Insys Therapeutics, Inc.
Form 10-Q
June 05, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2013

OR

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

For the transition period from _____ to _____

Commission file number: 001-35902

Insys Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

(602) 910-2617

(Registrant s telephone number, including area code)

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 x

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

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

Large Accelerated Filer ¨	Accelerated Filer ¨
Non-Accelerated Filer ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company x

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

As of May 23, 2013, the registrant had 21,395,227 shares of Common Stock ($0.0002145 par value) outstanding.

INSYS THERAPEUTICS, INC.

FORM 10-Q

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

(unaudited)

	March 31, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 686	$ 361
Accounts receivable	5,817	3,089
Inventories	8,178	7,095
Prepaid expenses and other assets	1,046	1,344
Total current assets	15,727	11,889
Property and equipment, net	6,467	6,791
Other assets	37	61
Total assets	$ 22,231	$ 18,741
LIABILITIES AND STOCKHOLDERS DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	$ 7,452	$ 5,971
Accrued compensation	2,163	1,392
Other current liabilities	508	508
Deferred patient discount program	1,591	1,540
Deferred revenue	3,614	3,767
Line of credit	11,358	11,858
Notes payable to related party, including interest	59,021	58,383
Total current liabilities	85,707	83,419
Total liabilities	85,707	83,419
Commitments and contingencies (see Note 7)		
Stockholders Deficit:		
Convertible preferred stock (par value $0.01 per share, 15,000,000 shares authorized, 14,864,607 shares issued and outstanding as of March 31, 2013 and December 31, 2012)	149	149
Common stock (par value $0.0002145 per share, 25,000,000 shares authorized; 856,026 shares issued and outstanding as of March 31, 2013 and December 31, 2012)		
Additional paid in capital	65,663	64,604
Notes receivable from stockholders	(21)	(21)
Accumulated deficit	(129,267)	(129,410)
Total stockholders deficit	(63,476)	(64,678)
Total liabilities and stockholders deficit	$ 22,231	$ 18,741

See accompanying notes to unaudited condensed consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

(In thousands, except share and per share data)

(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Net revenue	$ 11,059	$ 2,026
Cost of revenue	1,764	1,278
Gross profit	9,295	748
Operating expenses:		
Sales and marketing	4,423	2,404
Research and development	1,690	2,832
General and administrative	2,362	1,479
Total operating expenses	8,475	6,715
Income (loss) from operations	820	(5,967)
Other expense, net	(4)	(82)
Interest expense	(673)	(638)
Income (loss) before income taxes	143	(6,687)
Income tax benefit		
Net and comprehensive income (loss)	$ 143	$ (6,687)
Net income (loss) allocable to preferred stockholders	$ 130	$ (6,123)
Net income (loss) allocable to common stockholders	$ 13	$ (564)
Net income (loss) per common share:		
Basic	$ 0.02	$ (0.72)
Diluted	$ 0.01	$ (0.72)
Weighted average common shares outstanding:		
Basic	856,026	786,026
Diluted	1,937,891	786,026

See accompanying notes to unaudited condensed consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(unaudited)

	Three Months Ended March 31,	
	2013	**2012**
Cash flows from operating activities:		
Net income (loss)	$ 143	$ (6,687)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	429	433
Stock-based compensation	1,059	647
Interest expense accrued on notes payable	638	633
Accretion of contingent payment obligation		70
Changes in assets and liabilities:		
Accounts receivable	(2,727)	(2,307)
Inventories	(1,083)	(1,340)
Prepaid expenses and other assets	321	155
Accounts payable, accrued expenses, and other current liabilities	2,150	1,125
Net cash provided by (used in) operating activities	930	(7,271)
Cash flows from investing activities:		
Purchase of property and equipment	(105)	(328)
Net cash used in investing activities	(105)	(328)
Cash flows from financing activities:		
Proceeds (repayments) under line of credit	(500)	4,674
Proceeds from notes payable to related party		2,987
Proceeds from exercise of stock options		9
Net cash provided by (used in) financing activities	(500)	7,670
Net increase in cash and cash equivalents	325	71
Cash and cash equivalents, beginning of period	361	11
Cash and cash equivalents, end of period	$ 686	$ 82

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 its subsidiaries (collectively, Insys or the Company) maintain headquarters in Chandler, Arizona. The Company was in the development stage through December 31, 2011. The year 2012 is the first year during which the Company is considered an operating company and is no longer in the development stage.

Insys is a specialty pharmaceutical company that develops and commercializes innovative supportive care products. The Company launched its first two products in the United States in 2012: Subsys, a proprietary sublingual fentanyl spray for breakthrough cancer pain in opioid-tolerant patients and Dronabinol SG Capsule, a generic equivalent to Marinol, an approved second-line treatment for chemotherapy-induced nausea and vomiting and anorexia associated with weight loss in patients with AIDS.

The accompanying condensed consolidated financial statements include the accounts of the Company. All significant intercompany balances and transactions have been eliminated in the accompanying condensed consolidated financial statements.

The accompanying condensed consolidated financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles, pursuant to rules and regulations of the Securities and Exchange Commission (the SEC). Certain information and footnote disclosures have been condensed or omitted pursuant to such rules and regulations. In the opinion of management, the accompanying condensed consolidated financial statements include normal recurring adjustments that are necessary for a fair presentation of the results for the interim periods presented. These condensed consolidated financial statements should be read in conjunction with the Company s audited consolidated financial statements and notes thereto for the fiscal year ended December 31, 2012 included in the Company s final prospectus supplement filed with the SEC on May 2, 2013 and related to the Company s Registration Statement on Form S-1/A (File No. 333-173154). The results of operations for the three months ended March 31, 2013 are not necessarily indicative of results to be expected for the full fiscal year or any other period.

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, the Company evaluates its estimates, including those related to prescriptions dispensed, wholesaler discounts, patient discount programs, rebates and chargebacks, bad debts, inventories, deferred income taxes, stock-based compensation expenses, and contingencies and litigation. The Company bases its estimates on historical experience and on various other assumptions that are believed by management to be reasonable under the circumstances. Actual results may differ from these estimates.

Recent Accounting Pronouncements

In February 2013, the Financial Accounting Standards Board (FASB) issued guidance that requires entities to present information about reclassification adjustments from accumulated other comprehensive income in their financial statements or footnotes. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2012. The Company adopted this guidance in the first interim period for the fiscal year ending December 31, 2013 and, as the Company had no accumulated other comprehensive income as of March 31, 2013, there was no material impact on its financial position, results of operations or cash flows as of or for the period ended March 31, 2013, nor does the Company expect the adoption to have a material impact on its financial position, results of operations or cash flows as of the end of or for the full year.

2. Fair Value of Financial Instruments

The carrying values of the Company s financial instruments, including, cash, accounts receivable, accounts payable and short-term debt approximate their fair value due to the short term nature of these financial instruments. Based on the borrowing rates currently available to the Company for loans with similar terms, the fair value of long-term debt approximates its carrying value. The Company did not have financial assets or liabilities that are measured at fair value on a recurring basis as of March 31, 2013 and December 31, 2012.

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

the inputs used in measuring fair value as follows:

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

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

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

3. Revenue Recognition

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

Subsys

Subsys was commercially launched in March 2012, and is available through a U.S. Food and Drug Administration (FDA) mandated Risk Evaluation and Mitigation program known as the Transmucosal Immediate Release Fentanyl program (TIRF REMS). The Company sells Subsys in the United States to wholesale pharmaceutical distributors, and on a very limited basis directly to retail pharmacies, or collectively the Company s customers, subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. Subsys currently has a shelf life of 36 months from the date of manufacture. Given the limited sales history of Subsys, the Company currently cannot reliably estimate expected returns of the product at the time of shipment. Accordingly, the Company defers recognition of revenue on product shipments of Subsys until the right of return no longer exists, which occurs at the earlier of the time Subsys units are sold to healthcare facilities or dispensed through patient prescriptions, or expiration of the right of return. Units dispensed are generally not subject to return, except in the rare cases where the product malfunctions or the product is damaged in transit. The Company estimates patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. If this third-party data underestimates or overestimates actual patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

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

The Company recognizes 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 the Company s 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, the Company recognizes the cost of patient discounts as a reduction of revenue based on estimated utilization. If actual future results vary, the Company may need to adjust these estimates, which could have an effect on product revenue in the period of adjustment. The Company s product sales allowances include:

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

Prompt Pay Discounts. The Company offers cash discounts to its customers, generally 2.0% of the sales price, as an incentive for prompt payment. The Company accounts for cash discounts by reducing accounts receivable by the full amount and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Stocking Allowances. The Company may offer discounts and extended payment terms, generally in the month of the initial commercial launch of a new product and on the first order made by certain wholesale distributors and retail pharmacies based on contractually determined rates. The Company accrues the discount as a reduction of receivables due from the wholesalers upon shipment to the respective wholesale distributors and retail pharmacies and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

Patient Discount Programs. The Company offers discount card programs to patients for Subsys in which patients receive discounts on their prescriptions that are reimbursed by the Company to the retailer. The Company estimates the total amount that will be redeemed based on a percentage of actual redemption applied to inventory in the distribution and retail channel and recognizes the discount as a reduction of revenue in the same period the related revenue is recognized.

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Rebates. The Company participates in certain rebate programs, which provide discounted prescriptions to qualified insured patients. Under these rebate programs, the Company pays 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. The Company estimates and accrues these rebates based on current contract prices, historical and estimated future percentages of products sold to qualified patients and estimated levels of inventory in the distribution channel. Rebates are recognized as a reduction of revenue in the period the related revenue is recognized.

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

Dronabinol SG Capsule

Dronabinol SG Capsule was commercially launched in December 2011, and the Company sells 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, the Company manufactures Dronabinol SG Capsule under the Mylan label. Mylan distributes Dronabinol SG Capsule and on a monthly basis pays the Company 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, the Company is 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. The Company bears 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 the Company ships such products to Mylan. Accordingly, the Company recognizes revenue upon Mylan s sale of products to wholesale distributors, which is the point at which the sales price is fixed and determinable.

4. Inventories

Inventories, net are stated at lower of cost or market. Cost, which includes amounts related to materials and costs incurred by the Company s 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 it expects to obtain for products in their respective markets compared with historical cost and the remaining shelf life of goods on hand.

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

	March 31, 2013	December 31, 2012
Finished goods	$ 4,136	$ 2,221
Work-in-process	1,284	1,731
Raw materials and supplies	2,340	2,597
Deferred costs	418	546
Total inventories	$ 8,178	$ 7,095

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

As of March 31, 2013 and December 31, 2012, raw materials inventories consisted of raw materials used in the manufacture of the Company s active pharmaceutical ingredient (API) in its U.S.-based, state-of-the-art dronabinol manufacturing facility and component parts used in the manufacture of Subsys. Work-in-process consisted of actual production costs, including facility overhead and tolling costs of in-process Dronabinol SG Capsule and Subsys products. Finished goods inventories consisted of finished Dronabinol SG Capsule and Subsys products.

5. Line of Credit

In February 2012, the Company entered into a $15,000,000 revolving credit facility (the Facility) with Bank of America, N.A. (the Agent), which includes a $2,000,000 letter of credit facility. Under the terms of the Facility, amounts outstanding bear interest at the Company s election at (a) LIBOR plus 1.0% or (1.21% as of March 31, 2013) or (b) British Bankers Association Rate (BBA) LIBOR Daily Floating Rate plus 1.0%, which is a fluctuating rate of interest based on the BBA LIBOR Rate for U.S. dollar deposits for delivery on the date in question for a one month term beginning on that date. The Facility was scheduled to mature in February 2013 and is secured by The Kapoor Trust Letter of Credit issued by the Agent, with the John N. Kapoor Trust (The JNK Trust) as applicant. Dr. Kapoor is the Company s founder, Executive Chairman and

principal stockholder. The Company had an outstanding balance of $11,358,000 and $11,858,000 against the line of credit as of March 31, 2013 and December 31, 2012, respectively. The line of credit is subject to covenants. The Company believes that it was in material compliance with the covenants as of March 31, 2013. In February 2013, the Facility was amended to extend its maturity date to February 2014.

On May 10, 2013, the outstanding principal balance of $11,358,000 was paid in full.

6. Notes Payable to a Related Party

The Company has issued several promissory and demand notes (Kapoor Notes) payable in favor of a trust controlled by Dr. Kapoor, The JNK Trust, and a trust affiliated with Dr. Kapoor, the Kapoor Children 1992 Trust. Prior to completing its initial public offering on May 7, 2013, the Company drew on the Kapoor Notes as needed to pay its expenses. The Kapoor Notes carried interest at the prime rate plus 2.0% (5.25% as of March 31, 2013). The following is a summary of the Kapoor Notes that were outstanding as of March 31, 2013.

From 2002 to 2012, the Company issued a series of promissory and demand notes payable totaling $73,391,000 in favor of The JNK Trust and the Kapoor Children 1992 Trust. In 2008, the Company repaid approximately $3,141,000 of these notes. Additionally, a portion of the Kapoor Notes were converted into equity in 2008 and 2009. The JNK Trust also agreed to fund the Company on an as-needed basis through the earlier of March 31, 2014 or upon successful completion of an offering of common stock. The outstanding principal approximated $36,326,000 as of March 31, 2013. The Company had not repaid the principal or interest accrued on the Kapoor Notes as of March 31, 2013. Although by their terms the Kapoor Notes were payable on demand, the JNK Trust and the Kapoor Children 1992 Trust each agreed not to require the Company to repay any outstanding indebtedness under the Kapoor Notes until the earlier of March 31, 2014 or upon successful completion of a public offering.

In addition to the above, the Company issued a promissory note payable for $12,300,000 in favor of The JNK Trust on October 11, 2005. The principal and interest were due upon maturity, which was October 11, 2010. The Company had not repaid the principal or interest accrued on this note as of March 31, 2013. Although by its terms this note was payable on demand, the JNK Trust agreed not to require the Company to repay any outstanding indebtedness under this note until the earlier of March 31, 2014 or upon successful completion of a public offering.

Total interest accrued on these notes approximated $10,395,000 and $9,757,000 as of March 31, 2013 and December 31, 2012, respectively. Interest expense was approximately $638,000 and $633,000 for the three months ended March 31, 2013 and 2012, respectively.

The balance payable on these notes, including interest, was approximately $59,021,000 and $58,383,000 as of March 31, 2013 and December 31, 2012, respectively.

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

7. Contingencies

NeoPharm Contingent Consideration

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

In connection with the NeoPharm merger, the NeoPharm board approved the distribution, immediately after the NeoPharm merger, of non-transferable contingent payment rights to its stockholders of record as of November 5, 2010. These rights entitle the pre-NeoPharm merger stockholders of NeoPharm to receive cash payments aggregating $20,000,000 (equivalent to $0.70402 per share) if, prior to the five-year anniversary of the NeoPharm merger, the FDA approves a New Drug Application for any one or more of the NeoPharm product candidates that were under development at the time of the NeoPharm merger. The distribution is payable within nine months of FDA approval. The initial fair value of this contingent payment was determined to be approximately $1,829,000 based on the assumed probability of any payment being made to the prior NeoPharm stockholders in 2015, discounted to present value at a rate of 15%, a Level 3 fair value measurement. Changes in estimated fair value representing an increase of $285,000 during the year ended December 31, 2011, and an increase of $210,000 during 2012 through September 2012 (including $70,000 through March 31, 2012) were recorded in other expense.

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

Legal Matters

In September 2009, Insys Pharma and certain of its officers and directors, as well as their spouses, were named as defendants in a lawsuit in Arizona Superior Court brought by Santosh Kottayil, Ph.D., certain of his family members and a trust of which Dr. Kottayil is the trustee. Dr. Kottayil formerly served as President, Chief Scientific Officer and a director of Insys Pharma, among other positions. The complaint brought a cause of action for statutory and common law appraisal of Dr. Kottayil s Insys Pharma common stock. The cause of action for appraisal relates to a one-for-1,500,000 reverse stock split that Insys Pharma effected in June 2009, which resulted in Dr. Kottayil s ownership position becoming a fractional share of Insys Pharma common stock. Following the reverse stock split, Insys Pharma cancelled all resulting fractional shares, including the fractional share held by Dr. Kottayil, and offered a cash payment in lieu of the fractional shares. The complaint also states causes of action for breach of fiduciary duty and negligent misrepresentation in the defendants dealings with Dr. Kottayil on the subject of his compensation and stock ownership in Insys Pharma. In January 2010, the plaintiffs added claims seeking to rescind Dr. Kottayil s assignment to Insys Pharma of his interest in all of the fentanyl and dronabinol patent applications the Company owns and to recover the benefits of those interests. Dr. Kottayil is seeking, among other relief, the fair value of his Insys Pharma common stock as of June 2, 2009, compensatory and punitive damages, and rescission of all assignments to Insys Pharma of his interest in the patent applications, as well as attorneys fees, costs and interest.

In February 2010, Insys Pharma and the other defendants answered and filed counter-claims to Dr. Kottayil s amended complaint. The counter-claims include actions for breach of fiduciary duty, fraud and negligence with respect to the time during which Dr. Kottayil was employed at Insys Pharma. The counter-claims, among other relief, seek compensatory and punitive damages. Discovery is ongoing and a trial has been scheduled to commence in October 2013. The Company is not able at this time to estimate the range of potential loss or any potential recovery from the counter-claims, nor is it able to predict the outcome of this litigation. If the patent assignments are successfully rescinded, the Company will not have exclusive patent rights covering its fentanyl and dronabinol product candidates, and such exclusive patent rights may not be available to the Company on acceptable terms, if at all, which would have a material adverse effect on the Company s business. If the assignments are rescinded, Dr. Kottayil could assign his interest in the fentanyl and dronabinol patent applications to a competitor and the Company would not be able to prevent generic copies of its products. The Company intends to vigorously defend against the plaintiffs claims and pursue its counter-claims.

