cash and cash equivalents, beginning of period  | 58,106    | 45,382    |
| Cash and cash equivalents, end of period        | \$ 74,035 | \$ 46,139 |
| Supplemental cash flow disclosures:             |           |           |
| Cash paid for interest expense                  | \$ -      | \$ -      |
| Cash paid for income taxes                      | \$ 3,350  | \$ 2,199  |

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

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the 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, 2014 included in our Annual Report on Form 10-K. The results of operations for the three and six months ended June 30, 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 differ from these estimates.

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

On May 5, 2015, our board of directors approved a two-for-one stock split of our common stock to be effected through a stock dividend. The record date for the stock split was the close of business on 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.

### ***Recent Accounting Pronouncements***

In May 2014, the FASB issued Accounting Standards Update No. 2014-09, Revenue from Contracts with Customers (ASU 2014-09), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP. 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 and Dronabinol SG Capsule. Revenue is recognized when (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred and title has passed, (iii) the price is fixed or determinable and (iv) collectability is reasonably assured.

### *Subsys*

Subsys was commercially launched in March 2012, and is monitored by an FDA mandated Risk Evaluation and Mitigation program known as the Transmucosal Immediate Release Fentanyl program (“TIRF REMS”). We sell Subsys in the United States to wholesale pharmaceutical distributors, and on a very limited basis directly to retail pharmacies, collectively our customers, subject to rights of return within a period beginning 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 and recognize the estimated discount as a reduction of revenue in the same period the related revenue is recognized.

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

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

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

*Chargebacks.* We provide discounts primarily to authorized users of the FSS of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These entities purchase products from the wholesale distributors at a discounted price, and the wholesale distributors then charge back to us the difference between the current retail price and the price the entity paid for the product. We estimate and accrue chargebacks based on estimated wholesaler inventory levels, current contract prices and historical chargeback activity. 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.

### ***Dronabinol SG Capsule***

Dronabinol SG Capsule was commercially launched in December 2011, and we sell Dronabinol SG Capsule exclusively to Mylan Pharmaceuticals, Inc. (“Mylan”) in the United States under a supply and distribution agreement. Pursuant to the terms of the Mylan agreement, we manufacture Dronabinol SG Capsule under the Mylan label. Mylan distributes Dronabinol SG Capsule and on a monthly basis pays us an amount equal to the value of Dronabinol SG Capsule it sold to wholesale pharmaceutical distributors, less contractually defined deductions for chargebacks, rebates, sales discounts, distribution and storage fees, and royalties. Under the terms of the supply and distribution agreement with Mylan, we are obligated to pay Mylan a royalty of between 10% and 20% on Mylan’s net product sales, and a single digit percentage fee on such sales for distribution and storage services. We bear no risk of product return upon acceptance by Mylan. As Mylan has control over the amount it charges to wholesale pharmaceutical distributors for Dronabinol SG Capsule and the discounts offered to the distributors, the sales price is not fixed and determinable at the date we ship such products to Mylan. Accordingly, we recognize revenue upon Mylan’s sale of products to wholesale distributors, which is the point at which the sales price is fixed and determinable. The allowance for chargebacks is included in accrued sales allowances. See Note 6 for a discussion on our ongoing dispute with Mylan.

### **3.Short-Term and Long-Term Investments**

Our policy for short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Short-term and long-term investments consist of corporate and various government agency and municipal debt securities, as well as certificates of deposit that have maturity dates that are greater than 90 days. Certificates of deposit are carried at cost which approximates fair value. We classify our marketable securities as available-for-sale in accordance with FASB Accounting Standards Codification Topic 320, *Investments — Debt and Equity Securities*. Available-for-sale securities are carried at fair value with unrealized gains and losses reported in stockholders’ equity. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary, results in impairment of the fair value of the investment. We did not have any realized gains or losses or decline in values judged to be other than temporary during the three and six months ended June 30, 2015. 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 June 30, 2015, our certificates of deposit as well as our marketable securities have been recorded at an estimated fair value of \$41,248,000 and \$29,841,000 in short-term and long-term investments, respectively.

Investments consisted of the following at June 30, 2015 (in thousands):

|                               |                  | Other-<br>Than-     |                      |                         |                  |                                 |                           |                          |
|-------------------------------|------------------|---------------------|----------------------|-------------------------|------------------|---------------------------------|---------------------------|--------------------------|
|                               | Cost             | Unrealized<br>Gains | Unrealized<br>Losses | Temporary<br>Impairment | Fair<br>Value    | Cash and<br>Cash<br>Equivalents | Short-term<br>Investments | Long-term<br>Investments |
| Cash                          | \$54,164         | \$ -                | \$ -                 | \$ -                    | \$54,164         | \$ 54,164                       | \$ -                      | \$ -                     |
| Money market securities       | 18,851           | -                   | -                    | -                       | 18,851           | 18,851                          | -                         | -                        |
| Certificates of deposit       | 14,802           | -                   | -                    | -                       | 14,802           | -                               | 5,401                     | 9,401                    |
| <b>Marketable securities:</b> |                  |                     |                      |                         |                  |                                 |                           |                          |
| Corporate securities          | 17,982           | -                   | (26 )                | -                       | 17,956           | 600                             | 9,269                     | 8,087                    |
| Federal agency securities     | 11,244           | 4                   | (7 )                 | -                       | 11,241           | -                               | 7,617                     | 3,624                    |
| Municipal securities          | 28,098           | 18                  | (6 )                 | -                       | 28,110           | 420                             | 18,961                    | 8,729                    |
| Total marketable securities   | 57,324           | 22                  | (39 )                | -                       | 57,307           | 1,020                           | 35,847                    | 20,440                   |
|                               | <b>\$145,141</b> | <b>\$ 22</b>        | <b>\$ (39 )</b>      | <b>\$ -</b>             | <b>\$145,124</b> | <b>\$ 74,035</b>                | <b>\$ 41,248</b>          | <b>\$ 29,841</b>         |

Investments consisted of the following at December 31, 2014 (in thousands):

|                               |                  | <b>Other-<br/>Than-<br/>Temporary<br/>Impairment</b> |                              |                       |                       |  |                                   |                                  |
|-------------------------------|------------------|--|------------------------------|-----------------------|-----------------------|--|-----------------------------------|----------------------------------|
|                               | <b>Cost</b>      | <b>Unrealized<br/>Gains</b>                          | <b>Unrealized<br/>Losses</b> |                       | <b>Fair<br/>Value</b> | <b>Cash and<br/>Cash<br/>Equivalents</b> | <b>Short-term<br/>Investments</b> | <b>Long-term<br/>Investments</b> |
| Cash                          | \$44,785         | \$ -   | \$ -                         | <b>Losses</b><br>\$ - | \$44,785              | \$ 44,785                                | \$ -                              | \$ -                             |
| Money market securities       | 13,321           | -  | -                            | -                     | 13,321                | 13,321                                   | -                                 | -                                |
| Certificates of deposit       | 12,657           | -  | -                            | -                     | 12,657                | -  | 3,160                             | 9,497                            |
| <b>Marketable securities:</b> |                  |  |                              | -                     |                       |  |                                   |                                  |
| Corporate securities          | 10,837           | -  | (26 )                        | -                     | 10,811                | -  | 6,229                             | 4,582                            |
| Federal agency securities     | 9,512            | -  | (10 )                        | -                     | 9,502                 | -  | 5,009                             | 4,493                            |
| Municipal securities          | 15,037           | 15   | (3 )                         | -                     | 15,049                | -  | 10,359                            | 4,690                            |
| Total marketable securities   | 35,386           | 15   | (39 )                        | -                     | 35,362                | -  | 21,597                            | 13,765                           |
|                               | <b>\$106,149</b> | <b>\$ 15</b>   | <b>\$ (39 )</b>              | <b>\$ -</b>           | <b>\$106,125</b>      | <b>\$ 58,106</b>                         | <b>\$ 24,757</b>                  | <b>\$ 23,262</b>                 |

