Insys Therapeutics, Inc.
Form S-1/A
May 02, 2013
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As filed with the Securities and Exchange Commission on May 2, 2013

Registration No. 333-173154

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 14

TO

FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Insys Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	2834	51-0327886
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

444 South Ellis Street

Chandler, Arizona 85224

(602) 910-2617

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant s Principal Executive Offices)

Michael L. Babich

President and Chief Executive Officer

Insys Therapeutics, Inc.

444 South Ellis Street

Chandler, Arizona 85224

(602) 910-2617

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

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(858) 550-6000	**(858) 523-5400**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the Securities Act), check the following box. ¨

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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 the 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 þ (Do not check if a smaller reporting company)	Smaller reporting company ¨

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	**Proposed maximum aggregate offering price(1)**	**Amount of registration fee**
Common Stock, $0.0002145 par value per share	$46,000,000	$6,275(2)

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act. Includes the offering price of shares that the underwriters have the option to purchase to cover over-allotments, if any.
(2) Previously paid.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PROSPECTUS SUBJECT TO COMPLETION, DATED MAY 2, 2013

4,000,000 Shares

Common Stock

This is an initial public offering of Insys Therapeutics, Inc. We are offering 4,000,000 shares of common stock. We currently estimate that the initial public offering price of our common stock will be between $8.00 and $10.00 per share.

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol INSY.

Investing in our common stock involves risk. See the section entitled Risk Factors beginning on page 10.

	Per Share	Total
Initial price to public	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses, to Insys Therapeutics, Inc.	$	$

(1) We refer you to Underwriting beginning on page 158 for additional information regarding underwriting compensation.
We have granted to the underwriters an option to purchase up to 600,000 additional shares of common stock to cover over-allotments, if any, exercisable at any time until 30 days after the date of this prospectus.

We are an emerging growth company as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, have elected to comply with certain reduced public company reporting requirements.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares on or about , 2013.

Wells Fargo Securities **JMP Securities**

Oppenheimer & Co.

Prospectus dated , 2013.

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Neither we nor any of the underwriters has authorized anyone to provide you with information different from, or in addition to, that contained in this prospectus or any free writing prospectus we have prepared. If anyone provides you with different or inconsistent information, you should not rely on it. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where or to any person to whom the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates.

For investors outside the United States: neither we nor any of the underwriters has done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

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PROSPECTUS SUMMARY

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. You should read the entire prospectus carefully, especially the section entitled Risk Factors and our consolidated financial statements and related notes, before deciding to buy shares of our common stock.

Overview

We are a commercial-stage specialty pharmaceutical company that develops and commercializes innovative supportive care products. We have two marketed products, Subsys and Dronabinol SG Capsule, which leverage our sublingual spray drug delivery technology and dronabinol formulation and manufacturing capabilities, respectively. In March 2012, we launched Subsys, our proprietary sublingual fentanyl spray for breakthrough cancer pain, or BTCP, in opioid-tolerant patients, through our cost-efficient commercial organization of approximately 50 sales professionals. In March 2013, we increased the size of our commercial organization to approximately 67 sales professionals to enhance our Subsys sales and marketing capabilities. In February 2013, Subsys was the second most prescribed branded transmucosal immediate-release fentanyl, or TIRF, product with 16.1% market share on a prescription basis according to Source Healthcare Analytics. In December 2011, we launched Dronabinol SG Capsule, a generic equivalent to Marinol (dronabinol), an approved second-line treatment for chemotherapy-induced nausea and vomiting, or CINV, and anorexia associated with weight loss in patients with AIDS, through our exclusive distributor, a leading generic pharmaceutical company. Our lead product candidate is Dronabinol Oral Solution, a proprietary orally administered liquid formulation of dronabinol, which would be our second branded supportive care product, if approved. We believe this product candidate may provide increased flexibility in dosing, more convenient delivery and an improved absorption profile in patients, which may ultimately increase patient compliance because of more rapid onset of action and less dose-to-dose variability and allow us to further penetrate and potentially expand the market for the use of dronabinol. We intend to market Dronabinol Oral Solution and any other future supportive care products, if approved, through our commercial organization.

We employ a targeted, cost-efficient approach to commercialization and product development. Our commercial organization utilizes an incentive-based sales model similar to that employed by Sciele Pharma, Inc. and other companies previously led by members of our management team and board, including our founder and Executive Chairman. The physician prescriber base for TIRF products is concentrated with approximately 1,850 physicians writing 90% of all TIRF product prescriptions from the launch of Subsys through February 2013. As a result, we are able to promote Subsys using a highly targeted approach designed to maximize impact with physicians. In the fourth quarter of 2012, our aggregate sales and marketing expenditures were $3.1 million, and we generated $4.8 million in Subsys net revenue. We focus our development efforts on product candidates that utilize innovative formulations to address the clinical shortcomings of existing commercial pharmaceutical products. We intend to utilize our sublingual spray drug delivery technology and dronabinol formulation capabilities to develop novel formulations of approved medications where we believe improved efficacy, onset of action or patient convenience are needed.

We believe there is a large and underserved market for supportive care products. The National Cancer Institute estimates that, as of January 1, 2009, there were approximately 12.5 million people in the United States who had been diagnosed or were living with cancer. Cancer and the radiation or chemotherapy treatment regimens intended to eradicate or inhibit the progression of the disease often cause debilitating side effects and symptoms such as pain, nausea and vomiting in cancer patients.

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These side effects, among others, can impact a patient s quality of life and ability to tolerate cancer treatment regimens. Supportive care is an important component in the treatment of cancer patients, as suggested by an August 2010 article in the New England Journal of Medicine indicating that improved supportive care in cancer patients prolonged median survival by over two months. By focusing on supportive care products, we believe we can contribute to the improvement of cancer patients lives and survival rates.

We are led by a management team and board of directors with substantial experience founding and managing pharmaceutical and related companies. Our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, has held executive management and board positions at Sciele Pharma and OptionCare, Inc., among others. Dr. Kapoor has also had significant experience with supportive care products, including Marinol while he was Chairman of Unimed Pharmaceuticals, Inc. Our President and Chief Executive Officer, Michael L. Babich, has been involved with our company since 2002 in various roles. He was appointed as our President in November 2010 and as our Chief Executive Officer in March 2011. Prior to that, he served as the Chief Operating Officer since 2007 and as a board member since inception. He has worked with Dr. Kapoor for over 11 years, including at EJ Financial Enterprises, Inc., Dr. Kapoor s venture capital firm, and Alliant Pharmaceuticals, Inc., where he served on the board. Our Chief Medical Officer, Dr. Larry Dillaha, served as the Chief Medical Officer of Sciele Pharma until its acquisition by Shionogi and Co., Ltd. in 2008 where he designed and managed the clinical development and regulatory filings of six products that were approved by the U.S. Food and Drug Administration, or FDA, through the 505(b)(2) regulatory pathway. Our Chief Financial Officer, Darryl S. Baker, has previously served as Chief Financial Officer of iGo, Inc. and an audit manager for Ernst & Young LLP. He is a Certified Public Accountant. We intend to leverage the experience of our management team to build Insys into a leading specialty pharmaceutical company focused on commercializing innovative therapies that address unmet medical needs of supportive care.

Our Products and Product Candidates

The following table summarizes certain information regarding our marketed products and most advanced product candidates:

Franchise	Product or Product Candidate	Regulatory Pathway	Indication	Status
Spray	Subsys	505(b)(2)	BTCP in Opioid-Tolerant Patients	Marketed
Dronabinol	Dronabinol SG Capsule	ANDA	CINV and Anorexia Associated with Weight Loss in Patients with AIDS	Marketed[1]
	Dronabinol Oral Solution	505(b)(2)[2]		Pre-NDA[3]
	Dronabinol Line Extensions	505(b)(2)[2]		Preclinical

(1) Marketed in the United States under an exclusive distribution agreement with Mylan Pharmaceuticals Inc.
(2) Anticipated regulatory pathway. A 505(b)(2) New Drug Application (NDA) relies for its approval upon studies that were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. The applicant may rely on the FDA s findings of safety and/or effectiveness for a previously approved drug (the reference drug). However, the applicant must still provide any additional preclinical or clinical data necessary to ensure that differences from the reference drug do not compromise safety and effectiveness. For Dronabinol Oral Solution and our Dronabinol Line Extensions, we expect to use Marinol as the reference drug.
(3) Completed a pre-NDA meeting and pivotal bioequivalence study in 2012 and expect to submit an NDA in the second half of 2013.

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Subsys Sublingual Fentanyl Spray

Subsys is a proprietary, single-use product that delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue. We launched Subsys in March 2012 for the treatment of BTCP. BTCP is characterized by sudden, often unpredictable, episodes of intense pain which can peak in severity at three to five minutes despite background pain medication. We believe Subsys is an important, differentiated treatment option for patients and physicians relative to other TIRF products due to its rapid onset of action, improved bioavailability, most complete range of dosage strengths and ease of administration. According to Source Healthcare Analytics, TIRF products generated $388.1 million in U.S. sales in 2012. Subsys is the fourth new branded product in the TIRF market over the last four years. Within the first four weeks of product launch, Subsys realized greater market share than the previous three branded products combined at their respective peak market penetration levels to date according to Source Healthcare Analytics. Through our ongoing commercial initiatives, we believe we can continue to grow our market share and net revenue for Subsys.

Dronabinol Product Family

We have received FDA approval for Dronabinol SG Capsule, a generic equivalent to Marinol, and we are developing several innovative dronabinol product candidates for the treatment of CINV and appetite stimulation in patients with AIDS. Dronabinol, the active ingredient in Marinol, is a synthetic cannabinoid whose chemical name is delta-9-tetrahydrocannabinol, or THC. In 2012, dronabinol products generated $134.7 million in U.S. sales, according to IMS Health. We believe that Marinol and its generic equivalents have limitations in their current formulations. Marinol is characterized by a highly variable bioavailability and an onset of action that ranges from 30 minutes to one hour. We are developing additional proprietary formulations of dronabinol, the most advanced of which is Dronabinol Oral Solution, to address these limitations.

We produce dronabinol active pharmaceutical ingredient, or API, for our dronabinol product and product candidates at our U.S.-based, state-of-the-art manufacturing facility. We believe this capability provides us with a significant competitive advantage because dronabinol API is a Schedule I material and consequently is subject to annual production limits set by quota for each individual facility, cannot be readily procured, is difficult to import into the United States and has a limited number of suppliers domestically. 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. For our long-term needs, we plan to use a portion of the net proceeds from this offering 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.