8. Stock-based Compensation

The Company currently has the following stock-based incentive plans:

2013 Employee Stock Purchase Plan

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

2013 Equity Incentive Plan

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

2006 Equity Incentive Plan

The Company s 2006 Equity Incentive Plan (the 2006 Plan) provided for the grant of stock awards, including stock options, restricted stock, stock appreciation rights, performance units, performance shares and other stock awards, to the Company s employees, directors and consultants. The 2006 Plan was adopted in April 2006. As of March 31, 2013, options to purchase 1,139,158 shares of common stock were outstanding. The 2006 Plan has been terminated and Company will not grant additional equity awards under the 2006 Plan.

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

Insys Pharma, Inc. Amended and Restated Equity Incentive Plan

Insys Pharma s Amended and Restated Equity Incentive Plan (the Plan) provided for the grant of stock options to employees, directors and consultants to acquire Insys Pharma s voting and non-voting common stock. The Plan was originally adopted by Insys Pharma in December 2002 and was amended and restated in June 2006. In connection with the NeoPharm merger in November 2010, all of the outstanding options granted under the Plan were assumed by the Company and were converted into options to purchase shares of the Company s common stock at the exchange ratio set forth in the merger agreement. As of March 31, 2013, vested options to purchase an aggregate of 944,537 shares of the Company s common stock under the Plan were outstanding. There were no unvested options outstanding under the Plan as of March 31, 2013. The Plan has been terminated and the Company will not grant additional equity awards under the Plan.

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

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

	Three Months Ended March 31,	
	2013	2012
Research and development	$ 285	$ 264
General and administrative	774	383
Total cost of stock-based compensation	$ 1,059	$ 647

As of March 31, 2013, the Company expected to recognize $10,108,000 of stock-based compensation for its outstanding options over a weighted-average period of 2.6 years.

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

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in millions)
Vested and exercisable as of December 31, 2012	1,228,396	$ 2.78	7.43	$ 2.8
Outstanding as of December 31, 2012	2,091,195	$ 3.22	8.24	$ 12.4
Granted		$		
Cancelled	(7,500)	$ 3.10		
Exercised		$		
Outstanding as of March 31, 2013	2,083,695	$ 3.22	7.99	$ 12.3

Vested and exercisable as of March 31, 2013	1,318,520	$ 2.85	7.30	$	3.8

9. Net Income (Loss) per Share

The Company computes the net income (loss) per common share using the two-class method as its convertible preferred shares meet the definition of a participating security and thereby share in the net income or loss of the Company on a ratable basis with the common stockholders. The convertible preferred shares portion of the net income (loss) for the three months ended March 31, 2013 and 2012 was 90.9% and 91.6%, respectively. Basic net income (loss) per common share is computed

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

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

	Three Months Ended March 31,	
	2013	2012
Historical net income (loss) per share Basic:		
Numerator:		
Net income (loss) allocable to common stockholders	$ 13	$ (564)
Denominator:		
Weighted average number of common shares outstanding	856,026	786,026
Basic net income (loss) per common share	$ 0.02	$ (0.72)
Historical net income (loss) per share Diluted:		
Numerator:		
Net income (loss) allocable to common stockholders	$ 13	$ (564)
Denominator:		
Weighted average number of common shares outstanding	856,026	786,026
Effect of dilutive stock options	1,081,865	
	1,937,891	786,026
Diluted net income (loss) per common share	$ 0.01	$ (0.72)

As the Company incurred a net loss for the three months ended March 31, 2012, basic and diluted per share amounts are the same, since the effect of potential common share equivalents is anti-dilutive. Anti-dilutive share equivalents included 14,120 and 1,775,157 outstanding stock options as of March 31, 2013 and 2012, respectively.

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

The Company is engaged in the business of developing and selling pharmaceutical products. The Company has two product lines, consisting of Subsys and Dronabinol SG Capsule. The Company s chief operating decision-maker evaluates revenues based on product lines.

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

	Net Revenue by Product Line Three Months Ended March 31,	
	2013	2012
Subsys	$ 9,695	$ 13
Dronabinol SG Capsule	1,364	2,013
Total net revenue	$ 11,059	$ 2,026

	% of Revenue by Route to Market Three Months Ended March 31,	
	2013	2012

Pharmaceutical wholesalers	88%	1%
Generic pharmaceutical distributor	12%	99%
	100%	100%

All the Company s products are sold in the United States of America.

Three wholesalers accounted for 27%, 25% and 22% of net revenue for the three months ended March 31, 2013. One generic pharmaceutical distributor accounted for 99% of net revenue for the three months ended March 31, 2012. Three wholesalers accounts receivable balances accounted for 25%, 23% and 21% of accounts receivable as of March 31, 2013. Three wholesalers accounts receivable balances accounted for 34%, 22% and 21% of accounts receivable as of December 31, 2012.

11. Subsequent Events

Authorized Share Capital

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

Initial Public Offering

On May 7, 2013, the Company completed its initial public offering (IPO), whereby the Company sold a total of 4,600,000 shares of common stock at $8.00 per share for net proceeds of $30,960,000 (after underwriting discounts and commissions and estimated offering costs). This amount included the full exercise of an option to purchase 600,000 shares of common stock by the Company s underwriters. Upon completion of the IPO, all outstanding shares of the Company s convertible preferred stock were converted into 8,528,860 shares of common stock and all Kapoor Notes totaling $59,282,000 converted into 7,410,341 shares of common stock.

The financial statements as of March 31, 2013 and 2012, including share and per share amounts, do not include the effects of the IPO.

Pro Forma Balance Sheet

The balance sheet data below show, on a pro forma basis, the impact on certain balance sheet items of the significant debt and equity transactions which occurred since March 31, 2013 through May 10, 2013. Specifically, the pro forma balance sheet data give effect to the following in connection with the completion of the IPO on May 7, 2013: (i) the conversion of all of the Company s outstanding shares of convertible preferred stock into an aggregate of 8,528,860 shares of common stock, (ii) the sale of 4,600,000 shares of common stock at a price to the public of $8.00 per share in the IPO, net of underwriting discounts and offering costs, (including $483,000 of such costs paid by March 31, 2013 and previously reflected as other current assets), (iii) the issuance of 7,410,341 shares of common stock pursuant to the conversion of the outstanding amounts owed under the Kapoor Notes, and (iv) the repayment of the outstanding principal balance of $11,358,000 on the line of credit with Bank of America, N.A. on May 10, 2013.

	As of March 31, 2013	
	Actual	Pro Forma
	(unaudited)	
	(in thousands)	
Balance Sheet Data:		
Cash and cash equivalents	$ 686	$ 20,288
Total current assets	15,727	34,846
Total assets	22,231	41,349
Total current liabilities, including debt	85,707	15,328
Total liabilities	85,707	15,328
Total stockholders equity (deficit)	(63,476)	26,021

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto as of and for the year ended December 31, 2012 and the related Management s Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our final prospectus filed with the Securities and Exchange Commission (SEC) on May 2, 2013 relating to our Registration Statement on Form S-1/A (File No. 333-173154) for our initial public offering.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the Exchange Act), which are subject to the safe harbor created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words anticipates, believes, estimates, expects, intends, may, plans, projects, will, would and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item IA, Risk Factors in this Quarterly Report on Form 10-Q and in our other filings with the SEC. 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.

Overview

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

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

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

We market Subsys through our U.S.-based field sales force focused on supportive care, which numbered approximately 67 sales professionals as of March 31, 2013. Our commercial organization utilizes an incentive-based sales model that employs a pay structure where a significant component of the compensation paid to sales representatives is in the form of potential bonuses based on sales performance.

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

In addition, we are developing other product candidates, such as dronabinol line extensions and sublingual spray product candidates. Our most advanced potential dronabinol line extension is Dronabinol Oral Solution. This product candidate has demonstrated more rapidly detectable blood levels and a more reliable absorption profile than Marinol in our clinical studies. We believe these attributes may ultimately increase patient compliance because of more rapid onset of action and less dose-to-dose variability, which we believe will allow us to further penetrate and potentially expand the market for the medical use of dronabinol. We completed a pre-NDA meeting with the FDA and a pivotal

bioequivalence study for Dronabinol Oral Solution in 2012 and expect to submit an NDA for Dronabinol Oral Solution in the second half of 2013.

Factors Affecting Our Performance

We believe that our performance and future success are dependent upon a number of factors, including our approved product sales, investments in our infrastructure and growth, and our ability to successfully develop product candidates and complete related regulatory processes. While each of these areas presents significant opportunities for us, they also pose significant risks and challenges that we must successfully address. See the section entitled Risk Factors.

Approved Product Sales. Our operating results will depend significantly upon our, and any of our third-party distributors , sales of approved products. During the three months ended March 31, 2012 and 2013, all of our net revenues were generated from the sale of our two approved products, Subsys and Dronabinol SG Capsule. Our results will depend on prescription volume generally, which we believe will be driven primarily by achievement of broad market acceptance and coverage by third-party payors and effectiveness of the marketing and selling efforts with respect to our products. In addition, our results will also depend on our mix of sales between Subsys and Dronabinol SG Capsule as well as the amounts of dosage strengths sold. Subsys gross margins are substantially higher than those of Dronabinol SG Capsule. For example, though we expect gross margins to fluctuate from period to period, Subsys gross margin was approximately 89% and Dronabinol SG Capsule gross margin was approximately 52% for the three months ended March 31, 2013. Moreover, our gross margins improve on a unit-by-unit basis as we sell higher dosage strengths of our products. Importantly, the proportion of prescriptions written for repeat Subsys patients has continued to increase since July 2012 from 50% of prescriptions to over 70% of prescriptions as of March 2013. Generally, repeat Subsys patients receive significantly higher doses of Subsys on average than first-time patients as patients are titrated from a starter dose of Subsys to their effective dose in accordance with the TIRF REMS protocol. In addition, we currently defer recognition of revenue on product shipments of Subsys to our customers until the right of return no longer exists, which occurs at the earlier of the time Subsys units are sold to healthcare facilities or dispensed through patient prescriptions, or expiration of the right of return. We estimate patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. If this third-party data underestimates or overestimates actual patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

Investments in Our Infrastructure and Growth. Our ability to increase our sales and to further penetrate our target market segments is dependent in part on our ability to invest in our infrastructure and in our sales and marketing efforts. In order to drive further growth, we may hire additional sales and marketing personnel and invest in marketing our products to our target physician prescriber base. For example, in March 2013, we added 17 sales professionals to enhance our commercial infrastructure. This will lead to corresponding increases in our operating expenses, although we anticipate that these investments will result in increased product sales and net revenue. In addition, we plan to build a second dronabinol manufacturing facility, which we anticipate will supply us with sufficient commercial quantities of dronabinol API for our continued commercialization of Dronabinol SG Capsule and for the commercialization of our proprietary dronabinol product candidates, if approved. We expect the capital expenditures associated with the completion of our planned second dronabinol manufacturing facility will be approximately $11.0 million to $13.0 million. This second facility will also increase our operating expenses. We will also incur substantial operating costs in connection with our transition to operating as a public company, including increasing headcount and salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors and officers insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

Product Development and Related Regulatory Processes. Our operating results will also depend significantly on our research and development activities and related regulatory developments. Our research and development expenses were $1.7 million and $2.8 million for the three months ended March 31, 2013 and 2012, respectively. As of March 31, 2013, we had 17 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary dronabinol product candidates, including Dronabinol Oral Solution, and sublingual spray product candidates. For example, we estimate that our research and development expenses to complete the development of, and obtain FDA approval for, Dronabinol Oral Solution will be approximately $2.7 million. We do not expect to realize net revenues from all of these research and development initiatives in the near term and may never realize net revenues from these investments. Due to the risks inherent in conducting preclinical studies and clinical trials, the regulatory approval process and the costs of preparing, filing and prosecuting patent applications, our development completion dates and costs will vary significantly for each product candidate and are very difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals or acceptable U.S. Drug Enforcement Administration (DEA) classifications for our product candidates, in particular those related to Dronabinol Oral Solution, could cause our research and development expenditures to increase significantly and, in turn, have a material adverse effect on our results of operations.

Recent Developments

On May 7, 2013, we completed our IPO, whereby we sold a total of 4,600,000 shares of common stock at $8.00 per share for net proceeds of $31.0 million (after underwriting discounts and commissions and estimated offering costs). This amount included the full exercise of the option to purchase 600,000 shares of our common stock by our underwriters.

Upon completion of our IPO, all outstanding shares of our convertible preferred stock were converted into 8,528,860 shares of common stock and all outstanding Kapoor Notes converted into 7,410,341 shares of common stock.

On May 10, 2013, we repaid in full the outstanding principal balance of $11.4 million on our line of credit facility with Bank of America, N.A. As a result, we have the full $15.0 million under the credit facility available for borrowing.

Basis of Presentation

Net Revenue

During the three months ended March 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, our customers, at a wholesale acquisition cost. Sales to our customers are subject to specified rights of return. We currently defer recognition of revenue on product shipments of Subsys to our customers until the right of return no longer exists, which occurs at the earlier of the time Subsys units are sold to healthcare facilities or dispensed through patient prescriptions, or expiration of the right of return. We estimate patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. If this third-party data underestimates or overestimates actual patient prescriptions dispensed for a given period, adjustments to revenue may be necessary in future periods.

As a result of this policy, the deferred revenue balance was $3.6 million and $3.8 million at March 31, 2013 and December 31, 2012, respectively, for Subsys product shipments, which is net of estimated pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs. We will continue to recognize revenue upon the earlier to occur of prescription units dispensed or expiration of the right of return until we can reliably estimate product returns, at which time we will record a one-time increase in net revenue related to the recognition of revenue previously deferred, partially offset by an estimate of product returns.

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

Cost of Revenue, Gross Profit and Gross Margin

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

The cost of revenue associated with the deferred product revenues are recorded as deferred costs, which are included in inventories until such time as the deferred revenue is recognized. Deferred cost of revenue was $418,000 and $546,000 as of March 31, 2013 and December 31, 2012, respectively.

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

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries, benefits, consulting fees, costs of obtaining prescription and market data, and market research studies related to Subsys. As of March 31, 2013, we had 70 full-time sales and marketing personnel. We expect the number of our sales and marketing personnel to increase as we seek to continue to increase our existing product sales and as any subsequently approved products are commercialized. We expect our sales and marketing expenses, along with our research and development expenses, to be our largest categories of operating expenses for the foreseeable future. In addition, because we use an incentive-based compensation model for our sales professionals, we expect our sales and marketing expenses to fluctuate from period to period based on changes in Subsys net revenue. Specifically, we expect our sales and marketing expenses to increase in 2013 to the extent that expected increases in Subsys net revenue are realized.

Research and Development Expenses

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

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

To date, our research and development efforts have been focused primarily on our fentanyl and dronabinol programs. As of March 31, 2013, we had 15 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 anticipate determining which research and development projects to pursue as well as the level of funding available for each project based on the scientific and preclinical and clinical results of each product candidate and related regulatory action. We expect our research and development expenses, along with our sales and marketing expenses, to be our largest categories of operating expenses for the foreseeable future.

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development and internal support functions. In addition, general and administrative expenses include facility costs not otherwise included in research and development expenses, and professional fees for legal, consulting and accounting services. As of March 31, 2013, we had 12 full-time general and administrative personnel. We expect general and administrative expense to increase as a result of increasing related headcount, expanding our operating activities and the costs we will incur operating as a public company. We expect these increases to include salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors and officers insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

Other Expense, Net

In connection with the NeoPharm merger, the NeoPharm board approved the distribution, immediately after the merger, of non-transferable contingent payment rights to its stockholders of record as of November 5, 2010. These rights entitle the pre-merger stockholders of NeoPharm to receive cash payments aggregating $20.0 million (equivalent to $0.70402 per share) if, prior to the five year anniversary of the NeoPharm merger, the FDA approves an NDA for any one or more of the NeoPharm product candidates that were under development at the time of the merger. The distribution is payable within nine months of FDA approval. The initial fair value of this contingent payment was determined to be approximately $1.8 million based on the assumed probability of any payment being made to the prior NeoPharm stockholders in 2015, discounted to present value at a rate of 15%, a Level 3 fair value measurement. Changes in estimated fair value representing an increase of $70,000 during the three months ended March 31, 2012 were recorded in other expense.

In October 2012, in connection with our analysis of impairment of IPR&D, we determined it was not probable that the contingent consideration would be paid. Accordingly, a decrease in the estimated fair value of contingent consideration of $2.3 million was recorded as other income.

Interest Expense

Interest expense has consisted primarily of the interest accrued on outstanding promissory notes payable to The John N. Kapoor Trust and the Kapoor Children 1992 Trust. These trusts are controlled by or are affiliated with our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor. These promissory notes carried interest rates equal to the applicable

prime rate plus 2.0%, which was 5.25% as of March 31, 2013. As of March 31, 2013, we had $59.0 million in debt owed to these trusts, including accrued interest of $10.4 million, all of which was payable on demand as of March 31, 2013. We recorded interest expense of $638,000 and $633,000 related to accrued interest on these notes during the three months ended March 31, 2013 and 2012, respectively. Upon completion of our IPO in May 2013, all outstanding principal and accrued interest on the Kapoor Notes converted into 7,410,341 shares of common stock and all of the Kapoor Notes were cancelled.

During the year ended December 31, 2012, we entered into a $15.0 million revolving credit facility with Bank of America. The outstanding principal balance under this facility was $11.4 million as of March 31, 2013 and we recorded interest expense of $35,000 during the three months ended March 31, 2013 in connection with borrowings under this credit facility. This balance was paid off on May 10, 2013 with proceeds from the IPO.

Income Tax Benefit, Net Operating Loss Carryforwards

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

As of March 31, 2013, we had federal and state net operating loss carry forwards (NOLs) of approximately $301.0 million and $288.0 million, respectively. For federal tax purposes, the NOLs began expiring in 2011 and will continue expiring to the extent they are not utilized. For state tax purposes, the NOLs will begin expiring in 2017 if not utilized.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of NOLs that can be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period as determined under the Code, which we refer to as an ownership change. Any such annual limitation may significantly reduce the utilization of these NOLs before they expire. Our ability to utilize federal NOLs created prior to the NeoPharm merger is significantly limited. Prior to the NeoPharm merger, NeoPharm had completed a partial analysis of ownership changes under Section 382 of the Code to determine if a change in control had occurred. Based on this partial analysis, no change in control was identified. A complete formal analysis of ownership change would have to be performed in order to obtain certainty that a change in control had not occurred prior to the merger, which could further limit the utilization of our pre-merger NOLs.