The amortized cost and estimated fair value of the marketable securities at June 30, 2015, by maturity, are shown below (in thousands):

|                                    | <b>June 30, 2015</b> |                       |
|------------------------------------|----------------------|-----------------------|
|                                    | <b>Cost</b>          | <b>Fair<br/>Value</b> |
| <b>Marketable securities:</b>      |                      |                       |
| Due in one year or less            | \$36,864             | \$36,867              |
| Due after one year through 5 years | 20,460               | 20,440                |
| Due after 5 years through 10 years | -                    | -                     |
| Due after 10 years                 | -                    | -                     |
|                                    | <b>\$57,324</b>      | <b>\$57,307</b>       |

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 June 30, 2015 (in thousands):

|                               | <b>June 30, 2015</b> |                   | <b>Greater Than</b> |                   |
|-------------------------------|----------------------|-------------------|---------------------|-------------------|
|                               | <b>Less Than 12</b>  |                   | <b>12 Months</b>    |                   |
|                               | <b>Months</b>        |                   |                     |                   |
|                               | <b>Fair</b>          | <b>Unrealized</b> | <b>Fair</b>         | <b>Unrealized</b> |
|                               | <b>Value</b>         | <b>Loss</b>       | <b>Value</b>        | <b>Loss</b>       |
| <b>Marketable securities:</b> |                      |                   |                     |                   |
| Corporate securities          | \$15,404             | \$ (26 )          | \$ -                | \$ -              |
| Federal agency securities     | 3,623                | (7 )              | -                   | -                 |
| Municipal securities          | 6,478                | (6 )              | -                   | -                 |
|                               | <b>\$25,505</b>      | <b>\$ (39 )</b>   | <b>\$ -</b>         | <b>\$ -</b>       |

As of June 30, 2015, we have concluded that the unrealized losses on our marketable securities are temporary in nature. Marketable securities are reviewed quarterly for possible other-than-temporary impairment. This review includes an analysis of the facts and circumstances of each individual investment such as the severity of loss, the expectation for that security's performance and the creditworthiness of the issuer. Additionally, we do not intend to sell, and it is not probable that we will be required to sell, any of the securities before the recovery of their amortized cost basis.

#### 4. Fair Value Measurement

FASB 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 June 30, 2015, 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 June 30, 2015 have been valued based on Level 2 inputs. Available-for-sale securities classified within Level 2 of the fair value hierarchy are valued utilizing reports from third-party asset managers that hold our investments, showing closing prices on the last business day of the period presented. These asset managers utilize an independent pricing source to obtain quotes for most fixed income securities, and utilize internal procedures to validate the prices obtained. In addition, we use an independent third-party to perform price testing, comparing a sample of quoted prices listed in the asset managers’ reports to quotes listed through a public quotation service.

Our investments measured at fair value on a recurring basis subject to the disclosure requirements of ASC 820, *Fair Value Measurements and Disclosures*, at June 30, 2015 and December 31, 2014 were as follows (in thousands):

|                               | Fair Value Measurement at Reporting Date |                                 |                                     |                                 |
|-------------------------------|--|---------------------------------|-------------------------------------|---------------------------------|
|                               | June 30, 2015                            | Quoted Prices in active Markets | Significant Other Observable Inputs | Significant Unobservable Inputs |
|                               |  | (Level 1)                       | (Level 2)                           | (Level 3)                       |
| <b>Marketable securities:</b> |  |                                 |                                     |                                 |
| Corporate securities          | \$17,956                                 | \$ -                            | \$ 17,956                           | \$ -                            |
| Federal agency securities     | 11,241                                   | -                               | 11,241                              | -                               |
| Municipal securities          | 28,110                                   | -                               | 28,110                              | -                               |

**Total assets measured at fair value**    \$57,307    \$       -       \$ 57,307       \$       -

|  | Fair Value Measurement at Reporting Date |  |  |                                       |
|--|--|--|--|---------------------------------------|
|  | December<br>31,<br>2014                  | Quoted<br>Prices in<br>active<br>Markets | Significant<br>Other<br>Observable<br>Inputs | Significant<br>Unobservable<br>Inputs |
|  |  | (Level 1)                                | (Level 2)                                    | (Level 3)                             |
| <b>Marketable securities:</b>              |  |  |  |                                       |
| Corporate securities                       | \$ 10,811                                | \$       -                               | \$ 10,811                                    | \$       -                            |
| Federal agency securities                  | 9,502                                    | -  | 9,502  | -                                     |
| Municipal securities                       | 15,049                                   | -  | 15,049                                       | -                                     |
| <b>Total assets measured at fair value</b> | <b>\$ 35,362</b>                         | <b>\$       -</b>                        | <b>\$ 35,362</b>                             | <b>\$       -</b>                     |

## 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):

|                                   | <b>June<br/>30,<br/>2015</b> | <b>December<br/>31, 2014</b> |
|-----------------------------------|------------------------------|------------------------------|
| Finished goods                    | \$25,395                     | \$ 30,998                    |
| Work-in-process                   | 7,941                        | 4,316                        |
| Raw materials and supplies        | 5,709                        | 2,785                        |
| Total inventories                 | 39,045                       | 38,099                       |
| Less: non-current work-in-process | (3,492 )                     | (3,318 )                     |
|                                   | <b>\$35,553</b>              | <b>\$ 34,781</b>             |

As of June 30, 2015 and December 31, 2014, raw materials inventories consisted of raw materials used in the manufacture of the active pharmaceutical ingredient (“API”) in our U.S.-based, state-of-the-art dronabinol manufacturing facility and component parts 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 SG Capsule and Subsys products. Finished goods inventories consisted of finished Dronabinol SG Capsule and Subsys products. Non-current work-in-process represent those inventories pending FDA approval which is not expected before March 31, 2016 and are included in other assets in our condensed consolidated unaudited balance sheets.

## **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 believe are either individually or collectively material.

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

***Government Proceedings***

Like other companies in the pharmaceutical industry, we are subject to extensive regulation by national, state and local government agencies in the United States. As a result, interaction with government agencies occurs in the normal course of our operations. The following is a brief description of pending governmental investigations which we believe are potentially material at this time. It is possible that criminal charges and substantial 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.

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

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 the Company. We are currently looking into these issues.