Dronabinol SG Capsule. Dronabinol SG Capsule, the first approved product in our dronabinol family, is a dronabinol soft gelatin capsule which is a generic equivalent to Marinol. We launched Dronabinol SG Capsule in the United States through our exclusive distribution partner, Mylan, in December 2011.

Dronabinol Oral Solution. Dronabinol Oral Solution is a proprietary synthetic THC in an oral liquid formulation, which contains ingredients that enhance absorption. We believe that this product candidate may provide increased flexibility in dosing, more convenient delivery and an improved absorption profile in patients. 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 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.

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Our Strategy

Our goal is to become a leading specialty pharmaceutical company focused on commercializing innovative therapies for supportive care. Key elements of our strategy are to:

- Grow Subsys market share and revenues.
- Leverage our cost-efficient commercial organization to market Subsys and, if approved, Dronabinol Oral Solution and other complementary products.
- Achieve FDA approval for Dronabinol Oral Solution and advance our proprietary dronabinol product pipeline.
- Leverage and expand our dronabinol manufacturing capabilities.
- Develop additional sublingual spray product candidates.

Risks Associated with Our Business

Our business and our ability to execute our business strategy are subject to a number of risks that you should be aware of before you decide to buy our common stock. In particular, you should consider the following risks, which are discussed more fully in the section entitled Risk Factors.

- We are at an early stage of commercialization and have a history of net losses and negative cash flow from operations. Our accumulated deficit as of December 31, 2012 was $129.4 million. We cannot predict if or when we will become profitable.
- We are largely dependent on the commercial success of our two approved products, Subsys and Dronabinol SG Capsule. If these products, 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.
- 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.
- We may not be able to obtain regulatory approval of any of our product candidates, including Dronabinol Oral Solution, which would limit our future growth prospects.
- We produce our dronabinol API internally and plan to build a second dronabinol manufacturing facility, and may encounter manufacturing-related issues that could result in supply shortfalls for our dronabinol product and product candidates.
- We rely on third parties to manufacture our products and product candidates, supply API and conduct our clinical trials, and we have limited control over the activities of these third parties and their compliance with regulatory requirements.

We face intense competition from both branded and generic products, and our operating results will suffer if we fail to compete effectively.

We have had significant and increasing operating expenses and may require additional funding. Our operating expenses for the years ended December 31, 2012 and 2011 were $31.3 million and $17.4 million, respectively.

Our level of indebtedness, which was approximately $70.4 million as of March 31, 2013, could adversely affect our ability to raise additional capital to fund our operations.

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.

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

We may not be able to obtain and enforce patent rights or other intellectual property rights that cover our products or product candidates and that are of sufficient breadth to prevent third parties from competing against us.

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.

Recent Financial Results

Although our financial results as of and for the three months ended March 31, 2013 are not yet finalized, the following information reflects our expectations with respect to such results based on currently available information.

For the three months ended March 31, 2013, we expect to report between $10.7 million and $11.1 million of net revenue, including between $9.5 million and $9.7 million from sales of Subsys and between $1.2 million and $1.4 million from sales of Dronabinol SG Capsule, and between $1.7 million and $1.9 million of cost of revenue.

For the three months ended March 31, 2013, we expect to report between $8.4 million and $8.5 million in operating expenses.

For the three months ended March 31, 2013, we expect to report income from operations of between $0.5 million and $1.0 million.

As of March 31, 2013, we expect to report cash and cash equivalents of approximately $0.7 million, notes payable to related party, including interest, of approximately $59.0 million and a line of credit balance of approximately $11.4 million with Bank of America. During the three months ended March 31, 2013, we reduced our line of credit balance by $0.5 million.

The data presented above reflects our estimates based solely upon information available to us as of the date of this prospectus, is not a comprehensive statement of our financial results or position as of or for the three months ended March 31, 2013, and has not been audited, reviewed or compiled by our independent registered public accounting firm, BDO USA, LLP. Accordingly, BDO USA, LLP does not express an opinion or any other form of assurance with respect thereto. Our actual first quarter results will not be available until after this offering is completed, and may differ materially from these first quarter estimates. Accordingly, you should not place undue reliance upon these preliminary estimates. For example, during the course of the preparation of the respective condensed consolidated quarterly financial statements and related notes thereto, additional items that would require material adjustments to be made to the preliminary estimated financial information presented above may be identified. These estimates are not necessarily indicative of future performance or results of operations, and are not necessarily indicative of the results that may be expected for a full year. There can be no assurance that these estimates will be realized, and estimates are subject to risks and uncertainties, many of which are not within our control. See Risk Factors and Special Note Regarding Forward-Looking Statements. Where we have provided an estimated range for our financial results for the three months ended March 31, 2013, we are currently unable to provide an exact figure due to the incomplete information available to us as of the date of this prospectus and the fact that the review of our financial results for the quarter is on-going. We believe that our estimated quarterly financial results presented above are consistent with the applicable trends and expectations discussed in Management s Discussion and Analysis of Financial Condition and Results of Operations.

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Implications of Being an Emerging Growth Company

We qualify as an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- reduced disclosure about our executive compensation arrangements;
- no requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting.

We may take advantage of these exemptions until we are no longer an emerging growth company. We would cease to be an emerging growth company on the date that is 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering, (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 Securities and Exchange Commission, or SEC. We may choose to take advantage of some but not all of these exemptions. We have taken advantage of reduced reporting requirements in this prospectus. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. Pursuant to the JOBS Act, we were eligible to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies, but we have irrevocably elected not to do so.

Corporate Information

We were incorporated as Oncomed Inc. in Delaware in June 1990, and subsequently changed our name to NeoPharm, Inc. On October 29, 2010, we entered into an Agreement and Plan of Merger with Insys Therapeutics, Inc., a Delaware corporation, and ITNI Merger Sub Inc., our wholly-owned subsidiary and a Delaware corporation. On November 8, 2010, pursuant to the Agreement and Plan of Merger, ITNI Merger Sub Inc. merged with and into Insys Therapeutics, Inc., and Insys Therapeutics, Inc. survived as our wholly-owned subsidiary. We refer to this transaction herein as the NeoPharm merger. Following the NeoPharm merger, our wholly-owned subsidiary, Insys Therapeutics, Inc., changed its name to Insys Pharma, Inc. and we changed our name to Insys Therapeutics, Inc.

Our principal executive offices are located at 444 South Ellis Street, Chandler, Arizona 85224 and our telephone number is (602) 910-2617. Our corporate website address is www.insysrx.com. We do not incorporate the information contained on, or accessible through, our website into this prospectus, and you should not consider it part of this prospectus. For convenience in this prospectus, Insys, we, us, and our refer to Insys Therapeutics, Inc. and its subsidiaries taken as a whole, and NeoPharm refers to NeoPharm, Inc. prior to the NeoPharm merger, in each case unless otherwise noted. The design trademark Insys Therapeutics, Inc. in logo format, along with the word trademarks Insys Therapeutics, Inc., Insys and Subsys are officially registered on the Principal Register of the United States Patent and Trademark Office. This prospectus also contains trademarks and trade names of other companies, and those trademarks and trade names are the property of their respective owners. We do not intend our use or display of other companies trademarks or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies or products.

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The Offering

Common stock offered by us	4,000,000 shares (or 4,600,000 shares if the underwriters over-allotment option is exercised in full)
Common stock to be outstanding after this offering	19,971,068 shares (or 20,571,068 shares if the underwriters over-allotment option is exercised in full)
Use of proceeds from this offering	We intend to use the net proceeds from this offering to fund the establishment of a second dronabinol manufacturing facility; to repay all of the outstanding principal and interest under our revolving credit facility with Bank of America, N.A.; to support the submission of our planned NDA for Dronabinol Oral Solution; and to fund product development and other general corporate purposes. See the section entitled Use of Proceeds.
Risk factors	You should read the section entitled Risk Factors in this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.
Proposed NASDAQ Global Market symbol	INSY

The number of shares of our common stock that will be outstanding after this offering is based on 15,971,068 shares outstanding as of March 31, 2013 (after giving effect to the conversion of our convertible preferred stock outstanding as of such date into an aggregate of 8,528,860 shares of our common stock and the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, both of which will occur automatically immediately prior to the closing of this offering), and excludes:

- 2,083,695 shares of our common stock issuable upon the exercise of outstanding options as of March 31, 2013 under our equity incentive plans, with a weighted average exercise price of $3.22 per share; and
- an aggregate of 1,715,147 shares of our common stock reserved for future issuance under our 2013 equity incentive plan, or the 2013 plan, and our 2013 employee stock purchase plan, or the 2013 ESPP, each of which will become effective upon the signing of the underwriting agreement for this offering.

Unless otherwise stated, all information contained in this prospectus assumes:

- the automatic conversion of all of our outstanding convertible preferred stock into an aggregate of 8,528,860 shares of common stock immediately prior to the closing of this offering;
- the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the

cover page of this prospectus, immediately prior to the closing of this offering;

the filing of our amended and restated certificate of incorporation and adoption of our amended and restated bylaws, which will occur upon the closing of this offering; and

no exercise of the underwriters over-allotment option to purchase additional shares.

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Summary Consolidated Financial Data

The following tables set forth our summary consolidated financial data. The summary consolidated financial data for the years ended December 31, 2012 and 2011 and as of December 31, 2012 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. You should read this summary consolidated financial data in conjunction with the sections entitled Selected Consolidated Financial Data and Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of our results to be expected in the future.

	Years Ended December 31,	
	2012	2011
	(in thousands, except per share data)	
Statements of Comprehensive Loss Data:		
Net revenue	$ 15,476	$
Cost of revenue	7,627	
Gross profit	7,849	
Operating expenses:		
Sales and marketing	11,411	
Research and development	6,305	8,334
General and administrative	8,170	9,039
Impairment of intangible assets and goodwill	5,403	
Total operating expenses	31,289	17,373
Loss from operations	(23,440)	(17,373)
Other income (expense), net	1,746	(25)
Interest expense, net	(2,684)	(1,963)
Loss before income taxes	(24,378)	(19,361)
Income tax benefit		
Net and comprehensive loss	(24,378)	(19,361)
Net loss allocable to preferred stockholders	$ (22,318)	$ (17,731)
Net loss allocable to common stockholders	$ (2,060)	$ (1,630)
Basic and diluted net loss per common share[(1)]	$ (2.62)	$ (2.08)
Basic and diluted weighted average common shares outstanding used to compute net loss per common share[(1)]	787,174	784,020
Pro forma basic and diluted net loss per common share (unaudited)[(1)(2)]	$ (1.37)	
Pro forma basic and diluted weighted average common shares outstanding used to compute net loss per common share (unaudited)[(1)(2)]	15,902,216	

(1)

Please see Note 13 to our audited consolidated financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the net loss per common share and pro forma net loss per common share, and the number of common shares used in computing these amounts.