Based on the above, we have estimated the amount of pre-NeoPharm merger federal NOLs that are available to offset post-NeoPharm merger income are limited to approximately $158,000 per year for 20 years, or cumulatively $3.0 million as of March 31, 2013. Post-NeoPharm merger, federal NOLs of approximately $27.0 million are not subject to this annual limitation and begin expiring in 2030.

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

Significant Accounting Polices and Estimates

There were no changes in our significant accounting policies and estimates during the three months ended March 31, 2013 from those set forth in Significant Accounting Policies and Estimates in our final prospectus filed with the SEC on May 2, 2013 relating to our Registration Statement on Form S-1/A (File No. 333-173154) for our IPO.

Results of Operations

Comparison of three months ended March 31, 2013 to three months ended March 31, 2012

The following table presents certain selected consolidated financial data for the three months ended March 31, 2013 and 2012 expressed as a percentage of net revenue:

	Three Months Ended March 31,	
	2013	2012
Net revenue	100.0%	100.0%
Cost of revenue	16.0%	63.1%
Gross profit	84.0%	36.9%
Operating expenses:		
Sales and marketing	40.0%	118.7%
Research and development	15.3%	139.8%
General and administrative	21.4%	73.0%
Total operating expenses	76.6%	331.4%
Income (loss) from operations	7.4%	-294.5%
Other expense, net	0.0%	-4.0%
Interest expense	-6.1%	-31.5%
Income (loss) before income taxes	1.3%	-330.1%

Net Revenue. The following table summarizes the year-over-year comparison of our consolidated revenue for the periods indicated (dollars in millions):

	Three months ended March 31,					
	2013	Percentage of Applicable Gross Revenue	2012	Percentage of Applicable Gross Revenue	Change from Prior Year	Percentage Change from Prior Year
SUBSYS:						
Gross revenue	$ 13.7		$		$ 13.7	
Provision for wholesaler discounts	(1.1)	8.1%			(1.1)	
Provision for patient discount programs	(2.1)	15.4%			(2.1)	
Provision for rebates	(0.8)	5.6%			(0.8)	
Net revenue-Subsys	9.7	70.9%			9.7	
DRONABINOL SG CAPSULE:						
Gross revenue	1.6		2.3		(0.7)	(30.4)%
Royalties and fees	(0.2)	13.8%	(0.3)	13.8 %	0.1	(33.3)%
Net revenue-Dronabinol SG Capsule	1.4	86.2%	2.0	86.2 %	(0.6)	(30.0)%
Net revenue	$ 11.1		2.0		$ 9.1	450.0 %

Net revenue increased $9.1 million to $11.1 million for the three months ended March 31, 2013, compared to $2.0 for the three months ended March 31, 2012. The increase in net revenue was primarily attributable to the increase in sales of Subsys to $9.7 million for the three months

ended March 31, 2013 compared to $0 for the three months ended March 31, 2012, as Subsys was initially marketed in March 2012. We expect net revenue from sales of Subsys to continue to increase during 2013 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix. The increase in sales of Subsys was partially offset by a decrease in sales of Dronabinol SG Capsule of $0.6 million to $1.4 million for the three months ended March 31, 2013, compared to $2.0 million for the three months ended March 31, 2012. The decrease in sales of Dronabinol SG Capsule was due primarily to the impact of reduced product supply in late 2012. We expect net revenue from sales of Dronabinol SG Capsule to be consistent on a quarterly basis during 2013.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $0.5 million to $1.8 million for the three months ended March 31, 2013 compared to $1.3 million for the three months ended March 31, 2012. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the three months ended March 31, 2013. Gross profit increased $8.5 million to $9.3 million for the three months ended March 31, 2013 compared to $0.7 million for the three months ended March 31, 2012. Gross margin for the three months ended March 31, 2013 was approximately 84% compared to approximately 37% for the three months ended March 31, 2012. The increase in gross margin was due primarily to a higher mix of sales of Subsys, which yields higher gross margins than sales of Dronabinol SG Capsule, during the three months ended March 31, 2013 compared to the three months ended March 31, 2012. Subsys gross margin was approximately 89% and 0% for the three months ended March 31, 2013 and 2012, respectively. Dronabinol SG Capsule gross margin was approximately 52% and 37% for the three months ended March 31, 2013 and 2012, respectively.

Sales and Marketing Expense. Sales and marketing expense increased $2.0 million to $4.4 million for the three months ended March 31, 2013 compared to $2.4 million for the three months ended March 31, 2012. The increase in sales and marketing expense was due primarily to variable sales compensation expense and incremental product marketing expense associated with the increase in sales of Subys, as Subsys was initially marketed in March 2012. As Dronabinol SG Capsule is marketed by Mylan, we did not incur any sales and marketing expense related to Dronabinol SG Capsule. As of March 31, 2013, we had 70 full-time sales and marketing personnel.

Research and Development Expense. Research and development expense decreased $1.1 million to $1.7 million for the three months ended March 31, 2013 compared to $2.8 million for the three months ended March 31, 2012. The decrease in research and development expense was due primarily to the completion of development of Subsys during the three months ended March 31, 2012, combined with a decline in spending during 2013 on the IPR&D programs acquired from NeoPharm.

General and Administrative Expense. General and administrative expense increased $0.9 million to $2.4 million for the three months ended March 31, 2013 compared to $1.5 million for the three months ended March 31, 2012. The increase in general and administrative expense was due primarily to costs incurred in connection with increases in administrative infrastructure to support the growth of Subsys sales combined with investments in public company infrastructure during 2013.

Other Expense, Net. Other expense, net decreased to $(4,000) for the three months ended March 31, 2013 compared to $(82,000) for the three months ended March 31, 2012. In connection with our analysis of impairment of intangible assets as of October 1, 2012, we determined it was not probable that contingent consideration in connection with the NeoPharm merger, which was originally valued at $1.8 million, would be paid. During the three months ended March 31, 2012, changes in the estimated fair value of contingent consideration of $(70,000) were recorded as other expense. As a result of the reassessment of the probability of payment of the NeoPharm contingent consideration in October 2012, no further changes to the estimated fair value of contingent consideration were recorded during the three months ended March 31, 2013.

Interest Expense. Interest expense increased to $0.7 million for the three months ended March 31, 2013 from $0.6 million for the three months ended March 31, 2012. The $0.1 million increase was primarily a result of interest incurred on the $11.4 million outstanding balance of our line of credit during the three months ended March 31, 2013. As a result of the conversion of the Kapoor Notes to common stock and the repayment of the $15.0 million line of credit in May 2013, we do not expect to record significant interest expense for the remainder of 2013 absent new borrowings.

Income Tax Benefit. In each period since our inception, we have recorded a valuation allowance for the full amount of our deferred tax asset, as the realization of the deferred tax asset is uncertain. As a result, we have not recorded any federal or state income tax benefit in our consolidated statements of comprehensive income (loss) for the three months ended March 31, 2013 and 2012.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses from our inception through December 31, 2012. As of March 31, 2013, we had an accumulated deficit of $129.3 million. We have 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. During the years ended December 31, 2012 and 2011, we received net proceeds of $3.0 million and $16.0 million, respectively, from the issuance of such promissory notes.

As of March 31, 2013, we had $59.0 million in debt, including accrued interest of $10.4 million, under the promissory notes payable to The John N. Kapoor Trust and the Kapoor Children 1992 Trust, and $0.7 million in cash and cash equivalents. Upon the closing of our IPO on May 7, 2013, all principal indebtedness and accrued interest under these notes and other notes issued by us to trusts controlled by or affiliated with Dr. Kapoor converted into 7,410,341 shares of our common stock at the $8.00 per share offering price.

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During 2012, we entered into a $15.0 million revolving credit facility with Bank of America, which includes a $2.0 million letter of credit facility, which we established primarily to fund our working capital requirements. Under the terms of this credit facility, amounts outstanding bear interest at our election at (a) LIBOR plus 1.0% or (1.21% as of March 31, 2013) or (b) British Bankers Association Rate (BBA) LIBOR Daily Floating Rate plus 1.0%, which is a fluctuating rate of interest based on the BBA LIBOR Rate for U.S. dollar deposits for delivery on the date in question for a one month term beginning on that date. This credit facility is secured by The Kapoor Trust Letter of Credit issued by Bank of America, with the John N. Kapoor Trust as applicant. We had an outstanding balance of $11.4 million and $3.6 million in available borrowings against the line of credit as of March 31, 2013. The line of credit is subject to covenants, and as of March 31, 2013 we believe we were in material compliance with such covenants. On May 10, 2013, the outstanding principal balance of $11.4 million was paid in full using proceeds from the IPO, and $15 million was available for borrowings against the line of credit.

On May 7, 2013, we completed our IPO, pursuant to which we sold 4,600,000 shares of our common stock at a price of $8.00 per share, which included the underwriters exercise of their over-allotment option. As a result of the IPO, we raised a total of $31.0 million in net proceeds after deducting underwriting discounts and commissions of $2.6 million and estimated offering expenses of $3.3 million. Costs directly associated with our IPO were capitalized and recorded as deferred IPO costs prior to the completion of the IPO. These costs have been recorded as a reduction of the proceeds received in arriving at the amount to be recorded in additional paid-in capital. Upon completion of the IPO, all outstanding shares of our preferred stock were converted into 8,528,860 shares of common stock.

Cash Flows

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

	Three Months Ended March 31,	
	2013	**2012**
Net cash provided by (used in) operating activities	$ 0.9	$ (7.3)
Net cash used in investing activities	(0.1)	(0.3)
Net cash provided by (used in) financing activities	(0.5)	7.7
Net increase in cash and cash equivalents	0.3	0.1
Cash and cash equivalents, beginning of period	0.4	
Cash and cash equivalents, end of period	$ 0.7	$ 0.1

Net Cash From Operating Activities. Net cash provided by operating activities was $0.9 million for the three months ended March 31, 2013 and net cash used in operating activities was $7.3 million for the three months ended March 31, 2012. The net cash provided during the three months ended March 31, 2013 primarily reflects the net income for the period, increased in part by depreciation and amortization, stock-based compensation expense and non-cash interest expense and is also impacted by changes in working capital. The increase in net cash provided by operating activities is primarily attributable to cash received from sales of Subsys and Dronabinol SG Capsule during the three months ended March 31, 2013.

Net Cash From Investing Activities. Net cash used in investing activities was $0.1 million and $0.3 million for the three months ended March 31, 2013 and 2012, respectively. Net cash used in investing activities reflects the purchase of equipment and leasehold improvements.

Net Cash From Financing Activities. Net cash used in financing activities was $0.5 million for the three months ended March 31, 2013 and net cash provided by financing activities was $7.7 million for the three months ended March 31, 2012. During the three months ended March 31, 2013, a $0.5 million payment was made against the line of credit with Bank of America. Net cash provided by financing activities for the three months ended March 31, 2012 was primarily attributable to borrowings against the credit facility in the amount of $4.7 million combined with an increase in promissory notes payable to The John N. Kapoor Trust and The Kapoor Children 1992 Trust of $3.0 million.

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

Our cash flows for the rest of 2013 and beyond will depend on a variety of factors, including sales of Subsys and Dronabinol SG Capsule and any additional approved products, any regulatory approvals, investments in manufacturing and production such as our planned second dronabinol manufacturing facility, capital equipment, and research and development. We expect our net cash inflows from operating activities to increase as we expect to increase sales of Subsys and Dronabinol SG Capsule, partially offset by anticipated expansion in sales and marketing,

research and development, manufacturing, and general and administrative expenses as a public company.

Funding Requirements

We believe that the net proceeds from the May 7, 2013 IPO and our pre-existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months.

As of May 10, 2013, we had $15.0 million of undrawn funds available under our revolving credit facility with Bank of America.

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;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- our ability to acquire or in-license products and product candidates, technologies or businesses; and
- terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

Although we generated cash from operating activities during the three months ended March 31, 2013, until we can consistently generate significant cash from sales of our approved products and other operations, we expect to continue to fund our operations primarily from the net proceeds from offerings of our equity securities and through our revolving credit facility with Bank of America. We cannot be sure that our existing cash and cash equivalents will be adequate, or that additional financing will be available when needed, or that, if available, financing will be obtained on terms favorable to us or our stockholders. Having insufficient funds may require us to delay, scale back or eliminate some or all of our research or development programs or to relinquish greater or all rights to product candidates at an earlier stage of development or on less favorable terms than we would otherwise choose. If we raise additional funds by issuing equity or convertible securities, substantial dilution to existing stockholders will likely result. If we raise additional funds by incurring new debt obligations, the terms of the debt will likely require significant cash payment obligations as well as covenants and specific financial ratios that may restrict our ability to operate our business.

Off-Balance Sheet Arrangements

During the three months ended March 31, 2013, we did not have any relationships with unconsolidated organizations or financial partnerships, such as structured finance or special purpose entities that would have been established for the purpose of facilitating off-balance sheet arrangements.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed under the heading Management s Discussion and Analysis of Financial Condition and Results of Operations-Contractual Obligations and Commitments in our final prospectus filed with the SEC on May 2, 2013, relating to our Registration Statement on Form S-1/A (File No. 333-173154) for our IPO other than in regards to the conversion and retirement of our debt obligations as discussed above.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

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

Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation has had a material effect on our results of operations for the three months ended March 31, 2013 or 2012.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act as of March 31, 2013, have concluded that, based on such evaluation, our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms of the SEC, and is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(d) and 15d-15(d) under the Exchange Act) occurred during the three months ended March 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors in its entirety, in addition to other information contained in this report as well as our other public filings with the SEC.

Risks Related to Our Business and Industry

We are at an early stage of commercialization and have a history of net losses and negative cash flow from operations. We cannot predict if or when we will become profitable on a long-term basis.

We have a limited operating and commercialization history and there is little historical basis upon which to assess how we will respond to competitive or economic challenges or other challenges to our business. Our business and prospects must be considered in light of the risks and uncertainties frequently encountered by pharmaceutical companies in the early stages of commercialization.

We have generated substantial net losses and negative cash flow from operations since our inception. For example, for 2012 and 2011, we incurred net losses of $24.4 million and $19.4 million, respectively, our net cash used in operating activities was $13.6 million and $15.4 million, respectively, and, at March 31, 2013, our accumulated deficit was $129.3 million. Our only two approved products, Subsys and Dronabinol SG Capsule, have only recently been launched, with Subsys being launched by us in March 2012 and Dronabinol SG Capsule being launched through our exclusive distributor, Mylan, in December 2011. While we generated net income for the first quarter of 2013, we may not be able to sustain profitability through the full 2013 fiscal year or increase our profitability in subsequent quarters.

Our ability to generate sufficient revenues from Subsys and Dronabinol SG Capsule or from any of our product candidates, if approved, and to transition to profitability and generate positive cash flow on a long-term basis will depend on numerous factors described in the following risk factors, and we may continue to incur losses and negative cash flow and may never transition to profitability or positive cash flow on a long-term basis. In particular, we expect our operating expenses to continue to increase in the near-term as we expand our operations and transition to operating as a public company, and may not be able to generate sufficient revenues to offset this anticipated increase in expenses. In addition, we expect that our gross margin may fluctuate from period to period as a result of changes in product mix sold, potentially by the introduction of new products by us or our competitors, discounts, including discounts on Dronabinol SG Capsule that may be offered by Mylan, manufacturing efficiencies related to our products and a variety of other factors. If we are unable to transition to profitability and generate positive cash flow on a long-term basis, our business, results of operations and financial condition would be materially and adversely affected, which could result in our inability to continue operations.

We are largely dependent on the commercial success of our two approved products, Subsys and Dronabinol SG Capsule, and although we have generated revenue from sales of Subsys and Dronabinol SG Capsule, we may never become profitable on a long-term basis.

We anticipate that in the near term our ability to become sustainably profitable will depend upon the commercial success of our two approved products, Subsys and Dronabinol SG Capsule, which were only recently launched. To date, we have generated limited revenues from commercial sales of these products. In addition to the risks discussed elsewhere in this section, our ability to continue to generate revenues from these products will depend on a number of factors, including, but not limited to:

- achievement of broad market acceptance and coverage by third-party payors for our products;
- the effectiveness of our efforts in marketing and selling Subsys;
- the effectiveness of Mylan s efforts in distributing Dronabinol SG Capsule, as our exclusive distributor of that product;
- our and our contract manufacturers ability to successfully manufacture commercial quantities of our products at acceptable cost levels and in compliance with regulatory requirements;
- our ability to maintain a cost-efficient commercial organization and, to the extent we seek to do so, successfully partner with additional third parties;
- our ability to successfully expand and maintain intellectual property protection for Subsys;
- our ability to effectively work with physicians to ensure that patients are titrated to an effective dose of Subsys;
- the efficacy and safety of our products; and
- our ability to comply with regulatory requirements.

Because of the numerous risks and uncertainties associated with our commercialization efforts, including our reliance on Mylan for the distribution of Dronabinol SG Capsule, and other factors, we are unable to predict the extent to which we will continue to generate revenues from Subsys and Dronabinol SG Capsule or the timing for when or the extent to which we will become sustainably profitable, if ever. Even if we do achieve sustainable profitability, we may not be able to increase profitability on an ongoing basis.

If Subsys and Dronabinol SG Capsule, or any of our product candidates for which we receive regulatory approval, do not achieve broad market acceptance or coverage by third-party payors, the revenues that we generate from those products will be limited.