***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. These CIDs request documents regarding Subsys, including the Company's sales and marketing practices related to Subsys in the applicable state. 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 agreed to make 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.

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

### ***Federal Securities Litigation***

Between May 15 and May 19, 2014, two complaints (captioned *Larson v. Insys Therapeutics, Inc.*, Case No. 14-cv-01043-GMS) and (*Li vs. Insys Therapeutics, Inc.*, Case No 14-cv-01077-DGC) were filed in the U.S. District Court for the District of Arizona, or Arizona District Court, against us and certain of our current officers. The complaints were brought as purported class actions, on behalf of purchasers of our common stock. In general, the plaintiffs allege that the defendants violated federal securities laws by making intentionally false and misleading statements regarding our business and operations, therefore artificially inflating the price of our common stock. The plaintiffs seek unspecified monetary damages and other relief. On July 14, 2014, several purported shareholders filed motions to consolidate the two cases, appoint a lead plaintiff, and appoint lead counsel. On August 29, 2014, the Arizona District Court issued an order consolidating the action, appointing Hongwei Li as lead plaintiff, and appointing the lead counsel. Lead plaintiffs complaint was filed on October 27, 2014. On December 11, 2014, we moved to dismiss the amended consolidated complaint. On March 19, 2015, the parties participated in a mediation and the parties subsequently agreed in principle, on April 14, 2015, to settle the action. On April 20, 2015, the parties filed a Notice of Settlement with the Court. On April 29, 2015, the Court ordered that the lawsuit be dismissed within 60 days, vacated all pending hearings, and denied all pending motions as moot. On May 28, 2015, the parties filed a Stipulation of Settlement, which provided the terms of a settlement agreement. On June 2, 2015, the Court granted preliminary approval of the settlement agreement and the potential class members have been (or will be) notified of

the proposed settlement and the procedure by which they can object to the settlement or request to be excluded from the class. The settlement remains subject to final approval by the Court and the Court has scheduled a settlement hearing for December 5, 2015. Because we have met our retainage amount under the applicable policy, we believe that any potential obligations that may arise as result of the proposed settlement in this matter will be fully covered under our Directors and Officers insurance policy. Accordingly, we have not accrued for any contingencies in this matter into our operating results.

### ***General Litigation and Disputes***

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

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

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

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

On February 25, 2014, we filed a Motion to Dismiss the Kottayil Plaintiffs' 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 us 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. The court still has to resolve certain post-trial issues, which are currently being briefed by the parties, before a final judgment is entered.

As a result of the final ruling, we have accrued \$10,304,000 at June 30, 2015 including \$3,014,000 of estimated pre-and post-judgement interest. Any final judgement entered by the court is subject to a potential appeal which could cause the estimates to vary materially from the final award.

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

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

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

On September 23, 2014, the three member arbitration panel held a preliminary hearing wherein it decided that the arbitration proceeding would be bifurcated. The first phase of the proceeding will determine whether there has been a material breach of the Agreement. If either party is successful in establishing its claims during this first phase then there will be a second phase of the arbitration to determine damages.

In November 2014, the arbitration panel held Phase I of the arbitration proceeding which we anticipate will resolve (1) whether Mylan materially breached the Agreement by failing to accept the delivery of conforming shipments of product in October 2012, January 2014 and March 2014; (2) whether Mylan has materially breached the parties' Supply and Distribution Agreement by failing to use commercially reasonable efforts to market and sell the product; and (3) whether we are in breach of the Agreement by delivering non-conforming product.

On June 23, 2015, the Panel issued an interim order in connection with Phase I. The Panel's order found that (1) Mylan did not breach the Agreement with respect to the October 2012 shipment of the product, and (2) our termination of the Agreement because of the parties' dispute over floor pricing was effective as of March 22, 2014. The Panel determined that there was no need to address the issue of whether we properly terminated the Agreement because of the January 2014 or March 2014 shipments of the products. The Panel also determined that it is necessary to hold proceedings for Phase II of the arbitration to determine the amount, if any, of damages suffered by either party or whether Mylan used commercially reasonable efforts to sell the product. The parties have submitted preliminary briefing on their positions related to damages and the Panel has scheduled a hearing for August 12, 2015.

Except as it pertains to the \$10,304,000 accrued for the dispute with Dr. Kottayil, the \$1,100,000 accrued in connection with the ODOJ settlement payment and the potential for damages in the Federal Securities litigation that should be sufficiently covered by our Director and Officers insurance policies as noted above, 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.

### ***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. The following table sets forth minimum

purchase commitments with DPT under this agreement (in thousands):

| <b>Years ending December 31,</b> |          |
|----------------------------------|----------|
| 2015                             | -        |
| 2016                             | -        |
| 2017                             | 8,450    |
| 2018                             | 11,150   |
| 2019                             | 13,850   |
| Thereafter                       | 16,290   |
| Total                            | \$49,740 |



## 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):

|  | <b>Three Months<br/>Ended June<br/>30,<br/>2015</b> |             | <b>Six Months<br/>Ended June<br/>30,<br/>2015</b> |             |
|--|---|-------------|---|-------------|
|  | <b>2015</b>   | <b>2014</b> | <b>2015</b>                                       | <b>2014</b> |
| Research and development               | \$448   | \$3,535     | \$789   | \$3,862     |
| General and administrative             | 3,779   | 2,196       | 7,158   | 4,325       |
| Total cost of stock-based compensation | \$4,227   | \$5,731     | \$7,947   | \$8,187     |

As of June 30, 2015, we expected to recognize \$40,409,000 of stock-based compensation for outstanding options over a weighted-average period of 3.0 years.

The following table summarizes stock option activity as of December 31, 2014 and for the six months ended June 30, 2015:

|  | <b>Number of<br/>Shares</b> | <b>Weighted<br/>Average<br/>Exercise<br/>Price</b> | <b>Weighted<br/>Average<br/>Remaining<br/>Contractual<br/>Term (in<br/>years)</b> | <b>Aggregate<br/>Intrinsic<br/>Value<br/>(in<br/>millions)</b> |
|--|-----------------------------|--|---|--|
| Vested and exercisable as of December 31, 2014 | 2,660,720                   | \$ 3.95  |   |  |
| Outstanding as of December 31, 2014            | 7,707,162                   | \$ 7.57  |   |  |
| Granted  | 848,000                     | \$ 27.41   |   |  |
| Cancelled                                      | (199,606 )                  | \$ 16.21   |   |  |
| Exercised                                      | (1,029,598 )                | \$ 5.93  |   |  |
| Outstanding as of June 30, 2015                | 7,325,958                   | \$ 9.86  | 8.0   | \$ 190.9   |
| Vested and exercisable as of June 30, 2015     | 2,737,436                   | \$ 4.81  | 7.0   | \$ 85.1  |

Cash received from option exercises under all share-based payment arrangements for the six months ended June 30, 2015 and 2014 was \$6,111,000 and \$3,243,000, respectively. For the six months ended June 30, 2015, we recorded net reductions of \$7,416,000 of our federal and state income tax liability, with an offsetting credit to additional paid-in capital, resulting from the excess tax benefits of stock options.