(2) The calculations for pro forma net loss per common share assume the conversion of (i) our convertible preferred stock outstanding as of the date presented into 8,528,860 shares of our common stock, which will occur automatically immediately prior to the closing of this offering, and (ii) $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering, as if they had occurred as of the beginning of the period presented.

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	As of December 31, 2012		
	Actual	Pro Forma[2]	Pro Forma As Adjusted[3]
		(unaudited)	
		(in thousands)	
Balance Sheet Data:			
Cash and cash equivalents[1]	$ 361	$ 361	$ 18,719
Total current assets[1]	11,889	11,889	30,247
Total assets[1]	18,741	18,741	37,099
Total current liabilities, including debt	83,419	25,036	13,178
Total liabilities	83,419	25,036	13,178
Total stockholders equity (deficit)[1]	(64,678)	(6,295)	23,921

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, total current assets, total assets and total stockholders equity (deficit) by approximately $3.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) The pro forma balance sheet data as of December 31, 2012 above gives effect to (i) the filing of our amended and restated certificate of incorporation which will occur upon the closing of this offering, (ii) the conversion of our convertible preferred stock outstanding as of such date into 8,528,860 shares of our common stock, which will occur automatically immediately prior to the closing of this offering and (iii) the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering.

(3) The pro forma as adjusted balance sheet data as of December 31, 2012 above gives further effect to (1) our receipt of the estimated net proceeds from the sale of shares of common stock by us in this offering at an assumed initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (2) the application of approximately $11.9 million of the net proceeds from this offering to repay all of the outstanding principal and accrued interest under our revolving credit facility with Bank of America.

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RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the following risk factors, as well as the other information in this prospectus, before deciding whether to invest in shares of our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and prospects. In that case, the trading price of our common stock could decline, and you may lose all or part of your investment.

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.

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 December 31, 2012, our accumulated deficit was $129.4 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, and our losses and negative cash flow may continue.

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 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. 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 over time, 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.

We anticipate that in the near term our ability to become 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;

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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 profitable, if ever. Even if we do achieve profitability, we may not be able to sustain or 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.

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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.

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.

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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

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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

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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 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

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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 may be 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

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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

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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

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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.

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, which has a PDUFA date scheduled for March 27, 2013, 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

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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

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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 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.

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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

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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;

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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, 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

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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.

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

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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 more 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

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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 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

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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

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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;
- 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

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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.

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 may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, substantial changes in our ownership may limit the amount of NOLs and research and development income tax

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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 additional sales of common stock by us after this offering, 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.

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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.

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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

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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 transition to a public company and in connection with our planned research, development and commercialization activities. We believe that the net proceeds from this offering and 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 following this offering 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;

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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, your ownership 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. Our 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 our 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 profitability or to respond to competitive pressures would be significantly limited.

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Our level of indebtedness could adversely affect our ability to raise additional capital to fund our operations, limit our ability to react to changes in the economy or our industry and prevent us from meeting our obligations.

As of March 31, 2013, the amount of our total indebtedness, including accrued interest, was approximately $70.4 million, approximately $59.0 million of which we incurred from borrowings from trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, and approximately $11.4 million of which we borrowed pursuant to our revolving credit facility with Bank of America. As of March 31, 2013, approximately $3.6 million remained available to us for borrowing under this facility. In connection with this offering, the entire aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with Dr. Kapoor will convert into shares of our common stock at the initial public offering price.

Our outstanding debt and related debt service obligations could have important adverse consequences to us, including:

- heightening our vulnerability to downturns in our business or our industry or the general economy and restricting us from making improvements or acquisitions, or exploring business opportunities;
- requiring a significant portion of our available cash to be dedicated to the payment of principal and interest on our indebtedness, therefore reducing our ability to use our available cash to fund our operations, capital expenditures and future business opportunities;
- limiting our ability to adjust to changing market conditions and placing us at a competitive disadvantage compared to our competitors who have greater capital resources; and
- subjecting us to financial and other restrictive covenants in our debt instruments, the failure with which to comply could result in an event of default under the applicable debt instrument that allows the lender to demand immediate repayment of the related debt.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay product development, sales and marketing, capital and other expenditures, sell assets, seek additional capital or restructure or refinance our indebtedness. These alternative measures may not be successful and may not permit us to meet our scheduled debt service obligations. This risk is increased by the fact that borrowings under our revolving credit facility with Bank of America bear interest at a variable rates, exposing us to the risk that the amount of cash required to pay interest will increase to the extent that market interest rates increase.

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

Although we intend to use a portion of the proceeds from this offering to repay 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.

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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.

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;

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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 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;

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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

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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.

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;

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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.

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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

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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, 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. Please see the section entitled Business Legal Proceedings.

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.

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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.

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

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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.

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

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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 this Offering and an Investment in Our 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 March 31, 2013, our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, beneficially owned approximately 84% of our capital stock outstanding as of March 31, 2013, after giving effect to the issuance of shares of our common stock upon conversion of notes beneficially owned by him and accrued interest thereon immediately prior to the closing of this offering, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus. Upon the closing of this offering, assuming no exercise of the underwriters over-allotment option, Dr. Kapoor will beneficially own approximately 67% of our outstanding shares of common stock. 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 to date. As of March 31, 2013, we owed $59.0 million in debt and accrued interest to trusts controlled by or affiliated with Dr. Kapoor. While this outstanding debt will convert into shares of our common stock upon completion of this offering, 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

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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 expect to take 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.

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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 will be 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 will require, among other things, that we file annual, quarterly and current reports with respect to our business and financial condition.

The Sarbanes-Oxley Act will require, 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering, (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 will be 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.

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

Following this offering, 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 this offering. 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

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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. We do not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence coverage of our company, the trading price for our stock would be negatively impacted. If we obtain 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.

Although our common stock was once traded on the Nasdaq Capital Market and some of our common stock is currently quoted on the Pink Sheets, a centralized electronic quotation service for over-the-counter securities, immediately prior to this offering there is no liquid public market on which our common stock is actively and readily traded. The initial public offering price of our common stock for this offering will be determined through negotiations between us and the representatives of the underwriters, and may not be indicative of the market price of our common stock following this offering. If you purchase shares of our common stock, you may not be able to resell those shares at or above the initial public offering price. 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 after the offering. If an active public market does not develop or is not sustained, it may be difficult for you to sell your shares of common stock at a price that is attractive to you, 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. After this offering, we will have 19,971,068 outstanding shares of common stock based on the number of shares outstanding as of March 31, 2013. This includes the shares that we are selling in this offering, which may be resold in the public market immediately 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 will also be eligible for resale on the public market immediately, and 11,070,519 of the remaining shares may be sold after the expiration of lock-up agreements at least 180 days after the date of this prospectus 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, as more fully described in the section entitled Shares Eligible for Future Sale.

Moreover, we also intend to register all shares of common stock that we may issue after this offering under our equity compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to the lock-up agreements described above and in the section entitled Underwriting Lock-Up Agreements.

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.

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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;
- 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) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering, (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.

If you purchase shares of common stock sold in this offering, you will incur immediate and substantial dilution.

If you purchase shares of common stock in this offering, you will incur immediate and substantial dilution in the pro forma as adjusted amount of $7.80 per share, because the initial public offering

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price of $9.00 is substantially higher than the pro forma as adjusted net book value per share of our outstanding common stock as of December 31, 2012. This dilution is due in large part to the fact that our earlier investors paid substantially less than the initial public offering price when they purchased their shares. Moreover, investors who purchase shares of common stock in this offering will contribute approximately 21% of our total funding to date but will own only approximately 20% of our outstanding shares. In addition, you may also experience additional dilution upon future equity issuances, including upon conversion of any outstanding debt, or the exercise of stock options to purchase common stock granted to our employees, consultants and directors under our stock option and equity incentive plans. Please see the section entitled Dilution.

Because management has broad discretion as to the use of the net proceeds from this offering, you may not agree with how we use them, and such proceeds may not be applied successfully.

Our management will have considerable discretion over the use of proceeds from this offering. We intend to use the net proceeds from this offering:

- to fund the establishment of a second dronabinol manufacturing facility, including the purchase of related equipment;
- to repay all of the outstanding principal and interest under our revolving credit facility with Bank of America;
- to support the submission of our planned NDA for Dronabinol Oral Solution; and
- to fund working capital and other general corporate purposes, including further development of our family of dronabinol product candidates and our sublingual spray technology.

In addition, a portion of the net proceeds may also be used to acquire or license products, technologies or businesses. However, we do not currently have any specific plans for use of the net proceeds from this offering, nor have we performed studies or made preliminary decisions with respect to the best use of the capital resources resulting from this offering. As such, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common stock. You will be relying on the judgment of our management concerning these uses and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The failure of our management to apply these funds effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline.