The commercial success of Subsys and Dronabinol SG Capsule, and any product candidates for which we obtain marketing approval from the FDA or other regulatory authorities, will depend upon the acceptance of these products by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our approved products by third-party payors is also necessary for commercial success. The degree of market acceptance of Subsys and Dronabinol SG Capsule and any other product candidates for which we may receive regulatory approval will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- acceptance by physicians and patients of the product as a safe and effective treatment;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- limitations or warnings contained in a product s FDA-approved labeling;
- the clinical indications for which the product is approved;
- in the case of product candidates that are controlled substances, such as our dronabinol based product candidates, the U.S. Drug Enforcement Administration, or DEA, scheduling classification;
- availability and perceived advantages of alternative treatments;
- any negative publicity related to our or our competitors products;
- the effectiveness of our or any current or future collaborators sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage and reimbursement;
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage; and
- our ability to maintain compliance with regulatory requirements.

For example, while we believe our sublingual spray delivery method for Subsys appeals to patients, some patients may not view our sublingual spray device as easy to administer, safe and effective, and otherwise may not react favorably to sublingual delivery. In accordance with the risk

evaluation mitigation strategy, or REMS, protocol for all TIRF products, physicians are advised to begin patients at the lowest dose available for the applicable TIRF product, which for Subsys is 100 mcg. If patients do not experience pain relief at initial low-dose prescriptions of Subsys, they or their physicians may conclude that Subsys is ineffective in general and may discontinue use of Subsys before titrating to an effective dose. In addition, many third-party payors require usage and failure on cheaper generic versions of Actiq prior to providing reimbursement for Subsys and other branded TIRF products, which limits Subsys use as a first-line treatment option.

In addition, products used to treat and manage pain, especially in the case of controlled substances, are from time to time subject to negative publicity, including illegal use, overdoses, abuse, diversion, serious injury and death. These events have led to heightened regulatory scrutiny. Controlled substances are classified by the DEA as Schedule I through V substances, with Schedule I substances being prohibited for sale in the United States, Schedule II substances considered to present the highest risk of abuse and Schedule V substances being considered to present the lowest relative risk of abuse. Subsys contains fentanyl, an opioid, and is regulated as a Schedule II controlled substance, and our Dronabinol SG Capsule is regulated as a Schedule III controlled substance, and despite the strict regulations on the marketing, distributing, prescribing and dispensing of such substances, illicit use and abuse of controlled substances is well-documented. Thus, the marketing of Subsys, Dronabinol SG Capsule and, if approved, our product candidates that contain controlled substances, may generate public controversy that may adversely affect market acceptance of Subsys and Dronabinol SG Capsule and, if approved, such product candidates.

Our efforts to educate the medical community and third-party payors on the benefits of Subsys, and any of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities, and gain broad market acceptance may require significant resources and may never be successful. If our products do not achieve an adequate level of acceptance by physicians, third-party payors and patients, we may not generate sufficient revenue from these products to become or remain profitable on a long-term basis.

In addition, fentanyl and dronabinol treatments can be costly to third-party payors and patients. Accordingly, hospitals and physicians may resist prescribing our products and third-party payors and patients may not purchase our products due to cost.

The commercial success of Dronabinol SG Capsule, as a generic product, also depends to some extent on wholesalers, pharmacies and the medical community being willing to purchase and prescribe a generic versus the branded product. Although Marinol has been marketed safely for many years, there is a possibility that Dronabinol SG Capsule could produce an unanticipated clinical side effect, or be considered less effective or less convenient, or otherwise inferior, to Marinol, which could result in an adverse effect on our ability to achieve market acceptance for Dronabinol SG Capsule by third parties.

Furthermore, the potential market for dronabinol products may not expand as we anticipate or may even decline based on numerous factors, including the introduction of superior alternative products and regulatory action negatively impacting the dronabinol market. Moreover, even if Dronabinol SG Capsule and, if approved, our dronabinol product candidates are successfully commercialized, there is no guarantee that introduction of improved formulations of dronabinol will result in expansion of the dronabinol market or permit us to gain share in that market or maintain or increase any market share we may capture. New dronabinol products that we introduce could potentially replace our then currently marketed dronabinol products, thus not impacting the overall size of the market or increasing our overall share of that market. If we are unable to expand the market for the medical use of dronabinol or gain, maintain or increase market share in that market, this failure would have a material adverse effect on our ability to execute on our business plan and ability to generate revenue.

We or our collaborators may not be successful in executing sales and marketing strategies for Subsys, Dronabinol SG Capsule or any additional product candidates for which we obtain regulatory approval. If such sales and marketing strategies are not successful, we may not be able to maintain or increase our revenues.

Prior to our launch of Subsys in March 2012, we built a commercial organization including sales, marketing, managed markets, trade and distribution functions, which is now focused exclusively on marketing and selling Subsys. As of March 31, 2013 our field sales force included approximately 67 sales professionals who are promoting Subsys primarily to oncologists, pain management specialists and centers that cater to supportive care in the United States. We may either increase or decrease the size of our sales force in the future based upon market conditions and actual sales performance, as well as in the event that we obtain regulatory approval for any of our product candidates. In addition, we could lose sales personnel or the performance of our sales personnel as measured by actual sales may be disappointing. Many of our competitors have significantly larger sales and marketing organizations, and significantly greater experience than we do in selling, marketing and distributing pharmaceuticals, and we may not be able to compete successfully with them with our existing commercial organization.

We distribute Dronabinol SG Capsule exclusively through Mylan pursuant to our May 2011 supply and distribution agreement. In the event that Mylan fails to adequately commercialize Dronabinol SG Capsule because it lacks adequate financial or other resources, decides to focus on other initiatives or otherwise, our business, financial condition, results of operations and prospects would be harmed. In addition, we are subject to a number of other risks associated with our dependence on Mylan as our exclusive distributor of Dronabinol SG Capsule in the United States, including, but limited to:

- Mylan may not provide us with timely and accurate information regarding sales and marketing activities and supply forecasts, which could adversely impact our ability to comply with our supply obligations and manage our inventory of Dronabinol SG Capsule, as well as our ability to generate accurate financial forecasts;

- we do not have any control over discounts from the wholesale acquisition price that Mylan offers, which may reduce the payments we receive from Mylan from sales of Dronabinol SG Capsule;

- Mylan may disagree with us regarding whether any Dronabinol SG Capsule that we supply to Mylan conforms to specifications and may reject batches of Dronabinol SG Capsule, in which case we would realize lower gross margins and would lose revenues if we were unable to timely supply sufficient replacement quantities of Dronabinol SG Capsule to satisfy market demand; and

Mylan may not comply with applicable regulatory guidelines with respect to marketing and selling Dronabinol SG Capsule, which could adversely impact sales of Dronabinol SG Capsule in the United States.

Our agreement with Mylan may be terminated early by either party upon 45 days prior written notice to the other party if the other party commits a material breach of the agreement and fails to cure the breach within the 45-day period or immediately if the other party becomes insolvent. Mylan may also terminate the agreement in the event of a negative outcome of a quality audit of our and/or Catalent s manufacturing facilities. We cannot assure you that we would be able to generate equal or greater revenues from the commercialization of Dronabinol SG Capsule if we were to market and sell such product on our own or through another distribution partner rather than through Mylan, or that any dispute with or termination of our agreement with Mylan would not otherwise materially negatively impact our business or reputation.

We utilize in the United States, with respect to Subsys, and will utilize in the United States, with respect to any of our product candidates for which we obtain regulatory approval and maintain sales and marketing responsibility, an incentive-based sales model similar to that employed at Sciele Pharma and other companies previously led by members of our board, including our founder, Executive Chairman and principal stockholder. Under this model, we maintain a low-cost commercial organization that is smaller than many of our competitors, which could hinder our efforts to broadly market Subsys and any other products that we are able to commercialize as compared to our competitors. Our commercial organization has only recently been established, and may not perform over time as we currently anticipate. To the extent our commercial organization does not perform over time as we currently anticipate, we will need to consider alternatives, such as entering into arrangements with third parties to market and sell our products. Any arrangement would likely result in significantly greater sales and marketing expenses or lower revenues than our current estimates.

In international markets, we plan to enter into arrangements with third parties to pursue requisite regulatory approvals and market and sell our products as opposed to building an international commercial organization. We may not be successful in establishing arrangements with third parties for international development and commercialization on acceptable terms, or at all, which may limit the market potential for our products and product candidates.

We may not be able to obtain regulatory approval for Dronabinol Oral Solution, which would limit our future growth prospects.

In addition to growing sales of our two approved products, Subsys and Dronabinol SG Capsule, the ability to grow our business in the near-term will depend heavily on our ability to obtain regulatory approval and acceptable DEA classification for Dronabinol Oral Solution. Based on a pre-NDA meeting with the FDA in April 2012 and our progress to date, we currently expect to submit an NDA for Dronabinol Oral Solution in the second half of 2013. However, we can provide no assurance that we will submit such NDA or receive regulatory approval for Dronabinol Oral Solution on the timeframe we expect, or at all.

Obtaining approval of an NDA is a lengthy, expensive and uncertain process. We anticipate that the remaining total cost associated with obtaining FDA approval for Dronabinol Oral Solution will be approximately $2.7 million, which includes an NDA submission fee of approximately $2.0 million and an additional $0.7 million in payments to third-party vendors engaged in NDA preparation activities. We cannot assure you that our current estimate of the cost to obtain FDA approval for Dronabinol Oral Solution is accurate. The FDA also has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Our ability to obtain regulatory approval for Dronabinol Oral Solution will depend in large part of whether the FDA accepts our conclusion that the results of our pivotal bioequivalence study adequately demonstrate bioequivalence to Marinol, the reference drug. While Dronabinol Oral Solution demonstrated more rapidly detectable blood levels and more reliable absorption profile than Marinol in our pivotal bioequivalence study, which we believe are favorable product attributes, they may undermine our ability to bridge to existing dronabinol safety and efficacy information and may render insufficient our proposed NDA package once subject to FDA review. Following the FDA s review of our planned NDA, we may be required to run additional clinical trials and may not ever obtain FDA approval for Dronabinol Oral Solution.

If we are unable to obtain regulatory approval for Dronabinol Oral Solution, our ability to generate additional revenues beyond those derived from the commercial sale of Subsys and Dronabinol SG Capsule will be limited, which would have a material adverse impact on our business, results of operations, financial condition and prospects.

We produce our dronabinol API internally and may encounter manufacturing failures that could impede or delay commercial production of Dronabinol SG Capsule or our dronabinol product candidates, if approved, or the preclinical and clinical development or regulatory approval of our dronabinol product candidates.

Any failure in our internal dronabinol API manufacturing operations, including as conducted at any new facilities that we may construct, could cause us to be unable to meet demand for our Dronabinol SG Capsule and lose potential revenue, delay the preclinical and clinical development or regulatory approval of our dronabinol product candidates, and harm our reputation. Our internal manufacturing operations may encounter difficulties involving, among other things, production yields, regulatory compliance, quality control and quality assurance, obtaining DEA quotas which allow us to produce dronabinol in the quantities needed to execute on our business plan, and shortages of qualified personnel. Our ability to commercially supply

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Dronabinol SG Capsule, and regulatory approval of our dronabinol product candidates, could be impeded, delayed, limited or denied if the FDA does not approve and maintain the approval of our manufacturing processes and facilities. In addition, we have limited experience producing dronabinol in commercial quantities and may encounter difficulties with continuing to manufacture commercial quantities of dronabinol or the quantities needed for our preclinical studies or clinical trials. Such difficulties could result in commercial supply shortfalls of our Dronabinol SG Capsule, a delay in the commercial launch of Dronabinol Oral Solution, if approved, delays in our preclinical studies, clinical trials and regulatory submissions, or the recall or withdrawal of Dronabinol SG Capsule from the market.

We are only aware of two other manufacturers that are able to produce dronabinol in the United States. We are aware of only five manufacturers that hold Drug Master Files for the production of dronabinol in the United States. Because dronabinol is a controlled substance, inability to manufacture dronabinol in the United States would have a material adverse effect on our business given the regulatory restrictions associated with obtaining authorization to import and transport controlled substances into the United States. Moreover, we believe dronabinol is difficult to produce and if there was any problem in manufacturing it internally, we may not be able to identify a third party to manufacture it for us in a cost-effective manner, if at all.

We must comply with current Good Manufacturing Practices, or cGMPs, enforced by the FDA through its facilities inspection program and review of submitted technical information. In addition, we must obtain and maintain necessary DEA and state registrations, and must establish and maintain processes to assure compliance with DEA and state requirements governing, among other things, the storage, handling, security, recordkeeping and reporting for controlled substances. We must also apply for and receive a quota for dronabinol. Any failure to comply with these requirements may result in penalties, including fines and civil penalties, suspension of production, suspension or delay in product approvals, product seizure or recall, operating restrictions, criminal prosecutions or withdrawal of product approvals, any of which could significantly and adversely affect our business. If the safety of any product or product candidate or component is compromised due to a failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize or obtain regulatory approval for the affected product or product candidate, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay or termination of commercialization, preclinical studies and clinical trials, regulatory submissions or approvals of our products or product candidates, entail higher costs or result in our being unable to effectively commercialize our approved products. Certain changes in our dronabinol API manufacturing processes or procedures, including a change in the location where the material is manufactured, generally require prior FDA, or foreign regulatory authority, review and/or approval. We may need to conduct additional preclinical studies and clinical trials to support approval of such changes. This review and approval process may be costly and time-consuming, and could impede, delay, limit or prevent commercialization of a product.

We plan to expand our dronabinol API production capacity by constructing a second facility. We may encounter a number of challenges relating to the construction, management and operation of such facility, and we may never realize a return on our investment.

We plan to expand our dronabinol API production capacity by constructing a second facility designed to meet our expected future dronabinol API supply needs. The construction of the second facility will require significant capital expenditures and result in significantly increased fixed costs. In addition, we will need to transfer our manufacturing processes, technology and know-how to the second facility. We cannot assure you that we will be able to successfully establish or operate the second facility in a timely or profitable manner, or at all, or within the budget that we currently project. If we are unable to transition our dronabinol API manufacturing operations to the second facility in a cost-efficient and timely manner, then we may experience disruptions in our operations, which could negatively impact our business and financial results. Further, if we are unable to achieve certain minimum production efficiencies at the second facility, or if we fail to continue to successfully commercialize our Dronabinol SG Capsule or to obtain regulatory approval for and successfully commercialize our dronabinol product candidates, including Dronabinol Oral Solution, we may never realize a return on our investment. If the demand for our dronabinol products decreases or if we do not produce the output we plan or anticipate after our new facility is operational, we may not be able to spread a significant amount of our fixed costs over the production volume, thereby increasing our per unit fixed cost, which would have a negative impact on our financial condition and results of operations.

We will need to obtain a number of regulatory approvals in connection with the production of dronabinol API at our planned second manufacturing facility. Our ability to obtain these approvals may be subject to additional costs and possible delays beyond what we initially anticipate. In addition, any new dronabinol API manufacturing facility must comply on an ongoing basis with applicable regulatory requirements as discussed in the preceding risk factor. Failure to comply with any such regulatory requirements would harm our business and our results of operations.

Our ability to operate a new, larger facility successfully will greatly depend on our ability to hire, train and retain an adequate number of additional manufacturing employees, in particular employees with the appropriate level of knowledge, background and skills. Should we be unable to hire such employees, our business and financial results could be negatively impacted.

Disruptions or other adverse developments during the construction and planned operations of our planned second facility could materially adversely affect our business. If our dronabinol API production is disrupted for any reason, we may be forced to locate alternative dronabinol API production facilities, including facilities operated by third parties. Locating alternative facilities would be time-consuming and would disrupt our production and cause supply delays that could result in us defaulting on our obligations under our supply agreement with Mylan, as well as damage to our reputation and profitability and other possible adverse effects, including those described in the preceding risk factor. Additionally, we cannot assure you that alternative manufacturing facilities would offer the same cost structure as the planned second facility.

We have no internal manufacturing capabilities other than for our dronabinol API, we are dependent on numerous third parties in our supply chain for the commercial supply of Subsys and Dronabinol SG Capsule, and if we fail to maintain our supply and manufacturing relationships with these third parties or develop new relationships with other third parties, we maybe unable to continue to commercialize Subsys and Dronabinol SG Capsule or to develop our product candidates.

We rely on a number of third parties for the commercial supply of Subsys and Dronabinol SG Capsule and the clinical supply of our product candidates. Our ability to commercially supply Subsys and Dronabinol SG Capsule and to develop our product candidates depends, in part, on our ability to successfully obtain the API for Subsys and the starting materials for dronabinol API for Dronabinol SG Capsule and our dronabinol product candidates and the API for any other product candidates, and outsource most if not all of the aspects of their manufacturing at competitive costs, in accordance with regulatory requirements and in sufficient quantities for commercialization and clinical testing. If we fail to develop and maintain supply relationships with these third parties, we may be unable to continue to commercialize Subsys and Dronabinol SG Capsule or develop our Dronabinol Oral Solution or any other product candidates.

We purchase the fentanyl API utilized in connection with Subsys and the starting materials for our dronabinol API from several third parties. We do not have long-term agreements with any of these parties, but rather purchase material on a purchase order basis. Moreover, some of the starting material for our dronabinol API is difficult to procure and produce. Our ability to obtain fentanyl API and the starting materials for our dronabinol API in sufficient quantities and quality, and on a timely basis, is critical to our continued commercialization of Subsys and Dronabinol SG Capsule, respectively, and to our successful completion of preclinical studies and clinical trials for our product candidates. There is no assurance that these suppliers will continue to produce the materials in the quantities and quality and at the times they are needed, if at all, especially in light of the fact that we intend to significantly increase our orders for these materials in the near future. Moreover, the replacement of any of these suppliers, particularly the supplier of the starting material for our dronabinol API that is difficult to produce, could lead to significant delays and increase in our costs.

Our Dronabinol SG Capsule is manufactured and packaged by Catalent Pharma Solutions, LLC. We do not own or operate manufacturing facilities for Subsys and currently lack the in-house capabilities to manufacture Subsys. Our Subsys sub-component manufacturing is performed by AptarGroup, Inc., with the final fill, assembly and packaging of Subsys performed by DPT Lakewood, LLC. We have contracts in place with Catalent, Aptar and DPT. If there are problems relating to the equipment utilized by Aptar to manufacture Subsys, we will be responsible for fixing or replacing that equipment. Any requirement to do so could result in unexpected costs and expenses and delay the production of Subsys, which could in turn negatively impact our business.