## **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):

|  | <b>Three Months Ended<br/>June 30,</b> |             | <b>Six Months Ended<br/>June 30,</b> |             |
|--|--|-------------|--------------------------------------|-------------|
|  | <b>2015</b>                            | <b>2014</b> | <b>2015</b>                          | <b>2014</b> |
| <b>Historical net income per share - Basic</b>       |  |             |                                      |             |
| Numerator:   |  |             |                                      |             |
| Net income   | \$7,314                                | \$9,465     | \$15,337                             | \$17,123    |
| Denominator:   |  |             |                                      |             |
| Weighted average number of common shares outstanding | 71,517,442                             | 68,596,652  | 71,217,137                           | 67,864,742  |
| Basic net income per common share                    | \$0.10                                 | \$0.14      | \$0.22                               | \$0.25      |
| <b>Historical net income per share - Diluted</b>     |  |             |                                      |             |
| Numerator:   |  |             |                                      |             |
| Net income   | \$7,314                                | \$9,465     | \$15,337                             | \$17,123    |
| Denominator:   |  |             |                                      |             |
| Weighted average number of common shares outstanding | 71,517,442                             | 68,596,652  | 71,217,137                           | 67,864,742  |
| Effect of dilutive stock options                     | 3,961,207                              | 4,076,502   | 4,037,911                            | 5,230,902   |
| Weighted average number of common shares outstanding | 75,478,649                             | 72,673,154  | 75,255,048                           | 73,095,644  |
| Diluted net income per common share                  | \$0.10                                 | \$0.13      | \$0.20                               | \$0.23      |

Anti-dilutive share equivalents included 1,274,490 and 1,797,008 outstanding stock options as of June 30, 2015 and 2014, respectively.

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

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

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

### Net Revenue by Product Line

|                       | <b>Three Months<br/>Ended June 30,</b> |             | <b>Six Months Ended<br/>June 30,</b> |             |
|-----------------------|--|-------------|--------------------------------------|-------------|
|                       | <b>2015</b>                            | <b>2014</b> | <b>2015</b>                          | <b>2014</b> |
| Subsys                | \$76,700                               | \$54,576    | \$147,240                            | \$95,229    |
| Dronabinol SG Capsule | 933                                    | 1,120       | 1,163                                | 2,103       |
| Total net revenue     | \$77,633                               | \$55,696    | \$148,403                            | \$97,332    |

|                                     | <b>Percent of Revenue by<br/>Route to Market</b> |             |  |             |
|-------------------------------------|--|-------------|--|-------------|
|                                     | <b>Three<br/>Months<br/>Ended June<br/>30,</b>   |             | <b>Six Months<br/>Ended June<br/>30,</b> |             |
|                                     | <b>2015</b>                                      | <b>2014</b> | <b>2015</b>                              | <b>2014</b> |
| Pharmaceutical wholesalers          | 99 %   | 98 %        | 99 %                                     | 98 %        |
| Generic pharmaceutical distributors | 1 %  | 2 %         | 1 %                                      | 2 %         |
|                                     | 100 %  | 100 %       | 100 %                                    | 100 %       |

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

Product shipments to four pharmaceutical wholesalers accounted for 33%, 20%, 18% and 15% of total shipments for the six months ended June 30, 2015. Product shipments to four pharmaceutical wholesalers accounted for 38%, 17%, 15% and 12% of total shipments for the six months ended June 30, 2014. Four pharmaceutical wholesalers' accounts receivable balances accounted for 35%, 20%, 18%, and 12% of gross accounts receivable as of June 30, 2015. Four pharmaceutical wholesalers' accounts receivable balances accounted for 26%, 24%, 23% and 14% of gross accounts receivable as of December 31, 2014.

## 10. Related Party Transactions

In March of 2015, we entered into a consultancy agreement with Dr. John Kapoor, our Executive Chairman of our Board of Directors and our majority shareholder, to compensate Dr. Kapoor for his ongoing time and contribution to the Company. Under the terms of the agreement, Dr. Kapoor will receive an annual consulting fee of \$300,000.

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

*The following discussion and analysis of our financial condition and 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, 2014 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, 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; the sufficiency of our manufacturing capacity; the beneficial attributes of our dronabinol product candidates; our expectation that gross Dronabinol margins will fluctuate; that sales and marketing and research and development costs will be our largest categories of expenses; that sales and marketing expenses will fluctuate on changes in Subsys net revenue; that our Subsys revenue will increase during the remainder of 2015 and that Dronabinol SG Capsule revenue will continue to be insignificant; that cash flows from operating activities will increase; our development of different dronabinol delivery systems; the source and sufficiency of our liquidity and 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; 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; certain anticipated strategies and outcomes of our litigation with Mylan; trends in restrictions and impediments relating to reimbursement policies imposed by pharmacy benefit managers; the impact of pending litigation and our strategy relating thereto; our exposure to interest rate changes and market risks relating to our investments; that we will not recognize revenue in the near term from current research and development initiatives; the potential impact of Section 382 limitations on our NOLs; and the magnitude and impact of ownership changes, including pre-merger changes relating to NeoPharm, under Section 382 of the Internal Revenue Code. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "should," "could," "predicts," "potential," "continue," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements. All forward-looking statements in this Form 10-Q are made based on our current expectations, forecasts, estimates and assumptions, and involve risks, uncertainties and other*

*factors that could cause results or events to differ materially from those expressed in the forward-looking statements. In evaluating these statements, you should specifically consider various factors, uncertainties and risks that could affect our future results or operations as described from time to time in our SEC reports, including those risks outlined under “Risk Factors” in Item 1A of our Form 10-K for the year ended December 31, 2014. These factors, uncertainties and risks may cause our actual results to differ materially from any forward-looking statement set forth in this Form 10-Q. You should carefully consider these risk and uncertainties described and other information contained in the reports we file with or furnish to the SEC before making any investment decision with respect to our securities. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by this cautionary statement. Some of the important factors that could cause our actual results to differ materially from those projected in any forward-looking statements including, but are not limited to, the following:*

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

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

*our exposure to claims that our employees or independent contractors have wrongfully used or disclosed to the Company trade secrets of their other clients or former employers;*  
*our compliance with the procedural, document submission, fee payment and other requirements needed to apply for patents;*  
*control over the Company by its founder, Executive Chairman and principal stockholder;*  
*fluctuation in the price of our common stock;*  
*lack of, or inaccurate, published research about the Company;*  
*the impact of future sales of our common stock or securities convertible into our common stock;*  
*the effect of anti-takeover provisions in our charter documents and under Delaware law;*  
*the impact of our abbreviated disclosures as allowed by the JOBS Act because of our status as an “emerging growth company”;*  
*our intention to not pay dividends in the foreseeable future; and*  
*our ability to maintain and improve our financial controls and related compliance with SEC and stock exchange listing standards.*



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

## Overview

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

Subsys — a proprietary, single-use product that delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue, offered in 100, 200, 400, 600, 800, 1,200 and 1,600 mcg dosages. Subsys is approved for the treatment of 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 exclusive distribution partner, Mylan Pharmaceuticals, Inc., in December 2011.