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, if you purchase shares in this offering, realization of a gain on your investment 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 purchase our common stock.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. The forward-looking statements are contained principally in the sections entitled Prospectus Summary, Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and Business. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- the rate and degree of market acceptance and sales of any of our approved products, including our ability to increase sales of Subsys and Dronabinol SG Capsule;
- the size and potential growth of the markets for any of our existing or future approved products, and our ability to capture share in or impact the size of those markets;
- the benefits of our products and product candidates, especially in comparison to competitors products and product candidates;
- market and industry trends;
- our ability to successfully execute on our commercialization strategy for any of our approved products, including the performance of Mylan under our distribution agreement for Dronabinol SG Capsule and maintaining a sufficient commercial organization to sell and market Subsys and any additional proprietary products that are approved;
- our sales and marketing activities, including the performance of our current sales force in promoting Subsys as well as our ability to successfully leverage our existing commercial infrastructure and incentive compensation approach to market Dronabinol Oral Solution, if approved;
- our manufacturing activities, including our plans to build a second dronabinol manufacturing facility as well as our ability to manufacture, or otherwise secure the manufacture of, sufficient amounts of our API for our commercial activities, as well as for our preclinical studies and clinical trials;
- the benefits of operating our own dronabinol manufacturing facility or facilities;
- our research and development plans, including those regarding our potential dronabinol line extensions and sublingual spray product candidates;
- the safety and efficacy of our products and product candidates;
- the anticipated regulatory pathways for our product candidates;

our ability to successfully complete preclinical and clinical development of, and obtain regulatory approval and acceptable DEA classifications for, our product candidates, including Dronabinol Oral Solution, and commercialize any approved products on our expected timeframes or at all;

the content and timing of submissions to and decisions made by the FDA, the DEA and other regulatory agencies, including our anticipated NDA for Dronabinol Oral Solution;

our expectations regarding DEA quotas;

our ability to leverage the experience of our management team;

our ability to attract and keep management and other key personnel;

the capacities and performance of our suppliers, manufacturers, CROs and other third parties over whom we have limited control;

the actions of our competitors and success of competing drugs that are or may become available;

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our expectations with respect to future growth and investments in our infrastructure, and our ability to effectively manage any such growth;

the effects of government regulation and regulatory developments, including those associated with REMS and the legalization of marijuana, and our ability and the ability of the third parties with whom we engage to comply with applicable regulatory requirements;

our financial performance, including our net revenue, return rates and related estimates, cost of revenue, gross profit and gross margin, operating expenses, utilization of NOLs, stock-based compensation expense, cash flows, expected uses of anticipated cash flow, funding requirements and market risk;

our expected financial results as of and for the three months ended March 31, 2013;

our expectations regarding future planned expenditures, including those associated with our planned second dronabinol manufacturing facility and those associated with our planned Dronabinol Oral Solution NDA;

our expectations with respect to product pricing;

our ability to effectively remediate any significant deficiencies or material weaknesses in our internal control over financial reporting;

our ability to achieve and maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act;

our expectations with respect to the JOBS Act;

our expectations regarding ongoing litigation related matters;

our ability to obtain, maintain and successfully enforce adequate patent and other intellectual property protection of any of our products and product candidates;

our ability to operate our business without infringing the intellectual property rights of others;

our plans to potentially transact business outside the United States; and

our anticipated use of the net proceeds from this offering.

In some cases, you can identify these statements by terms such as anticipates, believes, could, estimates, expects, intends, may, plans predicts, projects, should, will, would or the negative of those terms, and similar expressions. These forward-looking statements reflect our management s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this prospectus and are subject to risks and uncertainties. We discuss many of these risks in greater detail in the section entitled Risk Factors. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual

results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. The forward-looking statements contained in this prospectus are excluded from the safe harbor protection provided by the Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act.

You should read this prospectus and the documents that we reference in this prospectus, and have filed as exhibits to the registration statement of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

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USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $30.2 million (or approximately $35.2 million if the underwriters over-allotment option is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on an assumed initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A $1.00 increase (decrease) in the assumed initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $3.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create an active public market for our common stock and to facilitate our future access to the public equity markets. We intend to use the net proceeds from this offering as follows:

- approximately $11.0 million to $13.0 million to fund the establishment of a second dronabinol manufacturing facility, including the purchase of related equipment;
- approximately $11.4 million to repay all of the outstanding principal and accrued interest under our revolving credit facility with Bank of America (assuming a repayment date of May 6, 2013);
- approximately $2.7 million to support the submission of our planned NDA for Dronabinol Oral Solution; and
- the remainder to fund working capital and other general corporate purposes, including further development of our family of dronabinol product candidates and our sublingual spray product candidates.

As of March 31, 2013, there was an aggregate of $11.4 million of principal outstanding under our revolving credit facility with Bank of America, which consists of short-term borrowings we have used for working capital. Amounts outstanding under our revolving line of credit bear interest at our election at either (a) LIBOR plus 1.0% (1.20% as of March 31, 2013) or (b) British Bankers Association LIBOR Daily Floating Rate plus 1.0%. The outstanding amounts under the facility are currently scheduled to mature on February 15, 2014.

We may also use a portion of the net proceeds to in-license, acquire or invest in complementary businesses or products; however, we have no current commitments or obligations to do so. Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term interest-bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the U.S. government. We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months.

The amounts and timing of our actual expenditures will depend on numerous factors, including the commercial success of Subsys and Dronabinol SG Capsule, whether and when we are able to obtain regulatory approval for and commercially launch Dronabinol Oral Solution, the timing and progress of our plans to build a second dronabinol manufacturing facility, the size of our sales force, our decisions to conduct, and the progress of, our preclinical and clinical trials and other development and commercialization efforts, as well as the amount of cash used in our operations. Therefore, the amount actually spent for the purposes described above may vary significantly. We also may find it necessary or advisable to use the net proceeds for other purposes, and we will have broad discretion in the application of the net proceeds.

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DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions and business prospects.

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MARKET, INDUSTRY AND OTHER DATA

Unless otherwise indicated, information contained in this prospectus concerning our industry and the market in which we operate, including our market position, market opportunity and market size, is based on information from various sources, on assumptions that we have made based on such data and other similar sources and on our knowledge of the markets for our products. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates.

While we believe the market position, market opportunity and market size information included in this prospectus is generally reliable, such information is inherently imprecise. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section entitled Risk Factors and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization as of December 31, 2012 on:

- an actual basis;
- a pro forma basis to give effect to (1) the filing of our amended and restated certificate of incorporation which will occur upon the closing of this offering, (2) the conversion of our convertible preferred stock outstanding as of such date into 8,528,860 shares of our common stock which will occur automatically immediately prior to the closing of this offering and (3) the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering; and
- a pro forma as adjusted basis to give further effect to (1) the sale of shares of common stock by us in this offering at an assumed initial offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and (2) the repayment of $11.9 million in outstanding principal and interest under our revolving credit facility with Bank of America.

The information in this table is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read the information in this table together with our audited consolidated financial statements and accompanying notes and the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations appearing elsewhere in this prospectus.

	As of December 31, 2012		
	Actual	Pro Forma	Pro Forma As Adjusted[1]
	(unaudited)		
	(in thousands, except share and per share data)		
Cash and cash equivalents	$ 361	$ 361	$ 18,719
Debt, current and long-term	$ 70,241	$ 11,858	$
Stockholders equity			
Convertible preferred stock, $0.01 par value: 15,000,000 shares authorized, 14,864,607 shares issued and outstanding, actual; no shares authorized, issued or outstanding, pro forma and pro forma as adjusted	149		
Preferred stock, $0.001 par value: no shares authorized, issued or outstanding, actual; 10,000,000 shares authorized and no shares issued and outstanding, pro forma and pro forma as adjusted			
Common stock, $0.0002145 par value: 25,000,000 shares authorized, 856,026 shares issued and outstanding, actual; 50,000,000 shares authorized, 15,971,068 shares issued and outstanding, pro forma; 50,000,000 shares authorized, 19,971,068 shares issued and outstanding, pro forma as adjusted		3	4
Additional paid-in capital	64,604	123,133	153,348
Notes receivable from stockholders	(21)	(21)	(21)
Accumulated deficit	(129,410)	(129,410)	(129,410)
Total stockholders equity (deficit)	(64,678)	(6,295)	23,921

Total capitalization	$ 5,563	$ 5,563	$ 23,921

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, would increase (decrease) each of the pro forma

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as adjusted cash and cash equivalents, additional paid-in capital, total stockholders equity (deficit) and total capitalization by approximately $3.7 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The number of shares of our common stock outstanding as of December 31, 2012 on an actual, pro forma and pro forma as adjusted basis excludes:

- 2,091,195 shares of our common stock issuable upon the exercise of outstanding options as of December 31, 2012 under our equity incentive plans, with a weighted average exercise price of $3.22 per share; and
- an aggregate of 1,715,147 shares of common stock reserved for future issuance under the 2013 plan and 2013 ESPP, each of which will become effective upon the signing of the underwriting agreement for this offering.

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DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value (deficit) per share of our common stock after this offering. The historical net tangible book deficit of our common stock as of December 31, 2012 was $64.7 million, or $75.56 per share of common stock, based on the number of shares of common stock outstanding as of December 31, 2012, without giving effect to the conversion of our outstanding convertible preferred stock or outstanding notes and accrued interest thereon into shares of our common stock immediately prior to the closing of this offering. Historical net tangible book value (deficit) per share is determined by dividing the number of shares of our common stock outstanding as of December 31, 2012 into the amount of our total tangible assets (total assets less intangible assets) less total liabilities allocable to holders of our common stock.

The pro forma net tangible book value as of December 31, 2012 of $(6.3) million, or $(0.39) per share of our common stock, represents our historical net tangible book deficit as of December 31, 2012 after giving effect to (1) the conversion of all of our outstanding convertible preferred stock into an aggregate of 8,528,860 shares of common stock which will occur automatically immediately prior to the closing of this offering and (2) the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering.

Investors participating in this offering will incur immediate, substantial dilution. After giving further effect to the sale of 4,000,000 shares of common stock by us in this offering at an assumed initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2012 would have been $23.9 million, or $1.20 per share. This represents an immediate increase in pro forma as adjusted net tangible book value of $1.59 per share to existing stockholders, and an immediate dilution of $7.80 per share to investors participating in this offering. The following table illustrates this per share dilution:

Assumed initial public offering price per share		$ 9.00
Historical net tangible book value (deficit) per share as of December 31, 2012	$(75.56)	
Pro forma increase in net tangible book value (deficit) per share as of December 31, 2012 attributable to the conversion of convertible preferred stock	$ 68.67	
Pro forma increase in net tangible book value (deficit) per share as of December 31, 2012 attributable to the conversion of outstanding notes and accrued interest	$ 6.50	
Pro forma net tangible book value (deficit) per share as of December 31, 2012	$ (0.39)	
Increase in pro forma net tangible book value per share attributable to investors participating in this offering	$ 1.59	
Pro forma as adjusted net tangible book value per share after this offering		$ 1.20
Pro forma as adjusted dilution per share to investors participating in this offering		$ 7.80

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The number of shares of our common stock outstanding as of December 31, 2012 on an actual, pro forma and pro forma as adjusted basis excludes 2,091,195 shares of our common stock issuable upon the exercise of outstanding options as of December 31, 2012 under our equity incentive plans, with a weighted average exercise price of $3.22 per share.

In addition, effective upon the signing of the underwriting agreement for this offering, an aggregate of 1,715,147 shares of our common stock will be reserved for issuance under the 2013 plan and the 2013 ESPP, and these share reserves will also be subject to automatic annual increases in accordance with the terms of the plans. Furthermore, we may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that any of these options are exercised, new stock awards are issued under our equity incentive plans or we issue additional shares of common stock or other equity or convertible debt securities in the future, investors participating in this offering will experience further dilution.