The manufacture of pharmaceutical products generally requires significant expertise and capital investment, often including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems can include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our manufacturers may experience difficulties due to resource constraints, labor disputes, unstable political environments or natural disasters. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations for any reason, our ability to commercially supply Subsys or Dronabinol SG Capsule or to provide dronabinol for any product candidates for preclinical studies or clinical trials could be jeopardized. Any delay or interruption in our ability to commercially supply Subsys or Dronabinol SG Capsule will result in the loss of potential revenues and could adversely affect the market s acceptance of these products. For example, in the fourth quarter of 2012, two batches of Dronabinol SG Capsule were not released for commercial sale due to manufacturing process inconsistencies at Catalent. This resulted in an inability to meet market demand for Dronabinol SG Capsule during the quarter and our net revenues from this product decreased dramatically compared to the third quarter of 2012. While we believe we have since resolved this manufacturing issue and have delivered new batches of Dronabinol SG Capsule that have been released for commercial sale, we cannot guarantee that we will not encounter other manufacturing issues in the future. In addition, any delay or interruption in the supply of preclinical study or clinical trial supplies could delay the completion of those studies or trials, increase the costs associated with maintaining our programs and, depending upon the period of delay, require us to commence new studies or trials at additional expense or terminate studies or trials completely.

Manufacturers and suppliers are subject to regulatory requirements including cGMPs, which cover, among other things, manufacturing, testing, quality control and recordkeeping relating to our products and product candidates, and are subject to ongoing inspections by FDA, DEA and other regulatory agencies. Moreover, if we seek regulatory approval for any product candidate, the facilities to be used by us or our third-party manufacturers for the manufacture of the product candidate must be approved by the applicable regulatory authorities before the product candidate may be approved and marketed. We do not control the manufacturing processes of third-party manufacturers and except for dronabinol API, we are currently completely dependent on them. If any of our third-party manufacturers cannot successfully manufacture product that conforms to our specifications and the applicable regulatory authorities strict regulatory requirements, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any other applicable regulatory authorities do not approve these facilities for the manufacture of our products or product candidates or if they withdraw any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercially supply Subsys and Dronabinol SG Capsule or develop or obtain regulatory approval for our product candidates.

If our third-party manufacturers or suppliers fail to deliver the required commercial quantities of Subsys or Dronabinol SG Capsule and their respective sub-components and starting materials, on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement manufacturers or suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality, and on a timely basis, the continued commercialization of Subsys and Dronabinol SG Capsule and the development of our product candidates would be impeded, delayed, limited or prevented, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We may encounter delays in the manufacturing of Subsys or fail to generate revenue if our supply of the components of our sublingual spray delivery system is interrupted.

Our sublingual spray drug delivery system is sourced, manufactured and assembled by multiple third parties across different geographic locations in the United States and Europe. All contract manufacturers and component suppliers have been selected for their specific competencies in the manufacturing processes and materials that make up the sublingual spray system. The components of the spray system include the actuator subassembly, vial subassembly, and the setting mechanism. The actuator subassembly is comprised of nine individual components which are collectively supplied by six different third-party manufacturers. The vial subassembly that houses the sterile drug formulation fentanyl is comprised of five different components supplied by four third-party manufacturers. Each of these third-party manufacturers is currently the single source of their respective components. If any of these manufacturers is unable to supply its respective component for any reason, including due to violations of cGMPs for medical devices, known as FDA s Quality System Regulation, or QSR, our ability to have the finished sublingual spray device manufactured and commercially supply Subsys will be adversely affected and we would lose potential revenue. Accordingly, a failure in any part of our supply chain may cause a material adverse effect on our ability to generate revenue from Subsys, which in turn could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face intense competition, including from generic products, and if our competitors market or develop alternative treatments that are approved more quickly or marketed more effectively than our product candidates or are demonstrated to be safer or more effective than our products, our commercial opportunities will be reduced or eliminated.

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, such as pharmaceutical companies, including generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, including well-established sales forces, manufacturing capabilities, research and development capabilities, experience in obtaining regulatory approvals for product candidates and other resources than us.

Subsys competes against numerous branded and generic products already being marketed and potentially those which are or will be in development. Many of these competitive products are offered in the United States by large, well-capitalized companies. Subsys is the fourth new branded TIRF product in the last four years. In the BTCP market, physicians often treat BTCP with a variety of short-acting opioid medications, including morphine, morphine and codeine derivatives and fentanyl. Some currently marketed products against which we directly compete include Teva Pharmaceutical Industries Ltd. s Fentora and Actiq, Orexo AB s Abstral, Archimedes Pharma Ltd. s Lazanda and BioDelivery Sciences International, Inc. s Onsolis. Some generic fentanyl products against which Subsys competes are marketed by Mallinckrodt, Inc., Par Pharmaceutical Companies, Inc. and Actavis, Inc. In addition, we are aware of numerous companies developing other treatments and technologies for rapid delivery of opioids to treat BTCP, including transmucosal, transdermal, nasal spray, and inhaled sublingual delivery systems. If these treatments and technologies are successfully developed and approved, they could represent significant additional competition to Subsys.

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With respect to our Dronabinol SG Capsule and our dronabinol product candidates, the market in which we compete is challenging in part because generic products generally face greater price competition than branded products. With respect to Dronabinol SG Capsule and any of our dronabinol product candidates, if approved, the competition from generic products may have an effect on our product prices, market share, revenues and profitability. We or our distributor may not be able to differentiate any products that we may market from those of our competitors, successfully develop or introduce new products that are less costly or offer better performance than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. In addition, there are a number of established therapies and products already commercially available and under development by other companies that treat the indications which Dronabinol SG Capsule and our dronabinol product candidates are intended to treat. Specifically, Dronabinol SG Capsule competes and, if approved, our dronabinol product candidates will compete, against therapies and products such as Abbvie, Inc. s Marinol and Marinol generics. Par Pharmaceutical Companies markets an approved generic version of Marinol and Actavis markets an authorized generic version of Marinol. We cannot give any assurance that other companies will not obtain regulatory approval or acceptable DEA classification for, or commercialize additional generic dronabinol products.

Moreover, our dronabinol products may compete with non-synthetic cannabinoid drugs, including therapies such as GW Pharmaceuticals plc s Sativex, especially in many countries outside of the United States where non-synthetic cannabinoids are legal. In addition, literature has been published arguing the benefits of natural cannabis, or marijuana, over dronabinol, and there are a number of states that have already enacted laws legalizing medicinal and recreational marijuana. There is some support in the United States for further legalization of marijuana. We also cannot assess the extent to which patients utilize marijuana illegally to alleviate CINV, instead of using prescribed therapies such as approved dronabinol products. Furthermore, in the treatment of CINV, physicians typically offer conventional anti-nausea drugs prior to initiating chemotherapy, such as Sanofi s Anzemet, Eisai Inc./Helsinn Group s Aloxi, Roche Holding AG s Kytril, Par Pharmaceutical Companies Zuplenz and GlaxoSmithKline plc s Zofran, as well as Neurokinin 1 receptor antagonists on the market including Kyowa Hakko Kirin Co., Ltd. s Sancuso and Merck & Co., Inc. s Emend. To the extent that Dronabinol SG Capsule and our dronabinol product candidates compete in the broader CINV market, we will also face competition from these products and their generic equivalents, as applicable.

Additionally, we are aware of companies with product candidates in late stage development for CINV, including A.P. Pharma s APF530, Aphios Corp. s Zindol, which is in Phase 2/3 development, Tesaro s rolapitant, which is in Phase 3 development and Roche Holding/Helsinn Group s netupitant, which is in Phase 3 development. If these products are successfully developed and approved over the next few years, they could represent significant competition for Dronabinol SG Capsule and, if approved, our dronabinol product candidates.

We also face competition from third parties in obtaining allotments of fentanyl and dronabinol under applicable DEA annual quotas, recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients in clinical trials, and in identifying and acquiring or in-licensing new products and product candidates.

Our competitors may also develop products that are more effective, better tolerated, subject to fewer or less severe side effects, more useful, more widely-prescribed or accepted, or less costly than ours. For each product we commercialize, sales and marketing efficiency are likely to be significant competitive factors. We have built a commercial organization to market Subsys in the United States without using third-party sales or marketing channels, and expect to expand and utilize this commercial organization in the United States for any additional proprietary product candidates that we develop, and there can be no assurance that we can maintain and augment these capabilities in a manner that will be cost efficient and competitive with the sales and marketing efforts of our competitors, especially since some or all of those competitors could expend greater economic resources than we do and/or employ third-party sales and marketing channels.

If we are unable to achieve and maintain adequate levels of coverage and reimbursement for Subsys and Dronabinol SG Capsule, or any future products we may seek to commercialize, on reasonable pricing terms, their commercial success may be severely hindered.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Assuming we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products will depend significantly on access to third-party payors drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. For example, many third-party payors require usage and failure on cheaper generic versions of Actiq prior to providing reimbursement for Subsys and other branded TIRF products, which limits Subsys use as a first-line treatment option.

Third-party payors, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Further, we believe that future coverage and reimbursement will likely be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for Subsys or Dronabinol SG Capsule or any of our product candidates for which we may receive regulatory approval may not be available or adequate in either the United States or international markets, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

We and Mylan depend on wholesale pharmaceutical distributors for retail distribution of Subsys and Dronabinol SG Capsule, respectively, and if we or Mylan lose any of our significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our sales of Subsys, and the majority of Mylan s sales of Dronabinol SG Capsule, are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2012, three wholesale pharmaceutical distributors, Cardinal Health, Inc., McKesson Corporation and AmerisourceBergen Corporation, individually comprised approximately 34%, 30% and 23%, respectively, of our total gross sales of Subsys, and McKesson Corporation comprised approximately 94% of Mylan s total gross sales of our Dronabinol SG Capsule. The loss by us or Mylan of any of these wholesale pharmaceutical distributors accounts or a material reduction in their purchases could have a material adverse effect on our business, results of operations, financial condition and prospects.

In addition, these wholesale customers comprise a significant part of the distribution network for pharmaceutical products in the United States. This distribution network has undergone, and may continue to undergo, significant consolidation marked by mergers and acquisitions. As a result, a small number of large wholesale distributors control a significant share of the market. Consolidation of drug wholesalers has increased, and may continue to increase, competitive and pricing pressures on pharmaceutical products. We cannot assure you that we or Mylan can manage these pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our sales of Subsys and Mylan s sales of Dronabinol SG Capsule can be greatly affected by the inventory levels our respective wholesalers carry. We monitor wholesaler inventory of Subsys using a combination of methods. Pursuant to distribution service agreements with our three largest wholesale customers, we receive inventory level reports. For most other wholesalers where we do not receive inventory level reports, however, our estimates of wholesaler inventories may differ significantly from actual inventory levels. Significant differences between actual and estimated inventory levels may result in excessive production (requiring us to hold substantial quantities of unsold inventory), inadequate supplies of products in distribution channels, insufficient product available at the retail level, and unexpected increases or decreases in orders from our or Mylan s wholesalers. These changes may cause our revenues to fluctuate significantly from quarter to quarter, and in some cases may cause our operating results for a particular quarter to be below our expectations or the expectations of securities analysts or investors. In addition, at times, wholesaler purchases may exceed customer demand, resulting in reduced wholesaler purchases in later quarters, which may result in substantial fluctuations in our results of operations from period to period. If our financial results are below expectations for a particular period, the market price of our common stock may drop significantly.

We rely on third parties to perform many necessary services for Subsys, including services related to distribution, invoicing, storage and transportation, and expect to do so for any future branded proprietary products, if approved.

We have retained third-party service providers to perform a variety of functions related to the sale and distribution of Subsys, key aspects of which are out of our direct control. For example, we rely on Cardinal Health 105, Inc. (a/k/a Specialty Pharmaceutical Services) to provide key services related to logistics, warehousing and inventory management, distribution, contract administration and chargeback processing, accounts receivable management and call center management, and, as a result, most of our Subsys inventory is stored at a single warehouse maintained by the service provider. We must rely on this provider as well as other third-party providers that perform services for us, including entrusting our inventories of Subsys to their care and handling. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet

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expected deadlines, or otherwise do not carry out their contractual duties to us, or encounter physical damage or natural disaster at their facilities, our ability to deliver Subsys to meet commercial demand would be significantly impaired. In addition, we utilize third parties to perform various other services for us relating to sample accountability and regulatory monitoring, including adverse event reporting, safety database management and other product maintenance services. If the quality or accuracy of the data maintained by these service providers is insufficient, our ability to continue to market Subsys could be jeopardized or we could be subject to regulatory sanctions. We do not currently have the internal capacity to perform these important commercial functions, and we may not be able to maintain commercial arrangements for these services on reasonable terms.

In addition to the level of commercial success of our approved products, our future growth is also dependent on our ability to successfully develop a pipeline of product candidates, and we cannot give any assurance that any of our product candidates will receive regulatory approval or acceptable DEA classification, if applicable, or that any approved products will be successfully commercialized.

Our long-term growth will be limited unless we can successfully develop a pipeline of additional product candidates. We do not have internal new drug discovery capabilities, and our primary focus is on developing improved formulations and delivery methods for existing FDA-approved products.

The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products containing controlled substances, among other things, are subject to extensive regulation by the FDA, the DEA and other regulatory authorities in the United States. Obtaining approval of an NDA is a lengthy, expensive and uncertain process. The FDA also has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. For example:

- the FDA may not deem a product candidate safe and effective;
- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to support approval;
- the FDA may require additional pre-clinical studies or clinical trials;
- the FDA may not approve of our third-party manufacturers processes and facilities; or
- the FDA may change its approval policies or adopt new regulations.

Any of our product candidates may fail to achieve their specified endpoints in clinical trials. Furthermore, product candidates may not be approved even if they achieve their specified endpoints in clinical trials. The FDA may disagree with our trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. The FDA may also approve a product candidate for fewer or more limited indications than we request, or may grant approval contingent on the performance of costly post-approval clinical trials. In addition, the FDA may not approve the labeling claims that we believe are necessary or desirable for the successful commercialization of our product candidates.

If we are unable to expand our pipeline and obtain regulatory approval for our product candidates on the timelines we anticipate, we will not be able to execute our business strategy effectively and our ability to substantially grow our revenues will be limited, which would have a material adverse impact on our long-term business, results of operations, financial condition and prospects.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy of any of our other product candidates, which could prevent or significantly delay their regulatory approval.

Our product candidates are prone to the risks of failure inherent in drug development. Before obtaining U.S. regulatory approval for the commercial sale of any product candidate, we must gather substantial evidence from well-controlled clinical trials that demonstrate to the satisfaction of the FDA that the product candidate is safe and effective for its proposed indication, and similar regulatory approvals would be necessary to commercialize the product candidate in other countries.

In light of widely publicized events concerning the safety risk of certain drug products, particularly drug products that contain controlled substances, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public

have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Federal

Food, Drug, and Cosmetic Act, or FDCA, authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require a REMS for certain drugs, including certain currently approved drugs. Under the FDCA, companies that violate these and other provisions of the law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties.

The increased attention to drug safety issues may result in a more cautious approach by the FDA in its review of our clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Clinical trials for our product candidates are expensive, time consuming, uncertain and susceptible to change, delay or termination.

Clinical trials are very expensive, time consuming and difficult to design and implement. Other than with respect to our lead product candidate, Dronabinol Oral Solution, most of our other product candidates are in preclinical development. We estimate that clinical trials for these product candidates, if and when initiated, will continue for several years and may take significantly longer than expected to complete. In addition, we, the FDA, an Institutional Review Board, or other regulatory authorities, including state and local, may suspend, delay or terminate our clinical trials at any time, or the DEA could suspend or terminate the registrations and quota allotments we require in order to procure and handle controlled substances, for various reasons, including:

- lack of effectiveness of any product candidate during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by study participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects who have initiated a clinical trial but may withdraw at any time due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials, in particular obtaining sufficient quantities of dronabinol due to regulatory and manufacturing constraints;
- inadequacy of or changes in our manufacturing process or product formulation;
- delays in obtaining regulatory authorization to commence a study, or clinical holds or delays requiring suspension or termination of a study by a regulatory agency, such as the FDA, before or after a study is commenced;
- DEA-related recordkeeping, reporting, or security violations at a clinical site, leading the DEA or state authorities to suspend or revoke the site s controlled substance license and causing a delay or termination of planned or ongoing studies;
- changes in applicable regulatory policies and regulations;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;

uncertainty regarding proper dosing;

unfavorable results from ongoing clinical trials and preclinical studies;

failure of our contract research organizations, or CROs, or other third-party contractors to comply with all contractual and regulatory requirements or to perform their services in a timely or acceptable manner;

failure by us, our employees, our CROs or their employees to comply with all applicable FDA, DEA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for controlled substances;

scheduling conflicts with participating clinicians and clinical institutions;

failure to design appropriate clinical trial protocols;

insufficient data to support regulatory approval;

inability or unwillingness of medical investigators to follow our clinical protocols;

difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or

regulatory concerns with cannabinoid or opioid products generally and the potential for abuse of the drugs.

Generally, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. In the event that we abandon or are delayed in our clinical development efforts related to our product candidates, we may not be able to execute on our business plan effectively, we may not be able to become profitable on a long-term basis, our reputation in the industry and in the investment community would likely be significantly damaged and our stock price would likely decrease significantly.

We have in the past relied and expect to continue to rely on third parties to conduct and oversee our clinical trials. If these third parties do not meet our deadlines or otherwise conduct the trials as required we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We have in the past relied and expect to continue to rely on third-party CROs to conduct and oversee our clinical trials. For example, we contracted with Worldwide Clinical Trials to conduct and oversee our pivotal bioequivalence study for Dronabinol Oral Solution.

We also rely upon various medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and all applicable regulatory requirements, including the FDA s good clinical practice regulations and DEA and state regulations governing the handling, storage, security and recordkeeping for controlled substances. These CROs and third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials. We rely heavily on these parties for the execution of our clinical and preclinical studies, and control only certain aspects of their activities.