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

Our sales of, and revenue from, Subsys depend in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers. All third-party payers are sensitive to the cost of drugs and consistently implement efforts to control these costs, which efforts include, but are not limited to, establishing excluded or preferred drug lists. Subsys has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, particularly 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.

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. This change in ESI formulary status took effect in 2015. Early indications suggest that the ESI formulary change will not have a material impact on our net revenue, however, we will continue to monitor the effects of this change closely. As we have in the past, we will continue working with other PBMs to evaluate price increases and to communicate with managed care and health-system decision-makers to ensure a balanced approach, which takes into account the clinical performance and efficacy of our products.

We produce the API for Dronabinol SG Capsule at our U.S.-based, state-of-the-art dronabinol manufacturing facility. While we believe that this facility has the capacity to supply sufficient commercial quantities of dronabinol API for our Dronabinol SG Capsule, initial launch quantities of Dronabinol Oral Solution, if approved, and support the continued development of our other dronabinol product candidates in the near-term, we have opened a second dronabinol manufacturing facility, which we anticipate will enable us to supply sufficient commercial quantities of dronabinol API for our continued commercialization of Dronabinol SG Capsule and for the commercialization of our proprietary dronabinol product candidates, if approved. In May 2011, we entered into a supply and distribution agreement with Mylan, pursuant to which we engaged Mylan to exclusively distribute Dronabinol SG Capsule within the United States. See Note 6 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

In addition, we are developing other product candidates, such as dronabinol line extensions and sublingual spray product candidates. Our most advanced potential cannabinoid line extension is Dronabinol Oral Solution. This product candidate has demonstrated more rapidly detectable blood levels and a more reliable absorption profile than Marinol in our clinical studies. We believe these attributes may ultimately increase patient compliance because of more rapid onset of action and less dose-to-dose variability, which we believe will allow us to further penetrate and potentially expand the market for the medical use of dronabinol. We completed a pre-NDA meeting with the FDA and a pivotal bioequivalence study for Dronabinol Oral Solution in 2012 and we completed the clinical dossier for this product candidate during the third quarter of 2013. We are currently engaged in an ongoing dialogue with the DEA regarding the potential scheduling classification for this product candidate. On June 2, 2015, we announced that we submitted the NDA to the FDA for our proprietary Dronabinol Oral Solution.

We have the capability to manufacture pharmaceutical CBD, a synthetically produced and 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 during 2015 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 six months ended June 30, 2015 and 2014, all of our net revenues were generated from the sale of our two approved products, Subsys and Dronabinol SG Capsule, with sales of Subsys accounting for 99% of our 2015 and 2014 year-to-date revenues. Our results will depend on prescription volume generally, which we believe will be driven primarily by achievement of broad market acceptance and coverage by third-party payors and effectiveness of the marketing and selling efforts with respect to our products. In addition, our results will also depend on our mix of sales between Subsys and Dronabinol SG Capsule as well as the amounts of dosage strengths sold. Subsys gross margins are substantially higher than those of Dronabinol SG Capsule. 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 88% of prescriptions as of June 30, 2015. Generally, repeat Subsys patients receive significantly higher doses of Subsys on average than first-time patients as patients are titrated from a starter dose of Subsys to their effective dose in accordance with the TIRF REMS protocol.

***Investments in Our Infrastructure and Growth.*** Our ability to increase our sales and to further penetrate our target market segments is dependent in part on our ability to invest in our infrastructure and in our sales and marketing efforts. In order to drive further growth, we may hire additional sales and marketing personnel and invest in marketing our products to our target physician prescriber base. For example, as of June 30, 2015, we had 370 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 our continued commercialization of Dronabinol SG Capsule and 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 \$28.4 million and \$13.2 million for the six months ended June 30, 2015 and 2014, respectively. As of June 30, 2015, we had 55 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary cannabinoid product candidates, including Dronabinol Oral Solution, and sublingual spray product candidates. 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 Dronabinol Oral Solution, could cause our research and development expenditures to increase significantly and, in turn, have a material adverse effect on our results of operations.

## **Basis of Presentation**

### ***Net Revenue***

During the year ended December 31, 2012, we began recognizing net revenue from sales of Subsys made by us, and from Dronabinol SG Capsule under our supply and distribution agreement with Mylan. We sell Subsys in packages of various sized single-dose units in dosage strengths of 100, 200, 400, 600, 800, 1,200 and 1,600 mcg, to wholesale pharmaceutical distributors and retail pharmacies, collectively, our customers, on a wholesale basis. Sales to our customers are subject to specified rights of return. We record revenue for Subsys at the time the wholesaler receives the shipment.

We sell Dronabinol SG Capsule exclusively to Mylan in dosage strengths of 2.5, 5.0 and 10.0 milligrams under the Mylan label. Mylan distributes Dronabinol SG Capsule and on a monthly basis pays us an amount equal to the value of Dronabinol SG Capsule it sold to wholesale pharmaceutical distributors and retail pharmacies, less contractually defined deductions for chargebacks, rebates, sales discounts, distribution and storage fees, and royalties. We are obligated to pay Mylan a royalty between 10% and 20% on Mylan's net product sales, and a single digit percentage fee on such sales for distribution and storage services. We bear no risk of product return upon acceptance by Mylan. As Mylan has control over the amount it charges to wholesale pharmaceutical distributors for Dronabinol SG Capsule and the discounts offered to the distributors, the sales price is not fixed and determinable at the date we ship such product to Mylan. Accordingly, we recognize revenue on the sale of Dronabinol SG Capsule upon Mylan's sale of product to wholesale distributors, which is the point at which the sales price is fixed and determinable. See Note 6 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

### ***Cost of Revenue, Gross Profit and Gross Margin***

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

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

***Sales and Marketing Expenses***

Our sales and marketing expenses consist primarily of salaries, commissions, benefits, consulting fees, costs of obtaining prescription and market data, and market research studies related to Subsys. As of June 30, 2015, we had 370 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 and dronabinol programs. As of June 30, 2015, we had 55 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 six months ended June 30, 2015 and 2014 (in millions):

|   | <b>Six Months<br/>Ended<br/>June 30,<br/>2015 2014</b> |         |
|---|--|---------|
| Cannabidiol                             | \$ 10.3  | \$ 0.7  |
| Dronabinol                              | 2.6  | 1.0     |
| LEP-ETU and IL-13                       | 2.0  | 0.6     |
| Buprenorphine/Naloxone                  | 1.8  | 0.5     |
| Ondansetron                             | 0.9  | 0.2     |
| Naloxone                                | 0.8  | -       |
| Buprenorphine                           | 0.7  | 0.5     |
| Fentanyl                                | 0.3  | 1.8     |
| Sildenafil                              | 0.2  | 0.2     |
| Other                                   | 0.3  | -       |
| Internal research and development costs | 8.5  | 7.7     |
| Total research and development expenses | \$ 28.4  | \$ 13.2 |

### ***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 June 30, 2015, we had 39 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 six months ended June 30, 2015 represent a legal accrual of \$10.3 million related to our dispute with Dr. Kottayil. 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***

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 difference, 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 Policies and Estimates

There were no changes in our significant accounting policies and estimates during the six months ended June 30, 2015 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, 2014.