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SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated financial data. The selected consolidated statements of comprehensive loss data for the years ended December 31, 2012 and 2011 and the selected consolidated balance sheets data as of December 31, 2012 and 2011 are derived from our audited consolidated financial statements appearing elsewhere in this prospectus. You should read this selected consolidated financial data in conjunction with the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations and our consolidated financial statements and related notes appearing elsewhere in this prospectus. Our historical results are not necessarily indicative of our results to be expected in the future.

	Years Ended December 31,	
	2012	2011
	(in thousands, except share and per share data)	
Consolidated Statements of Comprehensive Loss Data:		
Net revenue	$ 15,476	$
Cost of revenue	7,627	
Gross profit	7,849	
Operating expenses:		
Sales and marketing	11,411	
Research and development	6,305	8,334
General and administrative	8,170	9,039
Impairment of intangible assets and goodwill	5,403	
Total operating expenses	31,289	17,373
Loss from operations	(23,440)	(17,373)
Other income (expense), net	1,746	(25)
Interest expense	(2,684)	(1,963)
Loss before income taxes	(24,378)	(19,361)
Income tax benefit		
Net and comprehensive loss	(24,378)	(19,361)
Net loss allocable to preferred stockholders	$ (22,318)	$ (17,731)
Net loss allocable to common stockholders	$ (2,060)	$ (1,630)
Basic and diluted net loss per common share	$ (2.62)	$ (2.08)
Basic and diluted weighted average common shares outstanding used to compute net loss per common share[(1)]	787,174	784,020
Basic and diluted pro forma net loss per common share (unaudited)[(1)(2)]	$ (1.37)	
Basic and diluted weighted average common shares outstanding used to compute pro forma net loss per common share (unaudited)[(1)(2)]	15,902,216	

(1) Please see Note 13 to our audited consolidated financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the net loss per common share and proforma net loss per common share, and the number of common shares used in computing these amounts.

(2) The calculations for pro forma net loss per common share assume the conversion of (i) our convertible preferred stock outstanding as of the date presented into 8,528,860 shares of our common stock, which will occur automatically immediately prior to the closing of this offering, and (ii) $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering, as if they had occurred as of the beginning of the period presented.

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	As of December 31, 2012	2011
	(in thousands)	
Balance Sheets Data:		
Cash and cash equivalents	$ 361	$ 11
Total current assets	11,889	7,908
Total assets	18,741	20,960
Total current liabilities, including debt	83,419	61,701
Total liabilities	83,419	64,173
Total stockholders deficit	(64,678)	(43,213)

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MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the section entitled Selected Consolidated Financial Data and our consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in the section entitled Risk Factors and elsewhere in this prospectus. You should carefully read the Risk Factors section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please see the section entitled Special Note Regarding 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 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 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, in December 2011.

We have an exclusive license agreement with Aptar for our proprietary sublingual spray device. In March 2011, we entered into an exclusive supply agreement with Aptar. In May 2011, we entered into a manufacturing agreement with DPT pursuant to which we engaged DPT on an exclusive basis to provide processing and packaging services with respect to Subsys. We market Subsys through our U.S.-based field sales force focused on supportive care, which numbered approximately 50 sales professionals as of December 31, 2012. In March 2013, we increased the size of our sales force to approximately 67 sales professionals. Our commercial organization utilizes an incentive-based sales model similar to that utilized by Sciele Pharma and other companies previously led by members of our board and management team, including our founder, Executive Chairman and principal stockholder. This model 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.

For Dronabinol SG Capsule, we produce dronabinol API internally 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 use a portion of the proceeds from this offering 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 March 2011, we entered into a commercial manufacturing and packaging agreement with Catalent pursuant to which we engaged Catalent on an exclusive basis to provide processing and packaging services with respect to Dronabinol SG Capsule. 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.

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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.

Mylan accounted for 45% of our net revenue for the year ended December 31, 2012. Cardinal Health, McKesson and AmerisourceBergen accounted for 34%, 21% and 22%, respectively, of our accounts receivable as of December 31, 2012. Cardinal Health, McKesson and AmerisourceBergen accounted for 34%, 30% and 23%, respectively, of our total gross sales of Subsys for the year ended December 31, 2012.

Prior to the commercial launches for Subsys and Dronabinol SG Capsule in March 2012 and December 2011, respectively, we devoted substantially all of our efforts to research and development activities, including preclinical studies and clinical trials. Therefore, from inception to date, we have incurred significant operating losses. Our net loss was $24.4 million for the year ended December 31, 2012, and we had an accumulated deficit of $129.4 million as of December 31, 2012. We have financed our operations and internal growth primarily through the issuance of promissory notes to The John N. Kapoor Trust and the Kapoor Children 1992 Trust, some of which have been converted into shares of our common stock. These trusts are controlled by or are affiliated with our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor. As of March 31, 2013, we had $59.0 million in debt owed to these trusts, including accrued interest of $10.4 million. Although by their terms the promissory notes we issued to The John N. Kapoor Trust and the Kapoor Children 1992 Trust are payable on demand, each of these trusts has agreed not to require us to repay any outstanding indebtedness under these notes until March 31, 2014 and has further agreed to convert all outstanding indebtedness under these promissory notes into shares of our common stock at the initial public offering price immediately prior to the closing of this offering. In addition, in 2012, we obtained a $15.0 million revolving credit facility from Bank of America to provide working capital. As of March 31, 2013, we had approximately $11.4 million outstanding under this credit facility and approximately $3.6 million available for future borrowings.

As of March 31, 2013, we had cash and cash equivalents of $0.7 million. We believe that the net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for at least the next 12 months. However, we may need additional financing in the event that we do not obtain regulatory approval for our product candidates when expected, or if the future sales of Subsys and Dronabinol SG Capsule and of any additional approved products do not generate sufficient net revenues to fund operations. Failure to raise capital if and when needed would have a negative impact on our financial condition and our ability to pursue our business strategies.

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. In 2012, 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

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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 81% and Dronabinol SG Capsule gross margin was approximately 13% for the year ended December 31, 2012. 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 February 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 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, which includes capital equipment costs of approximately $5.0 million incurred over a period of approximately 18 months and $6.0 million to $8.0 million in payments under a commercial lease agreement over a period of approximately 120 months. 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 $6.3 million and $8.3 million for the years ended December 31, 2012 and 2011, 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 incurred over a period of approximately 18 months, 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 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

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applications, our development completion dates and costs will vary significantly for each product candidate and are very difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals or acceptable DEA classifications for our product candidates, in particular those related to Dronabinol Oral Solution, could cause our research and development expenditures to increase significantly and, in turn, have a material adverse effect on our results of operations.

Basis of Presentation

Net Revenue

During the year ended December 31, 2012, we began recognizing net revenue from sales of Subsys made by us, and from Dronabinol SG Capsule under our supply and distribution agreement with Mylan. For the year ended December 31, 2012, we recognized $15.5 million in net revenue. We had no net revenue in the year ended December 31, 2011. We expect our net revenue to increase in 2013 as we anticipate increases in prescription volume for both Subsys and Dronabinol SG Capsule, as well as a price increase for Subsys that was implemented in the first quarter of 2013.

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, we had a deferred revenue balance of $3.8 million as of December 31, 2012 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.

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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. Our cost of revenue for the year ended December 31, 2012 was $7.6 million. 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 $0.5 million as of December 31, 2012. We expect our cost of revenue to increase in absolute dollars in 2013 as we continue to increase our product sales and invest in our operations.

Gross profit is net revenue less cost of revenue. Gross margin is gross profit expressed as a percentage of net revenue. Our gross profit was $7.8 million for the year ended December 31, 2012. Our gross margin for the year ended December 31, 2012 was approximately 51%. Subsys gross margin was approximately 81% and Dronabinol SG Capsule gross margin was approximately 13% for the year ended December 31, 2012. We expect Subsys gross margins to be favorably impacted in 2013 primarily as a result of expected reductions in patient assistance funding combined with a price increase implemented in the first quarter of 2013. We expect Dronabinol SG Capsule gross margins to be favorably impacted in 2013 primarily as a result of gains resulting from improvements in our manufacturing efficiencies. 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.

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. Our sales and marketing expenses were $11.4 million for the year ended December 31, 2012. As of December 31, 2012, we had 58 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 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. Our research and development expenses were $6.3 million and $8.3 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, we had 15 full-

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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. 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 incurred over a period of approximately 18 months, 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. Clinical development timelines, likelihood of regulatory approval and commercialization, and associated costs are very uncertain and therefore very difficult to estimate and can vary significantly. 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.

The following table provides a breakdown of our research and development expenses during the years ended December 31, 2012 and 2011 (dollars in millions):

	Years Ended December 31,	
	2012	**2011**
Fentanyl[(1)]	$ 1.6	$ 1.4
Dronabinol[(1)]	1.7	1.2
LEP-ETU and IL-13[(1)]		0.8
Internal research and development costs[(2)]	3.0	4.9
Total	$ 6.3	$ 8.3

(1) Consists primarily of direct research and development costs related to product development.
(2) Comprised primarily of salary and benefits, depreciation, facilities expenses and stock-based compensation allocated to our research and development activities.

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. Our general and administrative expenses were $8.2 million and $9.0 million for the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, we had ten 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.

Impairment of Intangible Assets and Goodwill

In 2010, in connection with the NeoPharm merger, we recorded in-process research and development, or IPR&D, as an intangible long-lived asset with an indefinite useful life in the amount of $5.3 million, of which $4.2 million related to LEP-ETU and $1.1 million related to IL-13.

LEP-ETU is a liposomal formulation of the widely used cancer drug, paclitaxel. At the time of the NeoPharm merger, a Phase 2 clinical trial for LEP-ETU was ongoing in India and approximately 75% of

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the patients had been enrolled for that trial. Further development of this product candidate would entail substantial challenges and costs and therefore we are currently evaluating next steps with respect to this product candidate.

IL-13 is a potential therapeutic agent for the treatment of idiopathic pulmonary fibrosis, or IPF, and asthma. Prior to the NeoPharm merger, an Investigational New Drug Application was submitted for a Phase 1 study in IPF, and that submission was on hold by the FDA at the time of the NeoPharm merger and remains on hold as of December 31, 2012. A significant amount of additional work remains on this indication and the chances of success at this point for a commercially viable product using the agent are low. We are currently evaluating next steps with respect to this product candidate.