If any of our clinical trial sites terminate their involvement in one of our clinical trials for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be questioned by the FDA.

We have conducted and may in the future conduct clinical trials for our products or product candidates outside the United States and the FDA may not accept data from such trials.

We have conducted and may in the future choose to conduct one or more of our clinical trials outside the United States. For example, our Phase 3 Subsys safety trial was conducted at 46 sites in the United States and ten sites in India. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of such study data by the FDA is subject to certain conditions. For example, the study must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The study population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. Generally, the patient population for any clinical studies conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, such studies would be subject to the applicable local laws and FDA acceptance of the data would be dependent upon its determination that the studies also complied with all applicable U.S. laws and regulations. There can be no assurance the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept any such data, it would likely result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan.

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Since the starting materials we utilize to manufacture dronabinol are sourced out of India, we are exposed to a number of risks and uncertainties associated with that geographic region.

The suppliers of the starting materials we utilize to manufacture dronabinol are located in India. This exposes us to a number of risks and uncertainties outside our control. India has suffered political instability in the past due to various factors. There have also been armed conflicts between India and neighboring Pakistan. Moreover, extremist groups within India and neighboring Pakistan have from time to time targeted Western interests. In addition, India is susceptible to natural disasters such as earthquakes and floods. Political instability, future hostilities with countries such as Pakistan, targeting of our interests by extremist attacks, and earthquakes or other natural disasters in India could harm our operations and impede our ability to produce dronabinol on our anticipated timeline, or at all.

Failure to obtain or maintain Schedule III classification for any of our dronabinol product candidates would substantially limit our ability to produce and commercialize any such product candidates.

The DEA generally regulates dronabinol as a Schedule I controlled substance, except in the case of the FDA-approved Marinol product and its generics, such as Dronabinol SG Capsule, which are Schedule III controlled substances. Schedule I controlled substances have high potential for abuse, have no currently accepted medical use in the United States, lack accepted safety for use under medical supervision and may not lawfully be commercially sold or marketed to patients. After the initial FDA approval of Marinol in 1985, the DEA scheduled dronabinol in sesame oil and encapsulated in a soft gelatin capsule as a Schedule II substance. In 1999, the DEA promulgated a regulation that reclassified this formulation as a Schedule III controlled substance. This regulation directly corresponds to the product characteristics of Marinol, whose sponsor had petitioned the DEA for the scheduling change. DEA regulations currently limit the formulation of FDA-approved dronabinol products that are classified in Schedule III. Specifically, classification in Schedule III is limited to dronabinol (synthetic) in sesame oil and encapsulated in a soft gelatin capsule in an FDA-approved product. There is a possibility that some generic versions of Marinol would not meet these specific conditions, and therefore, would not be classified as a Schedule III substance, but rather would be considered as Schedule I products until otherwise scheduled for marketing. Currently, several products from other companies are the subject of Abbreviated New Drug Applications, or ANDAs, under review by the FDA. If this ruling is allowed, it may increase the number of generics approved as we believe there are active ANDAs which utilize naturally-derived dronabinol and hard gelatin capsule technology. Dronabinol SG Capsule is also subject to regulation by state-controlled substance authorities.

In addition, because the DEA currently regulates the scheduling of dronabinol on a product-specific basis as opposed to regulating all dronabinol-containing products under one schedule, we believe that the DEA will also need to make individual scheduling decisions with respect to our proprietary dronabinol product candidates, if approved, based on, among other factors, assessments of the drug abuse potential for each of our formulations. Therefore, even though Dronabinol SG Capsule has been classified under Schedule III, because our other proprietary dronabinol product candidates will, if approved, represent novel dosage forms, and in the case of the Dronabinol Inhalation Device, a novel route of administration for dronabinol, the DEA may determine that stricter scheduling controls than those applicable to Schedule III controlled substances are appropriate for the additional product candidates. In fact, these product candidates will likely default to Schedule II until the DEA completes a scheduling action for them. Moreover, there may be significant delay in the issuance of the DEA s scheduling decisions with respect to our products following FDA approval, if such approval is granted. Even with FDA approval, we will not be able to market any of our controlled substance products until the DEA has issued a scheduling decision with respect to each drug product.

Because the restrictions on the manufacture, sale, distribution, prescribing, and dispensing of Schedule II substances are greater than for Schedule III substances, failure to obtain Schedule III classification for our dronabinol product candidates could significantly impact our anticipated ability to produce and commercialize any such dronabinol products and would have a material adverse effect on our business and ability to generate revenue. For example, Schedule II drugs or substances generally may not be dispensed without the written prescription of a practitioner, and prescriptions for these drugs or substances may not be refilled. Although the DEA regulates the frequency of Schedule III prescription refills, physicians may call in the prescriptions and they may be refilled. A failure by the DEA to respond favorably to our classification petition before, or in a timely manner after, FDA approval of our dronabinol product candidates or a refusal by the DEA to grant our request to schedule our dronabinol product candidates under Schedule III, if approved by the FDA, would have an adverse impact on our ability to promptly or effectively commercialize such products.

If the FDA does not conclude that certain of our product candidates satisfy the requirements for the Section 505(b)(2) regulatory approval pathway, or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for those product candidates will likely take significantly longer, cost significantly more and entail significantly greater complications and risks than anticipated, and in either case may not be successful.

We are developing several proprietary dronabinol product candidates, including Dronabinol Oral Solution, Dronabinol Inhalation Device and Dronabinol IV Solution, for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway. Section 505(b)(2), if applicable to us under the FDCA, would allow an NDA we submit to FDA to rely in part on data in the public domain or the FDA s prior conclusions regarding the safety and effectiveness of approved compounds, which could expedite the development program for our product candidates by potentially decreasing the amount of clinical data that we would need to generate in order to garner FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for these product candidates, and complications and risks associated with these product candidates, would likely substantially increase. We could need to obtain additional funding, which could result in significant dilution to the ownership interests of our then existing stockholders to the extent we issue equity securities or convertible debt. We cannot assure you that we would be able to obtain such additional financing on terms acceptable to us, if at all. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway would likely result in new competitive products reaching the market more quickly than our product candidates, which would likely materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the Section 505(b)(2) regulatory pathway, we cannot assure you that our product candidates will receive the requisite approvals for commercialization.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain brand-name pharmaceutical companies and others have objected to the FDA s interpretation of Section 505(b)(2). If the FDA s interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2). In addition, the pharmaceutical industry is highly competitive, and Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs that are referenced in a Section 505(b)(2) NDA. These requirements may give rise to patent litigation and mandatory delays in approval of our NDAs for up to 30 months or longer depending on the outcome of any litigation. It is not uncommon for a manufacturer of an approved product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition. In addition, even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee this would ultimately lead to accelerated product development or earlier approval.

Moreover, even if our product candidates are approved under Section 505(b)(2), the approval may be subject to limitations on the indicated uses for which the products may be marketed or to other conditions of approval, or may contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the products.

Annual DEA quotas on the amount of dronabinol allowed to be produced in the United States and our specific allocation of dronabinol by the DEA could significantly limit the production or sale of Dronabinol SG Capsule and any dronabinol product candidates for which we obtain regulatory approval as well as significantly delay the clinical development of our dronabinol product candidates.

Dronabinol, a Schedule I substance, is subject to the DEA s production and procurement quota scheme. The DEA establishes annually an aggregate quota for the amount of dronabinol that may be produced in the United States based on the DEA s estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of dronabinol that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. We are required to obtain an annual quota from the DEA in order to manufacture and produce dronabinol. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year and has substantial discretion in deciding whether or not to make such adjustments. The DEA s aggregate production quota for dronabinol for 2013 is 393 kilograms, the same as established for 2012 and 2011. For 2013, we were allocated what we believe is a sufficient quantity of dronabinol to meet our currently anticipated production and testing needs through 2013. However, we may need additional amounts of dronabinol in future years to implement our business plan.

We do not know what amounts of dronabinol other companies developing or marketing dronabinol product candidates may have requested for 2013 or will request in future years. The DEA, in assessing factors such as medical need, abuse potential and other policy considerations, may have chosen to set the aggregate dronabinol quota for 2013 lower than the total amount requested by the companies, and may do so in the future. Though companies are permitted to petition the DEA to

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increase the aggregate quota for dronabinol in a given year after it is initially established, there is no guarantee the DEA would act promptly or favorably upon such a petition. The success of our business plan will depend in part on our being able to expand the overall market for the medical use of dronabinol by introducing new dronabinol formulations, and to sell significant amounts of our approved dronabinol products. In order to do so, we will need to receive from the DEA significantly increased allotments of dronabinol quotas over time and likely an increase in the aggregate annual quota. Any delay or refusal by the DEA in establishing quotas necessary for us to execute on our business plan could negatively impact our ability to sell Dronabinol SG Capsule and any other dronabinol product candidate for which we obtain regulatory approval, as well as our preclinical studies and clinical trials, which would in turn have a material adverse effect on our business, our ability to execute on our business plan, our financial position and results of operations, our prospects, and our ability to generate revenue to fund the development of our other product candidates.

Our failure to successfully acquire, develop and market additional product candidates or approved products would impair our ability to grow our business.

As part of our growth strategy we intend to seek to expand our product pipeline by developing or exploring acquisition or in-licensing opportunities of proven drugs that can be paired with our sublingual spray drug delivery system. Some of these drugs may require reformulation to accommodate the approved doses in smaller volumes that are compatible with our delivery system. Any reformulation may increase the risk of failure during development, extend the development timelines, increase development costs and add complexity to the regulatory approval process and in some cases reformulation may not be possible. If we are not able to identify additional drug compounds that can be delivered via the current version of our sublingual spray technology, or if we are unable to successfully develop higher dose versions of this technology, our ability to develop additional product candidates and grow our business would be adversely affected.

Furthermore, we intend to in-license, acquire, develop and/or market additional products and product candidates in the areas of supportive care. Because our internal research and development capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify and select promising pharmaceutical product candidates and products, negotiate licensing or acquisition agreements with their current owners and finance these arrangements.

The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing, sales and other resources, may compete with us for the license or acquisition of product candidates and approved products. We have limited resources to identify and execute the acquisition or in-licensing of third-party products, businesses and technologies and integrate them into our current infrastructure. Moreover, we may devote resources to potential acquisitions or licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts. We may not be able to acquire the rights to additional product candidates on terms that we find acceptable, or at all.

Further, any product candidate that we acquire may require additional development efforts prior to commercial sale, including pre-clinical or clinical testing and approval by the FDA and applicable foreign regulatory authorities. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by regulatory authorities. In addition, we cannot provide assurance that any approved products that we acquire will be manufactured or sold profitably or achieve market acceptance.

We have recently grown our business and will need to further increase the size and complexity of our organization in the future, and we may experience difficulties in managing our growth and executing our growth strategy.

Our management and personnel, systems and facilities currently in place may not be adequate to support our business plan and future growth. With the commercialization of two of our products beginning with Dronabinol SG Capsule in December 2011 followed by Subsys in March 2012, we have increased our number of full-time employees from 32 on December 31, 2010 to 119 as of March 31, 2013, primarily because we established a commercial organization, including approximately 67 sales professionals, and our commercial infrastructure over that period, and the complexity of our business operations has substantially increased. We will need to further expand our scientific, sales and marketing, managerial, operational, financial and other resources to support our planned research, development and commercialization activities.

Our need to effectively manage our operations, growth and various projects requires that we:

- continue to improve our operational, financial, management and regulatory compliance controls and reporting systems and procedures;

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attract and retain sufficient numbers of talented employees;

manage our commercialization activities for Subsys effectively and in a cost-effective manner;

manage our relationship with Mylan related to the commercialization of Dronabinol SG Capsule;

manage our clinical trials effectively;

manage our internal dronabinol production operations effectively and in a cost effective manner;

manage our development efforts effectively while carrying out our contractual obligations to contractors and other third parties; and

continue to improve our facilities, including the planned construction of a second dronabinol API production facility.

In addition, historically, we have utilized and continue to utilize the services of part-time outside consultants to perform a number of tasks for us, including tasks related to accounting and finance, compliance programs, clinical trial management, regulatory affairs, formulation development and other drug development functions. For example, in addition to seeking advice from our scientific advisory board, we utilize consultants for tasks such as state licensing procurement and accounting and book-keeping services. Our growth strategy may also entail expanding our use of consultants to implement these and other tasks going forward. Because we rely on consultants for certain functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. There can be no assurance that we will be able to manage our existing consultants or find other competent outside consultants, as needed, on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our use of consultants, we may be unable to successfully implement the tasks necessary to effectively execute on our planned research, development and commercialization activities and, accordingly, may not achieve our research, development and commercialization goals.

If we fail to attract and keep management and other key personnel, as well as our board members, we may be unable to continue to successfully commercialize Subsys or Dronabinol SG Capsule, develop our product candidates or otherwise implement our business plan.

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on our management, scientific and medical personnel, as well as our board members, including our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, our President and Chief Executive Officer, Michael L. Babich, and our Chief Medical Officer, Dr. Larry Dillaha. The loss of the services of any of these individuals could impede, delay or prevent the continuing commercialization of Subsys and Dronabinol SG Capsule and the development of our product candidates and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we may not be able to find suitable replacements on a timely basis or at all, and our business would likely be harmed as a result. We do not maintain key man insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice. In order to retain valuable employees at our company, in addition to salary and cash incentives, we provide incentive stock options that vest over time. The value to employees of stock options that vest over time will be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract offers from other companies.

We may not be able to attract or retain qualified management and other key personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the Chandler, Arizona area where we are headquartered and nearby geographic locales such as Southern California. Our industry has experienced a high rate of turnover of management personnel in recent years. As such, we could have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts. Many of the other biotechnology and pharmaceutical companies with whom we compete for qualified personnel have greater financial and other resources, different risk profiles and longer histories in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than that which we have to offer. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly our ability to implement our business strategy and achieve our business objectives.

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In addition, we have scientific and clinical advisors who assist us in formulating our development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with applicable manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, or illegal misappropriation of drug product, or illegal promotion of a drug product for off-label use, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Business Conduct and Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our ability to utilize our net operating loss carryforwards, or NOLs, and research and development income tax credit carryforwards maybe limited.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of NOLs and research and development income tax credit carryforwards that could be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. Any such annual limitation, whether as the result of prior transactions, sales of common stock by our existing stockholders or subsequent sales of common stock by us, may significantly reduce the utilization of the NOLs before they expire and could have an adverse effect on our future results of operations.

On November 8, 2010, we entered into the NeoPharm merger. The NeoPharm merger was accounted for as a reverse acquisition and resulted in a change of 50% or more of the ownership of NeoPharm. Based on the above, we have estimated the amount of pre-merger federal NOLs that are available to offset our post-merger income is limited to approximately $158,000 a year for 20 years, or cumulatively $3.0 million as of December 31, 2012. For state income tax purposes, we have $288.0 million of state NOLs including approximately $269.0 million of Illinois state NOLs which are available to offset future Illinois taxable income. We have placed a valuation allowance on our net deferred tax assets, which include our federal and Illinois state NOLs, because it is not more likely than not that such amounts will be realized.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management s time and attention in order to develop acquired products, product candidates or technologies;

incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;

higher than expected acquisition and integration costs;

write-downs of assets or goodwill or impairment charges;

increased amortization expenses;

difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;

impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and

inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial use of our products and clinical use of our product candidates expose us to the risk of product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with Subsys and Dronabinol SG Capsule, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Subsys or Dronabinol SG Capsule or our product candidates could result in injury to a patient or even death. For example, because our sublingual spray technology is designed to be self-administered by patients, it is possible that a patient could fail to follow instructions and as a result apply a dose in a manner that results in injury. In addition, Subsys is an opioid pain reliever that contains fentanyl, and Dronabinol SG Capsule is a synthetic cannabinoid, which are regulated controlled substances under the Controlled Substances Act of 1970, or CSA, and could result in harm to patients relating to its potential for abuse. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury. Product liability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, among others. If we cannot successfully defend ourselves against product liability claims we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

the inability to commercialize our products or, if approved, our product candidates;

decreased demand for our products or, if approved, product candidates;

impairment of our business reputation;

product recall or withdrawal from the market;

withdrawal of clinical trial participants;

costs of related litigation;

distraction of management s attention from our primary business;

substantial monetary awards to patients or other claimants; or

loss of revenues.

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $10.0 million per occurrence and a $10.0 million annual aggregate coverage limit. We also carry excess product liability insurance coverage for commercial product sales and clinical trials with an additional $10.0 million per occurrence and an additional $10.0 million annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a

reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage based on sales of Subsys and Dronabinol SG Capsule, approval, if applicable, of other product candidates or otherwise, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects, including side effects that are less severe than those of Subsys and Dronabinol SG Capsule and our product candidates. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse affect our business, results of operations, financial condition and prospects.

Our business involves the use of hazardous materials and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our research and development activities and our third-party manufacturers and suppliers activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our products and product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers facilities pending use and disposal. We cannot completely eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, injury to our employees and others, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources. We do not currently carry biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

In connection with the reporting of our financial condition and results of operations, we are required to make estimates and judgments which involve uncertainties, and any significant differences between our estimates and actual results could have an adverse impact on our financial position, results of operations and cash flows.

Our discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. For example, we estimate patient prescriptions dispensed using an analysis of third-party information and third-party market research data. If this third-party data underestimates or overestimates actual patient prescriptions dispensed for a given period, adjustments to revenues may be necessary in future periods. Any significant differences between our actual results and our estimates and assumptions could negatively impact our financial position, results of operations and cash flows.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and any future partners, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our commercialization activities, drug development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on a large number of third parties to supply components for and manufacture our products and product candidates, warehouse and distribute Subsys and Dronabinol SG Capsule and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further commercialization and development of our products and product candidates could be delayed.

Changes in accounting standards and their interpretations could adversely affect our operating results.