## Results of Operations

### *Comparison of Three Months Ended June 30, 2015 to Three Months Ended June 30, 2014*

The following table presents certain selected consolidated financial data for the three months ended June 30, 2015 and 2014 expressed as a percentage of net revenue:

|                                     | <b>Three Months<br/>Ended<br/>June 30,<br/>2015      2014</b> |        |
|-------------------------------------|---|--------|
| Net revenue                         | 100.0%  | 100.0% |
| Cost of revenue                     | 10.7  | 11.8   |
| Gross profit                        | 89.3  | 88.2   |
| Operating expenses:                 |   |        |
| Sales and marketing                 | 28.3  | 25.3   |
| Research and development            | 22.9  | 16.5   |
| General and administrative          | 19.7  | 19.1   |
| Charges related to litigation award | 3.0   | 0.0    |
| Total operating expenses            | 73.9  | 60.9   |
| Operating income                    | 15.4  | 27.3   |
| Other income (expense):             |   |        |
| Interest income                     | 0.1   | 0.0    |
| Other income (expense), net         | -   | 0.0    |
| Total other income (expense)        | 0.1   | 0.0    |
| Income before income taxes          | 15.5  | 27.3   |
| Income tax expense                  | 6.2   | 10.3   |
| Net income                          | 9.3 %   | 17.0 % |



**Net Revenue.** Net revenue increased \$21.9 million, or 39%, to \$77.6 million for the three months ended June 30, 2015, compared to \$55.7 million for the three months ended June 30, 2014. The increase in net revenue was attributable to the \$22.1 million, or 41%, increase in net revenue of Subsys to \$76.7 million for the three months ended June 30, 2015, compared to \$54.6 million for the three months ended June 30, 2014. The increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages and also price increases in July 2014 and January 2015. Provisions for wholesaler discounts, patient discounts, rebates and returns increased to \$10.0 million, \$14.4 million, \$16.8 million and \$0.6 million, respectively, from the sale of Subsys for the three months ended June 30, 2015, compared to \$5.4 million, \$5.6 million, \$6.1 million and \$1.4 million, respectively, from the sale of Subsys for the three months ended June 30, 2014. The increase in revenue provisions was primarily attributable to increased sales, higher volumes of patient assistance, and higher rebate rates due to recent price increases. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2015 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

During the three months ended June 30, 2015, Dronabinol SG Capsule net revenue was \$0.9 million as compared with \$1.1 million during the three months ended June 30, 2014

On March 23, 2015, the arbitration panel issued an interim ruling in phase 1 of our ongoing dispute with Mylan which effectively terminated our distribution agreement with Mylan as of March 22, 2014. As a result of this ruling, we recorded \$0.9 million in revenue related to the recognition of non-refundable deposits for amounts paid by Mylan for inventory held by Mylan, and a corresponding \$1.5 million charge to cost of goods sold into our operating results for the three and six months ended June 30, 2015. We do not expect that there will be any further meaningful Dronabinol SG Capsule revenues prospectively. See Note 6 for a discussion on our ongoing dispute with Mylan.

**Cost of Revenue, Gross Profit and Gross Margin.** Cost of revenue increased \$1.7 million to \$8.3 million for the three months ended June 30, 2015 compared to \$6.6 million for the three months ended June 30, 2014. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the three months ended June 30, 2015. Gross profit increased \$20.2 million to \$69.3 million for the three months ended June 30, 2015 compared to \$49.1 million for the three months ended June 30, 2014 due primarily to the increase in sales of Subsys. Gross margin for the three months ended June 30, 2015 was approximately 89% compared to approximately 88% for the three months ended June 30, 2014.

**Sales and Marketing Expense.** Sales and marketing expense increased \$7.9 million to \$22.0 million for the three months ended June 30, 2015 compared to \$14.1 million for the three months ended June 30, 2014. The increase in sales and marketing expense was due primarily to variable sales compensation expense and incremental product marketing expense associated with the increase in sales of Subsys. As Dronabinol SG Capsule is marketed by Mylan, we did not incur any sales and marketing expense related to Dronabinol SG Capsule.

**Research and Development Expense.** Research and development expense increased \$8.6 million to \$17.8 million for the three months ended June 30, 2015, compared to \$9.2 million for the three months ended June 30, 2014. The increase in research and development expense was due primarily to an increase in clinical expenses, product development, regulatory fees, and an increase in research and development personnel during 2014 in response to our growing product pipeline.

**General and Administrative Expense.** General and administrative expense increased \$4.6 million to \$15.3 million for the three months ended June 30, 2015 compared to \$10.7 million for the three months ended June 30, 2014. The increase in general and administrative expense was due primarily to increased stock-based compensation costs and increases in legal expense incurred in connection with various ongoing litigation and subpoena related matters, which includes an accrual of \$1.1 million in connection with the AVC entered into with the ODOJ.

**Charges Related to Litigation Award.** Charges related to litigation award expenses for the three months ended June 30, 2015 a \$2.3 million legal expense accrual associated with our dispute with Dr. Kottayil, See Note 6 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion on our ongoing dispute with Dr. Kottayil. There was no similar expense for the three months ended June 30, 2014

**Income Tax Expense.** Provision for income taxes was \$4.8 million for the three months ended June 30, 2015, representing an effective tax rate of 39.5%, as compared to \$5.7 million for the three months ended June 30, 2014, representing an effective tax rate of 37.8%. As of June 30, 2015, we had approximately \$1.5 million of federal and \$271.0 million of state net operating loss carry forwards.

We had unrecognized tax benefits of approximately \$2.0 million as of June 30, 2015, primarily associated with tax positions taken in prior year. No significant penalties or interest are included in income taxes or accounted for on the balance sheet related to unrecognized tax positions.

## Results of Operations

### *Comparison of Six Months Ended June 30, 2015 to Six Months Ended June 30, 2014*

The following table presents certain selected consolidated financial data for the six months ended June 30, 2015 and 2014 expressed as a percentage of net revenue:

|                                     | <b>Six Months<br/>Ended<br/>June 30,<br/>2015      2014</b> |        |
|-------------------------------------|---|--------|
| Net revenue                         | 100.0%  | 100.0% |
| Cost of revenue                     | 9.9   | 11.6   |
| Gross profit                        | 90.1  | 88.4   |
| Operating expenses:                 |   |        |
| Sales and marketing                 | 28.9  | 26.4   |
| Research and development            | 19.1  | 13.6   |
| General and administrative          | 19.2  | 19.7   |
| Charges related to litigation award | 6.9   | 0.0    |
| Total operating expenses            | 74.1  | 59.7   |
| Operating income                    | 16.0  | 28.7   |
| Other income (expense):             |   |        |
| Interest income                     | 0.2   | 0.0    |
| Other income (expense), net         | -   | 0.0    |
| Total other income (expense)        | 0.2   | 0.0    |
| Income before income taxes          | 16.2  | 28.7   |
| Income tax expense                  | 5.7   | 11.1   |
| Net income                          | 10.5 %  | 17.6 % |