As of October 1, 2012, as a result of our successful commercialization of Subsys and Dronabinol SG Capsule, and a product development strategy focused on the dronabinol line of products, including Dronabinol Oral Solution, and expansion of the Subsys spray technology, we determined that there was an indication that the recorded intangible assets and goodwill associated with the NeoPharm merger might be impaired. Accordingly, we performed an impairment analysis and determined that the intangible assets and goodwill associated with NeoPharm were fully impaired. As a result, during the quarter ended December 31, 2012, we recorded a related impairment charge of $5.4 million. No intangible assets remained on our balance sheet as of December 31, 2012.

Other Income (Expense), Net

Other income (expense), net consists primarily of one-time credits for cash received related to awards for government grants and other various items.

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 $0.3 million during the year ended December 31, 2011, and an increase of $0.2 million during 2012 through September 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 consists 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. The interest rate on these promissory notes is the applicable prime rate plus 2.0%, which was 5.25% as of December 31, 2012. As of December 31, 2012, we had $58.4 million in debt owed to these trusts, including accrued interest of $9.8 million, all of which is payable on demand. We recorded interest expense of $2.6 million related to accrued interest on these notes during the year ended December 31, 2012. Although by their terms the promissory notes we issued to The John N. Kapoor Trust and the Kapoor Children 1992 Trust are payable on demand, each of these trusts has agreed not to require us to repay any outstanding indebtedness under these notes until March 31, 2014 and has further agreed to convert all outstanding indebtedness under these promissory notes into shares of our common stock at the initial public offering price immediately prior to the closing of this offering.

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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 $11.9 million as of December 31, 2012 and we recorded interest expense of $0.1 million during the year ended December 31, 2012 in connection with borrowings under this credit facility.

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 loss.

As of December 31, 2012, we had federal and state NOLs of approximately $301.0 million and $288.0 million, respectively. If not utilized, the NOLs began expiring in 2011 for federal tax purposes and will begin expiring in 2017 for state tax purposes.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of NOLs 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 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 December 31, 2012. Post-NeoPharm merger, federal NOLs of approximately $27.0 million are not subject to an annual limitation and begin expiring in 2030.

We expect the issuance of common stock in this offering, together with the issuance of common stock in other transactions involving our common stock, may result 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 this offering, 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.

JOBS Act

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

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We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, as an emerging growth company, we intend to rely on certain of these exemptions, including without limitation:

- only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced Management s Discussion and Analysis of Financial Condition and Results of Operations disclosure;
- reduced disclosure about our executive compensation arrangements;
- no requirement that we solicit non-binding advisory votes on executive compensation or golden parachute arrangements; and
- exemption from the auditor s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act.

We will remain an emerging growth company until the earliest of (i) the last day of our fiscal year in which we have total annual gross revenues of $1 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of this offering, (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. To the extent that we have taken advantage of reduced reporting requirements in this prospectus, the information contained herein may be different than the information you receive from other public companies in which you hold stock. Pursuant to the JOBS Act, we were eligible to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies, but we have irrevocably elected not to do so.

Internal Control Over Financial Reporting

Assessing our staffing and training procedures to improve our internal control over financial reporting is an ongoing process. We are currently not required to comply with Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make an assessment of the effectiveness of our internal control over financial reporting. As a result, our management did not perform an evaluation of our internal control over financial reporting as of December 31, 2012. Further, our independent registered public accounting firm has not been engaged to express, nor have they expressed, an opinion on the effectiveness of our internal control over financial reporting. We also currently do not have an internal audit function.

For so long as we are an emerging growth company under the JOBS Act, our management will not be required to deliver a report that assesses the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. As a result, we will not be required to deliver a management assessment of the effectiveness of our internal control over financial reporting and our independent registered public accounting firm will not be required to deliver an attestation report on the effectiveness of our internal control over financial reporting for the year ending December 31, 2013.

Significant Accounting Policies and Estimates

Our management s discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in conformity with GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and related disclosures. Actual results could differ from those estimates.

While our significant accounting policies are more fully described in Note 2 to our consolidated financial statements appearing elsewhere in this prospectus, we believe the following accounting

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policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

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

Subsys

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

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

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

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

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

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

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

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

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

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

A roll forward of our product sales allowances for the year ended December 31, 2012 is as follows (dollars in thousands):

	Wholesale Discounts[1]	Patient Discount Programs	Rebates	Total
Balance at December 31, 2011	$	$	$	$
Revenue Allowances:				
Provision related to current period sales[2]	1,309	3,565	235	5,109
Provision related to sales made in prior years				
Recorded to balance sheet[2]	538	1,540	102	2,180
Payments and credits related to sales made in current period	(1,013)	(3,565)	(203)	(4,781)
Payments and credits related to sales made in prior periods				
Balance at December 31, 2012	$ 834	$ 1,540	$ 134	$ 2,508

(1) Includes wholesaler discounts, prompt pay discounts, stocking allowances and government chargebacks.

(2) Through December 31, 2012, we were unable to reasonably estimate expected returns of Subsys at the time of shipment. Accordingly, we currently defer recognition of revenue on product shipments of Subsys until the earlier of when units are sold to healthcare facilities or dispensed through patient prescriptions, or expiration of the right of return. Product sales allowances related to revenue that has been deferred are recorded on the balance sheet as a reduction of the related deferred revenue, and recognized within the statement of operations as a reduction in the same period the related revenue is recognized.

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Dronabinol SG Capsule

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

Inventories

Inventories consist of raw materials, work-in-process and finished product and are valued at the lower of cost (first-in, first-out cost method) or market. Inventory costs are capitalized prior to regulatory approval and product launch based on management s judgment of probable future commercial use and net realizable value of the inventory. Such judgment incorporates our knowledge and best estimate of where the relevant product is in the regulatory process, our required investment in the product, market conditions, competing products and our economic expectations for the product post-approval relative to the risk of manufacturing the product prior to approval. In evaluating the recoverability of inventories produced in preparation for product launches, we consider the probability that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process, as well as the market for the product in its current state. We could be required to permanently write down previously capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential factors including product expiration.

Goodwill and Intangible Asset Valuation

We test goodwill and intangible long-lived assets with indefinite useful lives for impairment on an annual basis as of October 1, or more frequently if an event occurs creating the potential for impairment.

Our long-lived asset impairment approach is based on an undiscounted cash flows approach. We evaluate IPR&D which has an indefinite useful life, for impairment on an annual basis as of October 1, or more frequently if an event occurs creating the potential for impairment, until such time as the research and development efforts are completed or abandoned. If the research and development efforts are abandoned, the related costs will be written off in the period of such determination. If the research and development efforts are completed successfully, the related assets will be amortized over the estimated useful life of the underlying products. We will amortize the cost of identified intangible assets using amortization methods that reflect the pattern in which the economic benefits of the intangible assets are consumed or otherwise realized. We have recorded long-lived asset impairment charges in the past, and if we fail to achieve our assumed growth rates or assumed gross margin, we may incur additional charges for impairment in the future.

We review intangible assets that have finite useful lives when an event occurs creating the potential for impairment. We review for impairment by examining facts or circumstances, either external or internal, indicating that we may not recover the carrying value of the asset. We measure impairment losses related to indefinite-lived intangible assets based on the amount by which the carrying amounts

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of these assets exceed their fair values. We measure fair value generally based on the estimated future cash flows. Our analysis is based on available information and on assumptions and projections that we consider to be reasonable and supportable. If necessary, we will perform subsequent calculations to measure the amount of the impairment loss based on the excess of the carrying value over the fair value of the impaired assets.

Stock-Based Compensation

Stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award. The cost is recognized, net of forfeitures, in our consolidated financial statements as expense ratably over the employee s requisite service period or vesting period, which is generally three to four years, on a straight-line basis. Equity awards issued to non-employees are recorded at their fair value on the grant date and are periodically re-measured as the underlying awards vest unless the instruments are fully vested, immediately exercisable and nonforfeitable on the date of grant. Expense recognized for consultant stock options was immaterial for the years ended December 31, 2012 and 2011.

We currently use the Black-Scholes option-pricing model to estimate the fair value of our stock-based payment awards. This model requires the input of highly subjective assumptions, including the fair value of the underlying common stock, the expected volatility of the price of our common stock, risk-free interest rates, the expected term of the option and the expected dividend yield of our common stock. These estimates involve inherent uncertainties and the application of management s judgment. If factors change and different assumptions are used, our stock-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

Fair Value of Our Common Stock Because our stock was not publicly traded prior to our initial public offering, we estimated the fair value of our common stock, as discussed in Common Stock Valuations below. Upon the completion of our initial public offering, our common stock will be valued by reference to the publicly-traded price of our common stock.

Expected Volatility Prior to the NeoPharm merger, we did not have a history of market prices for our common stock and since the merger, we do not have what we consider a sufficiently active and readily traded market for our common stock to use historical market prices for our common stock to estimate volatility. Accordingly, we estimate the expected stock price volatility for our common stock by taking the median historical stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of other public companies in the pharmaceutical industry similar in size, stage of life cycle and financial leverage. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available. Our industry peers for estimating stock price volatility changed for the year ended December 31, 2012 as compared to the year ended December 31, 2011 as a result of our transition from a development stage company to a commercial stage company.

Risk-Free Interest Rate The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our awards. The risk-free interest rate assumption is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group.

Expected Term The expected term represents the period that our stock-based awards are expected to be outstanding. The expected terms of the awards are based on a simplified method which defines the life as the average of the contractual term of the options and the weighted-average vesting period for all open tranches.

Expected Dividend Yield We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

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The following table presents the weighted-average assumptions used to estimate the fair value of employee stock options granted during the periods presented:

	2012	2011
Expected volatility	65.0%	108.1 109.2%
Risk-free interest rate	1.15%	1.9 3.5%
Expected term (in years)	6.5 7.0	6.5 7.0
Expected dividend yield	0.0%	0.0%

In addition to the assumptions used in the Black-Scholes option-pricing model, the amount of stock option expense we recognize in our consolidated statements of operations includes an estimate of stock option forfeitures. We estimate our forfeiture rate based on an analysis of our actual forfeitures and will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover and other factors. Changes in the estimated forfeiture rate can have a significant impact on our stock-based compensation expense as the cumulative effect of adjusting the rate is recognized in the period the forfeiture estimate is changed. If a revised forfeiture rate is higher than the previously estimated forfeiture rate, an adjustment is made that will result in a decrease to the stock-based compensation expense recognized in the consolidated financial statements. If a revised forfeiture rate is lower than the previously estimated forfeiture rate, an adjustment is made that will result in an increase to the stock-based compensation expense recognized in our consolidated financial statements.