GAAP are subject to interpretation by the Financial Accounting Standards Board, or FASB, the American Institute of Certified Public Accountants, or AICPA, the SEC, and various other bodies that promulgate and interpret appropriate accounting principles. These principles and related implementation guidelines and interpretations can be highly complex and involve subjective judgments. A change in these principles or interpretations could have a significant effect on our reported financial results, and could affect the reporting of transactions completed before the announcement of a change.

We may be adversely affected by natural disasters or other events that disrupt our business operations and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our corporate headquarters and other facilities are located in Chandler, Arizona and Round Rock, Texas, which are not areas that have experienced severe earthquakes. We do not carry earthquake insurance. However, other natural disasters or similar events, like fires or explosions or large-scale accidents or power outages, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects.

Our enterprise financial systems are located in our Chandler, Arizona headquarters. Our dronabinol API manufacturing facility is in Round Rock, Texas. If a disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters or our Round Rock facility, that damaged critical infrastructure, such as enterprise financial systems or manufacturing resource planning and enterprise quality systems, or that otherwise disrupted operations at either location, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business.

Risks Related to Our Financial Position and Capital Requirements

We have had significant and increasing operating expenses and may require additional funding.

Our operations have consumed substantial amounts of cash since inception. Our cash flow used for operating activities for the year ended December 31, 2012 was $13.6 million. We expect our operating and general and administrative expenses and cash used for operations to continue to be significant and increase substantially as we continue our transition to a public company and in connection with our planned research, development and commercialization activities. We believe that our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through at least the next 12 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Further, we may need to raise additional capital to fund our operations and continue to support our planned research and development and commercialization activities.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to:

- the timing and amount of revenue from sales of our approved products, Subsys and Dronabinol SG Capsule, and any subsequently approved product candidates that are commercialized;
- the size and cost of our commercial infrastructure;
- the timing and cost associated with establishing a second dronabinol manufacturing facility;
- the timing of FDA approval and DEA classification of our product candidates, if at all;
- the timing, rate of progress and cost of any future clinical trials and other product development activities for our dronabinol product candidates and any other product candidates that we may develop, in-license or acquire;

costs associated with marketing and distributing Subsys and any subsequently approved product candidates;

costs and timing of completion of any additional outsourced commercial manufacturing supply arrangements that we may establish;

costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Subsys, Dronabinol SG Capsule and our product candidates;

costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;

costs of operating as a public company;

the effect of competing technological and market developments;

our ability to acquire or in-license products and product candidates, technologies or businesses;

personnel, facilities and equipment requirements; and

the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

We may also need to raise additional funds to finance future cash needs through public or private equity offerings, debt financings (including the issuance of notes payable to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor), receivables or royalty financings or corporate collaboration and licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. To the extent that we raise additional capital by issuing equity securities or convertible debt, the ownership of our existing stockholders will be diluted. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Future borrowings under our loan agreement with Bank of America, and any borrowings under any future debt financing, will need to be repaid, which creates additional financial risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying-off or refinancing any outstanding debt obligations. In addition, if we raise additional funds through corporate collaboration and licensing arrangements, it may be necessary to relinquish potentially valuable rights to products or product candidates, or grant licenses on terms that are not favorable to us.

If we are unable to raise additional capital when required or on acceptable terms, we may be required to significantly delay, scale back or discontinue one or more of our product development programs or commercialization efforts, or other aspects of our business plan. We also may be required to relinquish, license or otherwise dispose of rights to products or product candidates that we would otherwise seek to commercialize or develop ourselves on terms that are less favorable than might otherwise be available. In addition, our ability to achieve long-term profitability or to respond to competitive pressures would be significantly limited.

The terms of our credit facility place restrictions on our operating and financial flexibility.

Although we have recently repaid all outstanding amounts under our $15.0 million revolving credit facility with Bank of America, we may make additional borrowings under this facility in the future. During any such times when credit remains available to us or we have outstanding borrowings under this facility, we will be prohibited from engaging in significant business transactions, such as a change of control or the acquisition by us of another company, or engaging in new business activities which are substantially different from our current business activities, without the prior consent of Bank of America. These restrictions could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders. In addition, in the event of a default under our credit facility, our repayment obligations may be accelerated in full. In the event that we do not have sufficient capital to repay the amounts then owed under the facility, we may be required to renegotiate our credit facility on terms less favorable to us or to cease operations. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations and liquidity could be materially negatively affected by economic conditions generally, both in the U.S. and elsewhere around the world. Domestic and international equity and debt markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue or worsen and the markets continue to remain volatile, our results of operations and liquidity could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may decline. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

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Risks Related to Regulation of our Products and Product Candidates

Our currently marketed products, Subsys and Dronabinol SG Capsule, 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 will also be 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 the product. 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 good laboratory practices, 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, Dronabinol SG Capsule and any of our product candidates containing controlled substances, we and our contract manufacturers will also 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.

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 long-term profitability.

Our products and our product candidates may cause undesirable side effects or have other unexpected properties that could result in post-approval regulatory action.

If we or others identify undesirable side effects, or other previously unknown problems, caused by our products, other products with the same or related active ingredients or our product candidates, after obtaining U.S. regulatory approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product;
- regulatory authorities may require us to recall product;
- regulatory authorities may require the addition of warnings in the product label or narrowing of the indication in the product label;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered or modify the product in some other way;
- the FDA may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety or efficacy of the product;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

Any of the above events resulting from undesirable side effects or other previously unknown problems could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our products.

We are subject to numerous complex regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

The research, testing, development, manufacturing, quality control, approval, labeling, packaging, storage, recordkeeping, promotion, advertising, marketing, distribution, possession and use of our products and product candidates, among other things, are subject to regulation by numerous governmental authorities in the United States and elsewhere. The FDA regulates drugs under the FDCA, and implementing regulations. Noncompliance with any applicable regulatory requirements can result in refusal to approve products for marketing, warning letters, product recalls or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or

refusal to allow the entering into of federal and state supply contracts, fines, civil penalties and/or criminal prosecution. Additionally, the FDA and comparable governmental authorities have the authority to withdraw product approvals that have been previously granted. Moreover, the regulatory requirements relating to our products and product candidates may change from time to time and it is impossible to predict what the impact of any such changes may be.

Subsys and Dronabinol SG Capsule and certain product candidates we are developing are controlled substances as defined in the CSA which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the DEA. The DEA regulates controlled substances as

Schedule I, II, III, IV or V substances. Schedule I substances by definition have high potential for abuse, no currently accepted medical use in the United States and lack accepted safety for use under medical supervision, and may not be marketed or sold in the United States. Except for research and industrial purposes, a pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Fentanyl is listed by the DEA as a Schedule II substance under the CSA. Dronabinol in sesame oil and encapsulated in a soft gelatin capsule in the form previously approved by the FDA is currently listed by the DEA as a Schedule III substance under the CSA. Dronabinol in bulk or other product forms is currently classified by the DEA as a Schedule I substance under the CSA. If the FDA approves formulations of dronabinol which differ from the current defined substance in Schedule III, the DEA will have to make a scheduling determination and place the products in a schedule other than Schedule I in order for such products to be marketed to patients in the United States.

The manufacture, shipment, storage, sale and use, among other things, of controlled substances that are pharmaceutical products are subject to a high degree of regulation. For example, generally all Schedule II substance prescriptions, such as prescriptions for fentanyl, must be written and signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription.

The DEA also conducts periodic inspections of certain registered establishments that handle controlled substances. Facilities that conduct research, manufacture, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate proceedings to restrict, suspend or revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule our products and product candidates as well. While some states automatically schedule a drug when the DEA does so, other states schedule drugs through rulemaking or a legislative action. State scheduling may delay commercial sale of any product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations, permits or licenses in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions by the states in addition to those from the DEA or otherwise arising under federal law.

Controlled substances are also regulated pursuant to several international drug control treaties. These treaties are enforced by the Untied National Commission on Narcotic Drugs. The United States is a signatory to these treaties and thus must conform its laws and regulations to the international requirements, which generally include licensing, recordkeeping and reporting requirements. Both fentanyl and dronabinol are currently classified under the international treaties and current U.S. controls adequately address international requirements. Any change in the international treaties regarding classification of these products could affect regulation of these substances in the United States and in other countries.

Annual DEA quotas on the amount of Subsys allowed to be produced in the United States and our specific allocation of fentanyl by the DEA could significantly limit the production or sale of Subsys.

The DEA limits the availability and production of all Schedule II substances through a quota system which includes a national aggregate quota and individual quotas. Because fentanyl is subject to the DEA s production and procurement quota scheme, the DEA establishes annually an aggregate quota for how much fentanyl may be produced in total in the United States based on the DEA s estimate of the quantity needed to meet legitimate scientific and medicinal needs. This limited aggregate amount of fentanyl that the DEA allows to be produced in the United States each year is allocated among individual companies, who must submit applications annually to the DEA for individual production and procurement quotas. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

Moreover, we do not know what amounts of fentanyl other companies developing product candidates containing fentanyl may request for future years. The DEA, in assessing factors such as medical need, abuse and diversion potential and other policy considerations, may choose to set the aggregate fentanyl quota lower than the total amount requested by the companies. We are permitted to petition the DEA to increase the annual aggregate quota after it is initially established, but there is no guarantee that the DEA would act favorably upon such a petition. Our production and procurement quota of fentanyl may not be sufficient to meet our commercial demand or clinical development needs. Any delay or refusal by the DEA in establishing the production and/or procurement quota or a reduction in our quota for fentanyl or a failure to increase it over time as we anticipate could delay or stop the commercial sale of Subsys or cause us to fail to achieve our expected operating results, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

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Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of our products and any of our product candidates that may be approved by the FDA.

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our potential customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If Subsys, Dronabinol SG Capsule or any of our product candidates that are approved by the FDA are not widely included on the formularies of these plans, our ability to market our products to the Medicare population could suffer.

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, President Obama signed into law the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, or collectively the PPACA, which includes measures to significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the PPACA of importance to the pharmaceutical industry are the following:

an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, beginning in 2011;

an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, retroactive to January 1, 2010, to 23% and 13% of the average manufacturer price for most branded and generic drugs, respectively;

a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer s outpatient drugs to be covered under Medicare Part D, beginning in 2011;

extension of manufacturers Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, effective March 23, 2010;

expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals beginning in April 2010 and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level beginning in 2014, thereby potentially increasing both the volume of sales and manufacturers Medicaid rebate liability;

expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program, effective in January 2010;

new requirements to report certain financial arrangements with physicians and teaching hospitals, as defined in PPACA and its implementing regulations, including reporting any transfer of value made or distributed to teaching hospitals, prescribers, and other healthcare providers and reporting any ownership and investment interests held by physicians and their immediate family members and applicable group purchasing organizations during the preceding calendar year, with data collection to be required beginning August 1, 2013 and reporting to the Centers for Medicare & Medicaid Services, or CMS, to be required by March 31, 2014 and by the 90th day of each subsequent calendar year;

a new requirement to annually report drug samples that manufacturers and distributors provide to physicians, effective April 1, 2012;

expansion of health care fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;

a licensure framework for follow-on biologic products;

a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

creation of the Independent Payment Advisory Board which, beginning in 2014, will have authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law even if Congress does not act on the recommendations; and

establishment of a Center for Medicare Innovation at the CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending beginning by January 1, 2011.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, starting in 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. The ATRA also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects.

In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement and may, in some cases, be unavailable. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products.

In the United States, the commercial success of Subsys, Dronabinol SG Capsule and our product candidates, if and when commercialized, will depend, in part, upon the availability of coverage and reimbursement from third-party payors at the federal, state and private levels. Third-party payors include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payors may deny coverage or reimbursement for a product or therapy in whole or in part if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors have attempted to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms and the amount of reimbursement for particular procedures or drug treatments.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. Alternatively, in response to legislation such as this, we might elect not to seek approval for or market our products in foreign jurisdictions in order to minimize the risk of re-importation, which could also reduce the revenue we generate from our product sales. It is also possible that other legislative proposals having similar effects will be adopted.

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Furthermore, regulatory authorities assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects. For example, average review times at the FDA for marketing approval applications have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. In addition, review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes.

If we fail to comply with federal and state healthcare laws, including fraud and abuse and health information privacy and security laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected.

As a pharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;

- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; and

- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our business activities could be subject to challenge under one or more of such laws. To the extent that any product we make is sold in a foreign country, we may be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could materially adversely affect our ability to operate our business and our financial results.

The FDA provides guidelines with respect to appropriate promotion and continuing medical and health education activities. Although we endeavor to follow these guidelines, the FDA or the Office of the Inspector General: U.S. Department of Health and Human Services may disagree, and we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. In addition, management s attention could be diverted and our reputation could be damaged.

Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business. Moreover, achieving and sustaining compliance with

applicable federal and state privacy, security and fraud laws may prove costly.

Risks Related to Intellectual Property

We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our products or product candidates, such as Subsys, Dronabinol Oral Solution, Dronabinol Inhalation Device and Dronabinol IV Solution, and that are of sufficient breadth to prevent third parties from competing against us.

Our success with respect to our products and product candidates, such as Subsys, Dronabinol Oral Solution, Dronabinol Inhalation Device and Dronabinol IV Solution will depend in part on our ability to obtain and maintain patent protection in both the United States and other countries, to preserve our trade secrets, and to prevent third parties from infringing upon our proprietary rights on our product candidates. Our ability to protect any of our approved drug products from unauthorized or infringing use by third parties depends in substantial part on our ability to obtain and maintain valid and enforceable patents. Fentanyl and dronabinol have been approved for many years and therefore our ability to obtain any patent protection is limited. Composition of matter patents on APIs are a particularly effective form of intellectual property protection for pharmaceutical products as they apply without regard to any method of use. However, we will not be able to obtain composition of matter patents or methods of use patents that cover the APIs in any of our products or product candidates. As a result, competitors who obtain the requisite regulatory approval can offer products with the same active ingredients as our products or product candidates so long as the competitors do not infringe any formulation patents that we may obtain or license, if any.

Our patent portfolio related to our sublingual spray technology that is used in Subsys includes patents and patent applications in the United States, Australia, Brazil, Canada, China, Europe, India Japan, Mexico, New Zealand and Russia. The covered technology and the scope of coverage varies from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our sublingual spray technology.

In addition, the only patent protection that we can expect will otherwise cover Subsys and dronabinol products and product candidates consists of patents relating to formulations, methods of treatment using certain formulations and methods of manufacturing and packaging. Formulation patents preclude competitors from using a similar formulation. Manufacturing or packaging patents preclude competitors from using the same manufacturing or packaging methods. However, these type of patents do not preclude a competitor from making and marketing the same composition of matter unless they use the same formulation or manufacturing or packaging methods. Any patents that we may obtain may be too narrow in scope and thus easily circumvented by competitors. Further, in countries where we do not have granted patents directed to our formulations or manufacturing or packaging, third parties may be able to make, use, or sell products identical to, or substantially similar to, Subsys, our dronabinol products or product candidates.

We have multiple pending patent applications in the United States and in some foreign jurisdictions directed to formulations for our fentanyl and dronabinol products and product candidates. We have a number of pending applications and issued patents in the United States and in many foreign countries, that pertain to either fentanyl or dronabinol formulations. We can give no assurances that any patents will issue, that if they do issue or have issued, they will provide sufficient protection against competitors, or that they would be valid and enforceable.

Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any patents we may obtain or license may not provide us with sufficient protection for our products and product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition, we cannot guarantee that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents have issued or will issue, we cannot guarantee that the claims of these patents are or will be held valid or enforceable by the courts or will provide us with any significant protection against competitive products or otherwise be commercially valuable to us.

Patent applications in the United States are generally maintained in confidence for up to 18 months after their filing. Similarly, publication of discoveries in scientific or patent literature often lag behind actual discoveries. Consequently, we cannot be certain that we or our licensors were the first to invent, or the first to file patent applications on our products or product candidates. In the event that a third party has also filed an U.S. patent application relating to our drug product or a similar invention, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a loss of our U.S. patent position.

In addition, third parties may challenge our in-licensed patents and any of our own patents that we may obtain, which could result in the invalidation or unenforceability of some or all of the relevant patent claims. Litigation or other proceedings to enforce or defend intellectual property rights is very complex, expensive, and may divert our management s attention from our core business and may result in unfavorable results that could adversely affect our ability to prevent third parties from competing with us.

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the patents of others may have an adverse effect on our business;
- it is possible that none of our or our licensors pending patent applications will result in issued patents;
- any patents we obtain or our licensors issued patents may not encompass commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; or
- we may not develop additional proprietary technologies that are patentable.

If we or our licensors fail to prosecute, maintain and enforce patent protection for our products or product candidates, our ability to develop and commercialize our products or product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to our products or product candidates could have a material adverse effect on our business, financial condition and results of operation. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Proprietary trade secrets and unpatented know-how are also very important to our business. Although we have taken steps to protect our trade secrets and unpatented know-how, by entering into confidentiality agreements with third parties, and proprietary information and invention agreements with certain employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect our rights. We also have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. There can be no assurance that binding agreements will not be breached, that we would have adequate remedies for any breach, or that our trade secrets and unpatented know-how will not otherwise become known or be independently discovered by our competitors. If trade secrets are independently discovered, we would not be able to prevent their use. Enforcing a claim that a third party illegally obtained and is using our trade secrets or unpatented know-how is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secret information.

We are a defendant in a lawsuit to seek rescission of certain invention assignments, and if we do not prevail, any resulting rescission of invention assignments could have a material adverse impact on our business by preventing us from obtaining exclusive patent rights covering certain of our products and product candidates.

Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidential information and invention agreements, we

cannot provide any assurances that all such agreements have been duly executed or will be held enforceable.