**Net Revenue.** Net revenue increased \$51.1 million, or 52%, to \$148.4 million for the six months ended June 30, 2015, compared to \$97.3 million for the six months ended June 30, 2014. The increase in net revenue was attributable to the \$52.0 million, or 55%, increase in net revenue of Subsys to \$147.2 million for the six months ended June 30,

2015, compared to \$95.2 million for the six months ended June 30, 2014. The increase in Subsys revenue is primarily as a result of increased prescriptions and change in mix of prescribed dosages and also price increases in January 2014, April 2014, July 2014 and January 2015. Provisions for wholesaler discounts, patient discounts, rebates and returns increased to \$18.0 million, \$31.4 million, \$25.2 million and \$1.1 million, respectively, from the sale of Subsys for the six months ended June 30, 2015, compared to \$9.2 million, \$9.7 million, \$9.7 million and \$1.5 million, respectively, from the sale of Subsys for the six months ended June 30, 2014. The increase in revenue provisions was primarily attributable to increased sales, higher volumes of patient assistance, and higher rebate rates due to recent price increases. We expect net revenue from sales of Subsys to continue to increase during the remainder of 2015 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix.

During the six months ended June 30, 2015, Dronabinol SG Capsule net revenue was \$1.2 million as compared with \$2.1 million during the six months ended June 30, 2014.

On March 23, 2015, the arbitration panel issued an interim ruling in phase 1 of our ongoing dispute with Mylan which effectively terminated our distribution agreement with Mylan as of March 22, 2014. As a result of this ruling, we recorded \$0.9 million in revenue related to the recognition of non-refundable deposits for amounts paid by Mylan for inventory held by Mylan, and a corresponding \$1.5 million charge to cost of goods sold into our operating results for the three and six months ended June 30, 2015. We do not expect that there will be any further meaningful Dronabinol SG Capsule revenues prospectively. See Note 6 for a discussion on our ongoing dispute with Mylan.

**Cost of Revenue, Gross Profit and Gross Margin.** Cost of revenue increased \$3.4 million to \$14.7 million for the six months ended June 30, 2015 compared to \$11.3 million for the six months ended June 30, 2014. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the six months ended June 30, 2015. Gross profit increased \$47.7 million to \$133.7 million for the six months ended June 30, 2015 compared to \$86.0 million for the six months ended June 30, 2014 due primarily to the increase in sales of Subsys. Gross margin for the six months ended June 30, 2015 was approximately 90% compared to approximately 88% for the six months ended June 30, 2014.

**Sales and Marketing Expense.** Sales and marketing expense increased \$17.2 million to \$42.9 million for the six months ended June 30, 2015 compared to \$25.7 million for the six months ended June 30, 2014. The increase in sales and marketing expense was due primarily to variable sales compensation expense and incremental product marketing expense associated with the increase in sales of Subsys. As Dronabinol SG Capsule is marketed by Mylan, we did not incur any sales and marketing expense related to Dronabinol SG Capsule.

**Research and Development Expense.** Research and development expense increased \$15.2 million to \$28.4 million for the six months ended June 30, 2015, compared to \$13.2 million for the six months ended June 30, 2014. The increase in research and development expense was due primarily to an increase in clinical expenses, product development, regulatory fees, and an increase in research and development personnel during 2014 in response to our growing product pipeline.

**General and Administrative Expense.** General and administrative expense increased \$9.2 million to \$28.5 million for the six months ended June 30, 2015 compared to \$19.3 million for the six months ended June 30, 2014. The increase in general and administrative expense was due primarily increases in legal expense incurred in connection with various ongoing litigation and subpoena related matters, which includes an accrual of \$1.1 million in connection with the AVC entered into with the ODOJ, and stock-based compensation costs. See Note 6 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion ongoing litigation matters.

**Charges Related to Litigation Award.** Charges related to litigation award for the six months ended June 30, 2015 represents a \$10.3 million legal expense accrual associated with our dispute with Dr. Kottayil, See Note 6 of the Notes to our Unaudited Condensed Consolidated Financial Statements for a discussion on our ongoing dispute with Dr. Kottayil. There was no similar expense for the six months ended June 30, 2014.

**Income Tax Expense.** Provision for income taxes was \$8.5 million for the six months ended June 30, 2015, representing an effective tax rate of 35.7%, as compared to \$10.8 million for the six months ended June 30, 2014, representing an effective tax rate of 38.6%. As of June 30, 2015, we had approximately \$1.5 million of federal and \$271.0 million of state net operating loss carry forwards.

We had unrecognized tax benefits of approximately \$2.0 million as of June 30, 2015, primarily associated with tax positions taken in prior year. No significant penalties or interest are included in income taxes or accounted for on the balance sheet related to unrecognized tax positions.

## **Liquidity and Capital Resources**

### ***Sources of Liquidity***

We incurred losses from our inception through December 31, 2012. Although we began generating positive operating cash flows in connection with the commercial launch of Subsys during the first quarter of 2013, and continued to do so through the current quarter, as of June 30, 2015, we have an accumulated deficit of \$35.7 million. Prior to our initial public offering, or IPO, we financed our operations primarily through the issuance of promissory notes to The John N. Kapoor Trust and the Kapoor Children 1992 Trust, which are controlled by or affiliated with our founder, Executive Chairman and principal stockholder.

On May 7, 2013, we completed our IPO, pursuant to which we sold 13,800,000 shares of our common stock (4,600,000 on a pre-split basis) at a price of \$2.67 per share (\$8.00 on a pre-split basis), which included the underwriters' exercise of their over-allotment option. As a result of the IPO, we raised a total of \$32.5 million in net proceeds after deducting underwriting discounts and commissions of \$2.6 million and offering expenses of \$1.8 million. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the completion of the IPO. These costs were recorded as a reduction of the proceeds received in arriving at the amount recorded in additional paid-in capital. Upon completion of the IPO, all outstanding shares of our preferred stock were converted into 25,586,580 shares of common stock (8,528,860 on a pre-split basis).



**Cash Flows**

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

|  | <b>Six Months<br/>Ended</b> |             |
|--|-----------------------------|-------------|
|  | <b>June 30,</b>             |             |
|  | <b>2015</b>                 | <b>2014</b> |
| Net cash provided by operating activities            | \$32.1                      | \$21.2      |
| Net cash used in investing activities                | (31.2)                      | (37.2)      |
| Net cash provided by financing activities            | 15.0                        | 16.7        |
| Net increase (decrease) in cash and cash equivalents | 15.9                        | 0.7         |
| Cash and cash equivalents, beginning of period       | 58.1                        | 45.4        |
| Cash and cash equivalents, end of period             | \$74.0                      | \$46.1      |

**Cash Flows From Operating Activities.** Net cash provided by operating activities was \$32.1 million and \$21.2 million for the six months ended June 30, 2015 and 2014, respectively. The net cash provided during the six months ended June 30, 2015 primarily reflects the net income for the period driven primarily by growth in Subsys net sales, adjusted in part by depreciation and amortization, stock-based compensation expense and is also impacted by changes in working capital.