Common Stock Valuations

The fair value of the common stock underlying our stock options was determined by our board of directors, which intended all options granted to be exercisable at a price per share not less than the per share fair value of our common stock underlying those options on the date of grant. The contemporaneous valuations of our common stock were determined in accordance with the guidelines outlined in the AICPA Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. The assumptions we used in the valuation model are based on future expectations combined with management judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our common stock as of the date of each option grant, including the following factors:

- likelihood of achieving a liquidity event, such as an initial public offering, given prevailing market conditions and the potential effect of such event on our stock price;
- contemporaneous valuations performed by an independent third-party specialist;
- the rights, preferences, and privileges of our convertible preferred stock relative to those of our common stock;
- lack of marketability of our common stock;
- actual operating and financial performance;
- our stage of development;
- development status of our product candidates and regulatory issues encountered during the relevant period;

current business conditions and projections;

hiring of key personnel and the experience of our management;

risk inherent to the development of our products and services;

trends and developments in our industry;

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market performance of comparable publicly traded companies;

our significant dependence on one investor for financing;

concentration in control of ownership of our stock; and

U.S. and global economic and capital market conditions.

We granted the following stock option awards between January 1, 2011 and the date of this prospectus:

Grant Date	Number of Common Shares Underlying Options Granted	Common Stock Fair Value Per Share at Grant Date[1]	Exercise Price Per Common Share	Intrinsic Value Per Common Share
March 28, 2011	508,491	$ 15.00	$ 4.88	$ 10.12
December 28, 2011	157,000	$ 15.00	$ 2.72	$ 12.28
December 27, 2012	571,500	$ 15.00	$ 3.54	$ 11.46

(1) See detailed discussion below regarding methodology utilized to determine common stock fair value solely for financial accounting purposes.

Contemporaneous fair value valuations of the common stock underlying our three sets of stock option awards granted in 2011 and 2012, were determined as of February 2011, September 2011 and March 2012 by an independent third-party specialist. These contemporaneous fair value valuations were utilized in determining the exercise prices of these stock option grants, and were also utilized in part in determining the common stock fair values for financial accounting purposes. Our contemporaneous valuation analysis utilized the Income Approach using Probability Weighted Expected Return Method, or PWERM. This approach involves the estimation of future potential outcomes for us, as well as values and probabilities associated with each respective potential outcome. The common stock per share value determined using this approach is ultimately based upon probability-weighted per share values resulting from the following potential future scenarios: initial public offering, acquisition, liquidation or continued operation as a private company. Under a PWERM analysis, in accordance with the AICPA guidelines, the value of the common stock is estimated based upon an analysis of future values for the enterprise assuming various future outcomes. Share value is based upon the probability-weighted present value of future expected investment returns, considering each of the possible future outcomes available to the enterprise, as well as the rights of each share class.

For each contemporaneous valuation, we first determined the value of our equity using the income approach (determined using the discounted cash flow method), the market approach (which calculates the equity value based on the Public Company Market Multiple Method based on an analysis of selected comparable publicly traded companies) or the Cost Approach (which approximates fair market value in connection with certain liquidation events). The values from these various approaches were then used to conclude a future value of our company through a PWERM analysis.

March 2011 Grant. In March 2011, we granted options to purchase a total of 508,491 shares of our common stock with an exercise price of $4.88 per share (equal to the contemporaneous third-party valuation described above made as February 2011 in accordance with the AICPA guidelines). Our board of directors assessed any events and circumstances that took place between the most recent contemporaneous valuation date and this grant date and concluded it was appropriate to set the exercise price for these options equal to the fair value determined in that contemporaneous valuation. Consistent with the practice of most private companies, we initially relied significantly on the contemporaneous valuation performed by the independent third-party specialist in determining the fair value of our common stock both for determining the option exercise prices of our options granted in March 2011 as well as for financial accounting purposes. In August 2011, believing an initial public offering was imminent, we retrospectively reassessed the fair market value of our common stock for

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financial accounting purposes as of March 2011 after giving consideration to our initial public offering activities at that time and we determined that for financial accounting purposes the reassessed fair market value of our common stock as of March 2011 was $15.00 per share. We then applied the Black-Scholes option-pricing model described above to determine the related stock-based compensation expense charge.

December 2011 Grant. In December 2011, we granted options to purchase a total of 157,000 shares of our common stock with an exercise price of $2.72 per share (equal to the contemporaneous third-party valuation described above made as September 2011 in accordance with the AICPA guidelines). Once again, our board of directors assessed any events and circumstances that took place between the most recent contemporaneous valuation date and this grant date and concluded it was appropriate to set the exercise price for these options equal to the fair value determined in that contemporaneous valuation. The primary reasons for the decrease in fair value since the March 2011 grant included the fact that we were unable to commercially launch Dronabinol SG Capsule at the time, our increased indebtedness and challenges related to our inability to raise capital from third parties on terms acceptable to us. However, although we were no longer formally engaged in the initial public offering process at the time and no such offering was imminent, given our experience of retrospectively reassessing the fair value of our common stock for financial accounting purposes in August 2011 and believing that market, business and other factors could change and result in us deciding to formally re-engage in the initial public offering process, we utilized what we believe was a conservative approach and decided to once again set the fair value of our common stock for financial accounting purposes at $15.00 per share. We once again then applied the Black-Scholes option-pricing model described above to determine the related stock-based compensation expense charge. In retrospect, we did not formally re-engage in initial public offering activities during the remainder of 2011 or 2012.

December 2012 Grant. In December 2012, we granted options to purchase a total of 571,500 shares of our common stock with an exercise price of $3.54 per share (equal to the contemporaneous third-party valuation described above made as March 2012 in accordance with the AICPA guidelines). Once again, our board of directors assessed any events and circumstances that took place between the most recent contemporaneous valuation date and this grant date and concluded it was appropriate to set the exercise price for these options equal to the fair value determined in that contemporaneous valuation. The primary reasons for the increase in fair value since the December 2011 grant included the commercial launch of Dronabinol SG Capsule and the receipt of regulatory approval for our primary product, Subsys, in January 2012. However once again, similar to the process that took place in connection with our December 2011 option grant, although we were still not formally engaged in the initial public offering process at the time and no such offering was imminent, given our experience of retrospectively reassessing the fair value of our common stock for financial accounting purposes in August 2011 and believing that market, business and other factors could change and result in us deciding to formally re-engage in the initial public offering process, we utilized what we believe was a conservative approach and decided to once again set the fair value of our common stock for financial accounting purposes at $15.00 per share. We once again then applied the Black-Scholes option-pricing model described above to determine the related stock-based compensation expense charge. In February 2013, market, business and other factors led us to decide to formally re-engage in the initial public offering process once again.

There is inherent uncertainty in the estimates utilized in connection with our fair value determinations, and if we had made different assumptions than those described above, the fair value of the underlying common stock and amount of our stock-based compensation expense and related items in our consolidated financial statements would have differed.

Based upon the assumed initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, the aggregate intrinsic value of options outstanding as of December 31, 2012 was approximately $5.6 million, of which approximately $1.2 million related to vested options and approximately $4.4 million related to unvested options.

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Deferred Tax Valuation Allowance

We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. In determining the amount of the valuation allowance, we consider estimated future taxable income as well as feasible tax planning strategies in each taxing jurisdiction in which we operate. Historically, we have recorded a deferred tax valuation allowance in an amount equal to our net deferred tax assets. If we determine that we will ultimately be able to utilize all or a portion of deferred tax assets for which a valuation allowance has been provided, the related portion of the valuation allowance will be released to income as a credit to income tax expense.

Results of Operations

Comparison of* Year *Ended December 31, 2012 to Year Ended December 31, 2011

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

	Year ended December 31,					
	2012	Percentage of Applicable Gross Revenue	2011	Percentage of Gross Revenue	Change from Prior Year	Percentage Change from Prior Year
SUBSYS:						
Gross revenue	$ 13.7		$		$ 13.7	%
Provision for wholesaler discounts	(1.3)	9.6%		%	(1.3)	%
Provision for patient discount programs	(3.6)	26.1%		%	(3.6)	%
Provision for rebates	(0.2)	1.7%		%	(0.2)	%
Net revenue-Subsys	8.6	62.6%		%	8.6	%
DRONABINOL SG CAPSULE:						
Gross revenue	8.0			%	8.0	%
Royalties and fees	(1.1)	13.9%		%	(1.1)	%
Net revenue-Dronabinol SG Capsule	6.9	86.1%		%	6.9	%
Net revenue	$ 15.5				$ 15.5	%

Net revenue for the year ended December 31, 2012 was $15.5 million and $0 for the year ended December 31, 2011, as both Subsys and Dronabinol SG Capsule were initially marketed in 2012. Net revenue for the year ended December 31, 2012 included $8.6 million of Subsys dispensed to patients, which was net of estimated wholesaler and retail pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs. For the year ended December 31, 2012, provisions for discounts, chargebacks and rebates were 37.4% of gross revenue from sales of Subsys. Net revenue for the year ended December 31, 2012 also included $6.9 million of Dronabinol SG Capsule sold to wholesale distributors through Mylan, which was net of royalties and fees. For the year ended December 31, 2012, royalties and fees were 13.8% of gross revenue from sales of Dronabinol SG Capsule.

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Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue for the year ended December 31, 2012 was $7.6 million and $0 for the year ended December 31, 2011, as both Subsys and Dronabinol SG Capsule were initially marketed in 2012. Cost of revenue for the year ended December 31, 2012 represents the cost of Subsys units dispensed to patients and the cost of Dronabinol SG Capsule sold to wholesale distributors through Mylan, combined with the impact of two batches of Dronabinol SG Capsule not being released for commercial sale in the fourth quarter of 2012. We have recorded an allowance of $0.4 million in cost of revenue for the estimated non-recoverable manufacturing cost associated with these batches. Gross profit for the year ended December 31, 2012 was $7.8 million compared to $0 for the year ended December 31, 2011. Gross margin for the year ended December 31, 2012 was approximately 51% compared to 0% for the year ended December 31, 2011. Subsys gross margin was approximately 81% and Dronabinol SG Capsule gross margin was approximately 13% for the year ended December 31, 2012.

Sales and Marketing Expense. Sales and marketing expense was $11.4 million for the year ended December 31, 2012 and $0 for the year ended December 31, 2011. During 2012, we formed our U.S.-based commercial organization and we began investing in other sales and marketing activities related to Subsys. As Dronabinol SG Capsule is marketed by Mylan, we did not incur any sales and marketing expense related to Dronabinol SG Capsule.