For example, in September 2009, Insys Pharma and certain of its officers and directors, as well as their spouses, were named as defendants in a lawsuit in Arizona Superior Court brought by Santosh Kottayil, Ph.D., certain of his family members and a trust of which Dr. Kottayil is the trustee. Dr. Kottayil formerly served as President, Chief Scientific Officer and a director of Insys Pharma, among other positions. The complaint brought a cause of action, among others, seeking to rescind Dr. Kottayil s assignment to Insys Pharma of his interest in all of the fentanyl and dronabinol patent applications we own and to recover the benefits of those interests. Insys Pharma and the other defendants answered and filed counter-claims to Dr. Kottayil s complaint. If the patent assignments are successfully rescinded, we may not have exclusive patent rights covering our fentanyl and dronabinol product candidates, and such exclusive patent rights may not be available to us on acceptable terms, if at all, which would have a material adverse effect on our business. If the assignments are rescinded, Dr. Kottayil could assign his interest in the fentanyl and dronabinol patent applications to a competitor and we would not be able to prevent generic copies of our products.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

If we or our collaborators or licensors choose to go to court to stop a third party from using the inventions claimed in our own or in-licensed patents, that third party may ask the court to rule that the patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third-party s activities do not infringe our owned or in-licensed patents. In addition, our own or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in a reexamination or opposition proceeding before a governmental patent agency, or during litigation.

We may also not be able to detect infringement of our own or in-licensed patents, which may be especially difficult for methods of manufacturing or formulation products. While we intend to take actions reasonably necessary to enforce our patent rights, we depend, in part, on our licensors and collaborators to protect a substantial portion of our proprietary rights.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our products and product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our products and product candidates. As the medical device, biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert our products or product candidates infringe the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of medical devices, drugs, products or their methods of use. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our products, product candidates, technology or methods.

In addition, there may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our products, product candidates or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our own and in-licensed issued patents or our pending applications. Our competitors may have filed, and may in the future file, patent applications covering our products, product candidates or technology similar to ours. Any such patent application may have priority over our own and in-licensed patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed an U.S. patent application on inventions similar to those owned or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate, in the United States, in an interference proceeding to determine priority of invention.

If another party has reason to assert a substantial new question of patentability against any of our claims in our own and in-licensed U.S. patents, the third party can request that the patent claims be reexamined, which may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential infringement suits and, interference and reexamination proceedings, we may become a party to patent opposition proceedings where either the patentability of the inventions subject of our patents are challenged, or we are challenging the patents of others. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful.

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We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our products and/or product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party s patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party s patents.

If a third-party s patents was found to cover our products and/or product candidates, proprietary technologies or their uses, we or our collaborators could be enjoined by a court and required to pay damages and could be unable to continue to commercialize our products or our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us or our collaborators on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

There is a substantial amount of litigation involving patent and other intellectual property rights in the device, biotechnology and pharmaceutical industries generally. If a third party claims that we or our collaborators infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management s attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product at issue infringes or violates the third party s rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner s attorneys fees;
- a court prohibiting us from selling or licensing the product unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed to us alleged trade secrets of their other clients or former employers.

As is common in the biotechnology and pharmaceutical industry, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. For example, we have in the past received letters from third parties asserting that one of our employees may have used proprietary information of his former employers in connection with our prior regulatory filings. Litigation may be necessary to defend against these types of claims. Even if we are successful in defending against any such claims, any such litigation 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.

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Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on our own and in-licensed patents are due to be paid to the governmental patent agencies over the lifetime of the patents. Future maintenance fees will also need to be paid on other patents which may be issued to us. We have systems in place to remind us to pay these fees, and we employ outside firms to remind us or our licensor to pay annuity fees due to patent agencies on our patents and pending patent applications. The various governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

Risks Relating to Our Common Stock

Our founder, Executive Chairman and principal stockholder can individually control our direction and policies, and his interests may be adverse to the interests of our stockholders.

As of May 23, 2013, our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, beneficially owned approximately 68% of our capital stock outstanding as of May 23, 2013. By virtue of his holdings, Dr. Kapoor can and will continue to be able to effectively control the election of the members of our board of directors, our management and our affairs and prevent corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders or cause a transaction that we or our other stockholders may view as unfavorable. Accordingly, this concentration of ownership may harm the market price of our common stock by:

delaying, deferring or preventing a change in control;

impeding a merger, consolidation, takeover or other business combination involving us; or

discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

In addition, sales of shares beneficially owned by Dr. Kapoor could be viewed negatively by third parties and have a negative impact on our stock price. Moreover, upon his passing, we cannot assure you as to how these shares will be distributed and subsequently voted.

Moreover, trusts controlled by or affiliated with Dr. Kapoor have been our primary source of financing prior to our recently-completed IPO. We may in the future issue additional debt to entities controlled by or affiliated with Dr. Kapoor and Dr. Kapoor s interest as a holder of our debt may conflict with your interest as a holder of our common stock.

If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, or identify any additional significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

In connection with the audit of our consolidated financial statements for the year ended December 31, 2010, our management and independent registered public accounting firm concluded that there was a material weakness in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness we and our independent registered public accounting firm identified related to a lack of sufficient staff with appropriate training in GAAP and various rules and regulations with respect to financial reporting. During 2011, we did not hire the additional finance staff required to remediate this material weakness. Consequently, this material weakness was identified again in connection with the audit of our consolidated financial statements for the year ended December 31, 2011. Multiple audit adjustments to our consolidated financial statements were made during the course of our 2010 and 2011 audits stemming from this material weakness. Subsequently, with the goal of remediating this material weakness, we hired a new Chief Financial Officer in October 2012 and a new Director of Accounting in December 2012. This material weakness was not identified again in connection with the audit of our consolidated financial statements for the year ended December 31, 2012.

In connection with the audit of our consolidated financial statements for the year ended December 31, 2012, our management and independent registered public accounting firm identified significant deficiencies in our internal control over financial reporting. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial

reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of our financial reporting. These significant deficiencies related to (i) our processes for posting journal entries and performing reconciliations, (ii) our processes related to option grants and (iii) a lack of segregation of duties as a result of access to accounting system data by certain of our internal finance personnel. We have been working to remediate certain of these significant deficiencies, by starting to establish and formalize certain procedures related to the posting of journal entries and performing reconciliations as well as our option grant practices. In addition, we plan to restrict access by certain of our internal finance personnel to certain of our accounting system data with the goal of more clearly segregating duties amongst this personnel.

While we believe we are taking the measures necessary to address the underlying causes of all of these significant deficiencies, we cannot at this time estimate how long it will take and our efforts may not prove to be successful in remediating these significant deficiencies. While we have not incurred and do not expect to incur material expenses specifically related to the remediation of these significant deficiencies, actual expenses may exceed our current estimates and overall costs of compiling the system and processing documentation necessary to assess the effectiveness of our internal control over financial reporting may be material.

We cannot assure you that we have identified all or that we will not in the future have additional significant deficiencies or material weaknesses. In addition, our management and independent registered public accounting firm did not perform an evaluation of our internal control over financial reporting as of December 31, 2012, 2011 or 2010 in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation was required. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional significant deficiencies or material weaknesses may have been identified. If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, or identify any additional significant deficiencies or material weaknesses that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

Maintaining and improving our financial controls and the requirements of being a public company may strain our resources, divert management s attention and affect our ability to attract and retain qualified board members.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, the Sarbanes-Oxley Act and the Nasdaq Stock Market Rules, or Nasdaq rules. The requirements of these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. We are in the process of documenting, reviewing and, where appropriate, improving our internal controls and procedures in preparation for compliance with the SEC regulations adopted pursuant to Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting beginning with the second annual report that we would expect to file with the SEC and, if we are an accelerated filer, a report by our independent auditors addressing these assessments. In addition, beginning with our annual report on Form 10-K following the date we are no longer an emerging growth company as defined in the JOBS Act, we will be required to obtain from our independent registered public accounting firm an attestation report on the effectiveness of our internal control over financial reporting. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more, (ii) December 31, 2018, (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We currently do not have an internal audit group, and we may need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Implementing any appropriate changes to our internal controls may require specific compliance training for our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Moreover, effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent fraud. As a result, our failure to satisfy the requirements of Section 404 on a timely basis could result in the loss of investor confidence in the reliability of our financial statements, which in turn could cause the market value of our common stock to decline.

In accordance with Nasdaq rules, we are required to maintain a majority independent board of directors. We also expect that the various rules and regulations applicable to public companies will make it more difficult and more expensive for us to maintain directors and officers liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to maintain coverage. If we are unable to maintain adequate directors and officers insurance, our ability to recruit and retain qualified directors, especially those directors who may be deemed independent for purposes of Nasdaq rules, and officers will be significantly curtailed.

Compliance with these reporting rules, Sarbanes-Oxley Act and Nasdaq requirements may require us to build out our accounting and finance staff. We may need to expand our accounting and financing staff, and our failure to adequately do so would harm our ability to comply with the requirements listed above.

We expect that the price of our common stock will fluctuate substantially.

The market price for our common stock is likely to be volatile, in part because there has not been a true public market for our common stock reflecting our consolidated operations prior to our recently-completed IPO. In addition, the market price of our common stock may fluctuate significantly in response to a number of factors, most of which we cannot control, including:

- the success of, and fluctuations in, the commercial sales of Subsys, Dronabinol SG Capsule or any other products approved for commercialization;
- the development status of our product candidates, including Dronabinol Oral Solution, and when any of our product candidates receive regulatory approval or acceptable scheduling by the DEA;
- our execution of our sales and marketing, manufacturing and other aspects of our business plan;
- variations in the level of expenses related to our commercialization activities;
- the performance of third parties on whom we rely to manufacture our products and product candidates, supply API and conduct our clinical trials, including their ability to comply with regulatory requirements;
- the results of our preclinical studies and clinical trials;
- variations in the level of expenses related to our product candidates or preclinical and clinical development programs, including relating to the timing of invoices from, and other billing practices of, our CROs and clinical trial sites;
- price and volume fluctuations in the overall stock market;
- changes in operating performance and stock market valuations of other pharmaceutical companies;
- market conditions or trends in our industry or the economy as a whole;
- our execution of collaborative, co-promotion, licensing or other arrangements, and the timing of payments we may make or receive under these arrangements;

the public s response to press releases or other public announcements by us or third parties, including our filings with the SEC and announcements relating to litigation or other disputes, strategic transactions, intellectual property or fentanyl, dronabinol or cannabinoids or other controlled substances impacting us or our business;

the financial projections we may provide to the public, any changes in these projections or our failure to meet these projections;

changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;

ratings downgrades by any securities analysts who follow our common stock;

the development and sustainability of an active trading market for our common stock;

future sales of our common stock by our officers, directors and significant stockholders;

other events or factors, including those resulting from war, incidents of terrorism, natural disasters or responses to these events; and

changes in accounting principles.

In addition, the stock markets, and in particular the Nasdaq Global Market, have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many pharmaceutical companies. Stock prices of many pharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have instituted securities class action litigation following periods of market volatility. If we were involved in securities litigation, we could incur substantial costs and our resources and the attention of management could be diverted from our business.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. As of May 29, 2013, only one securities analyst has published a research report about our business. If no additional securities or industry analysts commence coverage of our company, the trading price for our stock could be negatively impacted. If we obtain additional securities or industry analyst coverage and if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price would likely decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, demand for our stock could decrease, which could cause our stock price and trading volume to decline.

There may not be a viable public market for our common stock.

We cannot predict the extent to which investor interest in our company will lead to the development of an active trading market on the Nasdaq Global Market or otherwise or how liquid that market might become. An active public market for our common stock may not develop or be sustained. If an active public market does not develop or is not sustained, it may be difficult for our stockholders to sell their shares of common stock at a price that is attractive, or at all.

Future sales of our common stock or securities convertible into our common stock may depress our stock price.

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of May 23, 2013, we had 21,395,227 outstanding shares of common stock. This includes the shares that we sold in our IPO, which are eligible to be resold in the public market at any time unless held by an affiliate of ours. 464,353 of the remaining shares were outstanding prior to the NeoPharm merger and, unless held by an affiliate of ours, substantially all of these shares are also be eligible for resale on the public market at any time, and over 11,000,000 of the remaining shares may be sold after the expiration of lock-up agreements at least 180 days after May 2, 2013 pursuant to Rule 144 or Rule 701 under the Securities Act of 1933, as amended, or the Securities Act, unless held by an affiliate of ours.

Moreover, we have registered all shares of common stock that we may issue after our IPO under our equity compensation plans, and these shares can be freely sold in the public market upon issuance, subject to the lock-up agreements described above.

If a large number of shares of our common stock or securities convertible into our common stock are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Anti-takeover provisions in our charter documents and Delaware law might deter acquisition bids for us that you might consider favorable.

Our amended and restated certificate of incorporation and bylaws contain provisions that may make the acquisition of our company more difficult without the approval of our board of directors. These provisions:

establish a classified board of directors so that not all members of our board are elected at one time;

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authorize the issuance of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval, and which may include rights superior to the rights of the holders of common stock;

prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;

provide that the board of directors is expressly authorized to make, alter, or repeal our bylaws; and

establish advance notice requirements for nominations for elections to our board or for proposing matters that can be acted upon by stockholders at stockholder meetings.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law which, subject to certain exceptions, prohibits stockholders owning in excess of 15% of our outstanding voting stock from merging or combining with us. These anti-takeover provisions and other provisions under Delaware law could discourage, delay or prevent a transaction involving a change in control of our company, even if doing so would benefit our stockholders. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing so as to cause us to take certain corporate actions you desire.

We qualify as an emerging growth company as defined in the JOBS Act and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies, which could make our common stock less attractive to investors.

We qualify as an emerging growth company as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including certain reduced financial statement reporting obligations, reduced disclosure obligations about our executive compensation arrangements, exemptions from the requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements, and exemption from the auditor s attestation requirements of Section 404(b) of the Sarbanes-Oxley Act. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more, (ii) December 31, 2018, (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

The continued operation and expansion of our business will require substantial funding. Accordingly, we do not anticipate that we will pay any cash dividends on shares of our common stock for the foreseeable future. Any determination to pay dividends in the future will be at the discretion of our board of directors and will depend upon results of operations, financial condition, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant. Accordingly, any gain from an investment in our common stock will depend on the appreciation of the price of our common stock, which may never occur. Investors seeking cash dividends in the foreseeable future should not invest in our common stock.

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

Use of Proceeds from Registered Securities

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

The underwriting discounts and commissions connected with the offering totaled approximately $2.6 million. We incurred estimated additional costs of approximately $3.3 million in offering expenses, which when added to the underwriting discounts and commissions paid by us, amounts to total fees and costs of approximately $5.9 million. Thus, net offering

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proceeds to us, after deducting underwriting discounts and commissions and offering costs, were $31.0 million. No offering costs were paid directly or indirectly to any of our directors or officers (or their associates) or persons owning ten percent or more of any class of our equity securities or to any other affiliates.

Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents, money market funds and government agency securities. Through May 23, 2013, we have used approximately $11.4 million of the net proceeds from our IPO to repay the outstanding principal balance on our line of credit with Bank of America. We intend to invest the remaining funds in the future in some combination of short and intermediate-term, interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. We plan to use the net proceeds from our IPO to fund capital expenditures and lease expenses for the a second dronabinol manufacturing facility in Austin, Texas and to fund clinical and research and development costs, including fees for a new drug application for dronabinol oral solution and for working capital and other general corporate purposes. Our expected use of net proceeds from our IPO represents our current intentions based upon our present plans and business condition. We cannot predict with certainty all of the particular uses for our current funds, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of these funds will vary depending on numerous factors, including our ability to obtain additional financing, the relative success and cost of our research, preclinical and clinical development programs, and the amount and timing of additional revenues. As a result, our management will have broad discretion in the application of these funds, and investors will be relying on our judgment regarding the application of the net proceeds of the offering.

ITEM 6. EXHIBITS

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

INSYS THERAPEUTICS, INC.

SIGNATURES

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

INSYS THERAPEUTICS, INC.

Dated: June 5, 2013

By: /s/ Michael L. Babich
Michael L. Babich
President and Chief Executive Officer

(Principal Executive Officer)

By: /s/ Darryl S. Baker
Darryl S. Baker

Chief Financial Officer

(Principal Financial and Accounting Officer)

EXHIBIT INDEX

Exhibit Number	Description of Document
3.1(1)	Amended and Restated Certificate of Incorporation of Insys Therapeutics, Inc.
3.2(2)	Amended and Restated Bylaws of Insys Therapeutics, Inc.
3.3(3)	Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
3.4(4)	Certificate of Amendment of Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
3.5(5)	Certificate of Amendment of Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
4.1(6)	Form of Common Stock Certificate of Insys Therapeutics, Inc.
10.1(7)	Chandler 101 Business Center Office Lease dated as of January 4, 2013 between Insys Pharma, Inc. and Frye Road Industrial LLC.
10.2(8)	Amendment No. 1 to Loan Agreement dated as of February 11, 2013 by and between Insys Therapeutics, Inc. and Bank of America, N.A.
10.3(9)	Amendment No. 2 to Loan Agreement and Waiver dated as of March 27, 2013 by and between Insys Therapeutics, Inc. and Bank of America, N.A.
31.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
31.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certification of Principal Executive Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

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

(1) Previously filed as Exhibit 3.1 to the Registrant s Current Report on Form 8-K, filed with the SEC on May 8, 2013, and incorporated herein by reference.
(2) Previously filed as Exhibit 3.2 to the Registrant s Current Report on Form 8-K, filed with the SEC on May 8, 2013, and incorporated herein by reference.
(3) Previously filed as Exhibit 3.5 to the Registrant s Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC, as amended, and incorporated herein by reference.
(4) Previously filed as Exhibit 3.6 to the Registrant s Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC, as amended, and incorporated herein by reference.
(5) Previously filed as Exhibit 3.7 to the Registrant s Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC, as amended, and incorporated herein by reference.
(6) Previously filed as Exhibit 4.1 to the Registrant s Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC, as amended, and incorporated herein by reference.
(7) Previously filed as Exhibit 10.11 to the Registrant s Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC, as amended, and incorporated herein by reference.
(8) Previously filed as Exhibit 10.20 to the Registrant s Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC, as amended, and incorporated herein by reference.
(9) Previously filed as Exhibit 10.21 to the Registrant s Registration Statement on Form S-1 (File No. 333-173154), originally filed with the SEC, as amended, and incorporated herein by reference.