**Cash Flows From Investing Activities.** Net cash used in investing activities was \$31.2 million and \$37.2 million for the six months ended June 30, 2015 and 2014, respectively, and consists primarily of the purchase of investments and property and equipment.

**Cash Flows From Financing Activities.** Net cash provided by financing activities was \$15.0 million for the six months ended June 30, 2015, as compared to \$16.7 million for the six months ended June 30, 2014. During the six months ended June 30, 2015, we recorded excess tax benefits on stock options and awards of \$7.4 million, proceeds from the exercise of stock options of \$6.1 million and proceeds from shares issued under our employee stock purchase plan of \$1.5 million. During the six months ended June 30, 2014, we recorded excess tax benefits on stock options and awards of \$12.4 million, proceeds from the exercise of stock options of \$3.2 million and proceeds from shares issued under our employee stock purchase plan of \$1.1 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 2015 and beyond will depend on a variety of factors, including sales of Subsys and Dronabinol SG Capsule and any additional approved products, regulatory approvals, investments in manufacturing and production such as our planned second dronabinol manufacturing facility, capital equipment, and research and development. We expect our net cash flows from operating activities to increase as we expect to increase sales of Subsys, partially offset by anticipated expansion in sales and marketing, research and development, manufacturing, and general and administrative expenses as a public company.

### ***Funding Requirements***

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

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

the levels and mix of our product sales;

the rates of progress, costs and outcomes of our clinical trials and other product development programs, including for Dronabinol Oral Solution and any other product candidates that we may develop, in-license or acquire; regulatory approvals, DEA classifications and other regulatory related events; personnel, facilities, equipment and other similar requirements; costs of operating as a public company; the effects of competing technological and market developments; costs associated with litigation and government investigations; costs 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 six months ended June 30, 2015 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 six months ended June 30, 2015, 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 June 30, 2015, \$18.9 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 \$72.1 million as of June 30, 2015, and \$48.0 million as of December 31, 2014. 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 June 30, 2015

|  | <b>Financial instruments mature during year ended:</b> |             |             |             |             |                   |
|--|--|-------------|-------------|-------------|-------------|-------------------|
|  | <b>Remainder<br/>of<br/>2015</b>                       | <b>2016</b> | <b>2017</b> | <b>2018</b> | <b>2019</b> | <b>Thereafter</b> |
| CD's and Available-for-sale securities | \$26.2   | \$27.6      | \$14.1      | \$4.2       | \$ -        | \$ -              |
| Weighted-average yield rate            | 0.08%  | 0.21%       | 0.17%       | 0.70%       | -           | -                 |

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, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

##### ***Changes in Internal Control over Financial Reporting***

There was no change in our internal control over financial reporting that occurred during the quarterly period ended June 30, 2015 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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



## **PART II OTHER INFORMATION**

### **ITEM 1. LEGAL PROCEEDINGS**

The information contained in Note 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, 2014, 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 other than as set forth below:

***Our currently marketed product, Subsys is, and any of our product candidates that receive regulatory approval will be, subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.***

Even after we achieve U.S. regulatory approval for a product, the FDA may still impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product’s approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase 4 clinical trials, to monitor the safety and efficacy of the product. We are also subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and with GCPs and GLPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In the case of Subsys, and any of our product candidates containing controlled substances, we and our contract manufacturers also are and will be subject to ongoing DEA regulatory obligations, including, among other things,

annual registration renewal, security, recordkeeping, theft and loss reporting, periodic inspection and annual quota allotments for the raw material for commercial production of our products. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP regulations, QSR requirements for medical device components or similar requirements, if applicable. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where, or processes by which, the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturer or us, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing. In that regard, because certain of our contract manufacturers for Subsys are located outside the United States, they may be subject to foreign laws and regulations governing the manufacture of drugs and devices, and any failure by them to comply with those laws and regulations may delay or interrupt supplies of our products.

If we, our products or product candidates or the manufacturing facilities for our products or product candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- impose restrictions on the marketing or manufacturing of the product, suspend or withdraw product approvals or revoke necessary licenses;
- issue warning letters, show cause notices or untitled letters describing alleged violations, which may be publicly available;
- commence criminal investigations and prosecutions;
- impose injunctions, suspensions or revocations of necessary approvals or other licenses;
- impose fines or other civil or criminal penalties;
- suspend any ongoing clinical trials;
- deny or reduce quota allotments for the raw material for commercial production of our controlled substance products;
- delay or refuse to approve pending applications or supplements to approved applications filed by us;
- refuse to permit drugs or precursor chemicals to be imported or exported to or from the United States;
- suspend or impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require us to initiate a product recall.



In addition, our product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution.

For example, we received subpoenas dated December 9, 2013 and September 8, 2014 from the U.S. Department of Health and Human Services, Office of Inspector General and the U.S. District Attorney's Office for the District of Massachusetts, respectively. The subpoenas primarily request documents relating to the marketing of Subsys. We are cooperating in responding to the subpoenas. We have also received CIDs from each of the Office of the Attorney General of the State of Arizona, Oregon Department of Justice, the Attorney General of the Commonwealth of Massachusetts and the Office of the Attorney General of Illinois. These CIDs request documents regarding Subsys, including our sales and marketing practices related to Subsys in the applicable state. 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 addition, in connection with the investigation by the ODOJ we have entered into a settlement agreement with the ODOJ, referred to as an AVC, and agreed to make monetary payments totaling approximately \$1.1 million. The AVC requires us to maintain certain controls and processes around our promotional and sales activity in Oregon, and creates affirmative obligations to comply with applicable laws. Even if we are successful in defending against, or settling, any such investigations or allegations in connection therewith, these matters would likely be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

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

Not applicable.

## **ITEM 3. DEFAULTS UPON SENIOR SECURITIES**

Not applicable.

#### **ITEM 4. MINE SAFETY DISCLOSURE**

Not applicable.

#### **ITEM 5. OTHER INFORMATION**

##### **Item 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT**

On April 30 2015, we entered into an amendment to our manufacturing and supply agreement with DPT Lakewood, LLC, which, among other things, extended our existing manufacturing and supply agreement to produce Subsys until the end of 2020 and added certain minimum purchase commitments as discussed in more detail in Note 6 to the Unaudited Condensed Consolidated Financial Statements. The information contained in Note 6 to the Unaudited Condensed Consolidated Financial Statements, with respect to this amendment, is incorporated herein by reference. The full manufacturing and supply agreement, as amended, is filed as an exhibit to this Quarterly Report on Form 10-Q and this description is qualified in its entirety by reference to this exhibit.

#### **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: August 6, 2015 By: /s/ Michael L. Babich  
Michael L. Babich  
President and Chief Executive Officer  
(Principal Executive Officer)

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

## EXHIBIT INDEX

| <b>Exhibit Number</b> | <b>Description of Document</b>  |
|-----------------------|---|
| 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)  |
| 10.1                  | Manufacturing Agreement dated as of May 24, 2011 by and between the Registrant and DPT Lakewood, LLC, as amended on October 29, 2013 and April 30, 2015 (filed herewith)                                    |
| 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.   |

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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.