Research and Development Expense. Research and development expense was $6.3 million for the year ended December 31, 2012 compared to $8.3 million for the year ended December 31, 2011. Of these amounts, for the years ended December 31, 2012 and 2011, we incurred direct costs attributable to our fentanyl program of $1.6 million and $1.4 million, respectively, direct costs attributable to our dronabinol program of $1.7 million and $1.2 million, respectively, and internal research and development costs of $3.0 million and $4.9 million, respectively. We also incurred $0.8 million in costs related to our LEP-ETU and IL-13 programs during the year ended December 31, 2011. The $2.0 million, or 24.1%, decrease in research and development expenses between the year ended December 31, 2012 and the year ended December 31, 2011 was primarily due to a shift in focus during 2012 to the marketing of Subsys, combined with completion of Phase 3 clinical trials for Subsys during 2011. Also contributing to the decrease was a decline in spending on the LEP-ETU and IL-13 programs during 2012.

General and Administrative Expense. General and administrative expense decreased to $8.2 million for the year ended December 31, 2012 compared to $9.0 million for the year ended December 31, 2011. The decrease of $0.8 million was due primarily to costs incurred during 2011 in connection with a contemplated initial public offering of common stock that did not occur.

Impairment of Intangible Assets and Goodwill. During the quarter ended December 31, 2012, we recorded an impairment charge of $5.4 million in connection with long-lived, non-amortizing intangible assets and goodwill acquired in connection with the NeoPharm merger. No intangible assets remain on our balance sheet as of December 31, 2012.

Other Income (Expense), Net. Other income (expense), net, increased to $1.7 million for the year ended December 31, 2012 compared to $(25,000) for the year ended December 31, 2011. 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 year ended December 31, 2011, changes in the estimated fair value of contingent consideration of $(0.3) million were recorded as other expense. Other expense for the year ended December 31, 2011 was partially offset by grant income of $0.2 million. During the nine months ended September 30, 2012, changes in the estimated fair value of contingent consideration of $(0.2) million were recorded as other expense, and as of October 1, 2012 a decrease in the estimated fair value of contingent consideration of $2.3 million was recorded as other income.

Interest Expense. Interest expense increased to $2.7 million for the year ended December 31, 2012 from $2.0 million for the year ended December 31, 2011. The $0.7 million increase was primarily a result of greater amounts outstanding under promissory notes payable to The John N. Kapoor Trust and

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the Kapoor Children 1992 Trust during the year ended December 31, 2012 as compared to the year ended December 31, 2011. As of December 31, 2012 and December 31, 2011, the aggregate principal balance of these notes payable was $48.6 million and $45.6 million, respectively, excluding accrued interest expense payable of $9.8 million and $7.2 million, respectively. We recorded $2.6 million of interest expense associated with accrued interest on these notes during the year ended December 31, 2012. During the year ended December 31, 2012, we entered into a $15.0 million line of credit facility. The outstanding principal balance under this facility was $11.9 million as of December 31, 2012 and we recorded interest expense of $0.1 million during the year ended December 31, 2012 in connection with borrowings under this credit facility.

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 loss for the years ended December 31, 2012 and 2011.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred losses since our inception. As of December 31, 2012, we had an accumulated deficit of $129.4 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 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 December 31, 2012, we had $58.4 million in debt, including accrued interest of $9.8 million, under the promissory notes payable to The John N. Kapoor Trust and the Kapoor Children 1992 Trust, and $0.4 million in cash and cash equivalents. Immediately prior to the closing of this offering, all principal indebtedness and accrued interest under these notes and other notes issued by us to trusts controlled by or affiliated with Dr. Kapoor will convert into shares of our common stock at the price to the public of the shares sold in this offering.

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 December 31, 2012) 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 John N. Kapoor Trust as applicant. We had an outstanding balance of $11.9 million and $3.1 million in available borrowings against the line of credit as of December 31, 2012. The line of credit is subject to covenants, and as of December 31, 2012 we believe we were in material compliance with such covenants.

In 2012, The John N. Kapoor Trust agreed to fund our operations on an as-needed basis through the earlier of March 31, 2014 or upon successful completion of a public offering. In addition, The John N. Kapoor Trust and the Kapoor Children 1992 Trust have each agreed not to require us to repay any outstanding indebtedness under the notes we issued to such trusts until March 31, 2014 and have further agreed to convert all outstanding indebtedness under these notes into shares of our common stock at the initial public offering price immediately prior to the closing of this offering.

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Cash Flows

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

	Years Ended December 31,	
	2012	**2011**
Net cash used in operating activities	$ (13.6)	$ (15.4)
Net cash used in investing activities	(1.0)	(0.6)
Net cash provided by financing activities	15.0	15.9
Net increase (decrease) in cash and cash equivalents	0.4	(0.1)
Cash and cash equivalents, beginning of year	0.0	0.1
Cash and cash equivalents, end of year	$ 0.4	$ 0.0

Net Cash Used in Operating Activities. Net cash used in operating activities was $13.6 million and $15.4 million for the years ended December 31, 2012 and 2011, respectively. The net cash used in each of these years primarily reflects the net loss for those periods, offset 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 decrease in net cash used in operating activities is partially attributable to cash received from sales of Subsys and Dronabinol SG Capsule during the year ended December 31, 2012.

Net Cash Used in Investing Activities. Net cash used in investing activities was $1.0 million and $0.6 million for the years ended December 31, 2012 and 2011, respectively. The increase in net cash used in investing activities during the year ended December 31, 2012, primarily reflects the purchase of equipment and leasehold improvements associated with our new corporate office and research and development facility, which we entered into in November 2012.

Net Cash Provided by Financing Activities. Net cash provided by financing activities was $15.0 million and $15.9 million for the years ended December 31, 2012 and 2011, respectively. Net cash provided by financing activities for the year ended December 31, 2012 was primarily attributable to borrowings against the credit facility in the amount of $11.9 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. Net cash provided by financing activities for the year ended December 31, 2011 was primarily attributable to an increase in promissory notes payable to The John N. Kapoor Trust and The Kapoor Children 1992 Trust.

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 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, as well as timing of the closing of this offering and our use of net offering proceeds as described in this prospectus in the section entitled Use of Proceeds. We expect our net cash outflows to decrease 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 this offering and our 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 December 31, 2012, we had $3.1 million of undrawn funds available under our revolving credit facility with Bank of America. In 2012, The John N. Kapoor Trust agreed to fund our operations on an as-needed basis through the earlier of March 31, 2014 or upon successful completion of a public

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offering. In addition, these trusts have agreed to convert all outstanding indebtedness under the promissory notes we issued to these trusts at the initial public offering price immediately prior to the closing of this offering.

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.

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, including this offering, from the issuance of notes payable to trusts controlled by or affiliated with Dr. John N. Kapoor 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 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 year ended December 31, 2012, 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.

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Contractual Obligations

The following table summarizes our outstanding contractual obligations as of December 31, 2012 (dollars in millions):

	Payments Due by Period				
	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
Operating leases	$ 0.5	$ 0.9	$ 0.7	$	$ 2.1
Promissory notes payable (including accrued interest and assumed accrued interest through December 31, 2013)[1]	$ 61.0				$ 61.0
Line of credit[2]		11.9			11.9
Manufacturing agreement expenses[3]		1.8			1.8
Total	$ 61.5	$ 14.6	$ 0.7	$	$ 76.8

(1) These promissory notes and related accrued interest are payable upon demand. For purposes of this table, the notes and interest are assumed to be required to be paid by December 31, 2013. Immediately prior to the closing of this offering, these notes, and other notes issued by us to trusts controlled by or affiliated with Dr. Kapoor, including accrued interest, totaling $59.3 million will convert into shares of our common stock at the price to the public of the shares sold in this offering. Includes estimated future interest at an assumed interest rate of 5.25%, based on the prevailing prime interest rate as of December 31, 2012.

(2) The revolving credit facility with Bank of America matures in February 2014. We expect to use a portion of the proceeds from this offering to repay the outstanding principal and accrued interest under this facility.

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

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

Quantitative and Qualitative Disclosure About Market Risk

Historically our primary exposure to market risk has related to interest rate risk with respect to the interest expense we incur on our outstanding indebtedness under the promissory notes held by certain trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder. Our outstanding indebtedness accrues interest at a rate that fluctuates based on the prime rate. While the outstanding indebtedness under the promissory notes held by these trusts will be converted into shares of our common stock immediately prior to the closing of this offering, in the event we issue additional promissory notes to any such trusts in the future that bear interest at a rate that fluctuates based on the prime rate, our interest expense may increase if the prime interest rate were to increase. In addition, our cash and cash equivalents, which we hold in an account with a large, U.S. commercial bank, may be subject to interest rate risk and could fall in value if interest rates were to fall. We do not hedge interest rate exposure. Because all of our transactions are denominated in U.S. dollars, we do not believe that fluctuations in currency exchange rates had a material effect on our business, financial condition or results of operations during the years ended December 31, 2012 and 2011. If we expand our

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commercialization activities to outside of the United States, our results of operations and cash flows may become subject to fluctuations due to changes in foreign currency exchange rates, which may materially affect our financial condition. Inflation generally affects us by increasing our cost of labor and clinical trial costs. We do not believe that inflation had a material effect on our business, financial condition or results operations during the years ended December 31, 2012 and 2011.

Our $15.0 million revolving credit facility bears interest at LIBOR plus 1.0% (1.20% as of March 31, 2013). As of March 31, 2013, we had $11.4 million outstanding on this revolving credit facility.

Recently Issued Accounting Pronouncements

In June 2011, FASB issued an amendment to the existing guidance on the presentation of comprehensive income. Under the amended guidance, entities have the option to present the components of net income and other comprehensive income in either a single continuous statement of comprehensive income or in two separate but consecutive statements. Entities no longer have the option of presenting the components of other comprehensive income within the statement of changes in stockholders equity. For public entities, the amendment is effective on a retrospective basis for fiscal years, and interim periods within those years, beginning after December 15, 2011. Adoption of this amendment resulted in a change to our presentation of comprehensive income.

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BUSINESS

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 sublingual fentanyl spray for breakthrough cancer pain, or BTCP, in opioid-tolerant patients and Dronabinol SG Capsule, a generic equivalent to Marinol (dronabinol), an approved second-line treatment of chemotherapy-induced nausea and vomiting, or CINV, and anorexia associated with weight loss in patients with AIDS. We market Subsys through our cost-efficient commercial organization of approximately 67 sales professionals, which we increased from 50 sales professionals in March 2013 to enhance our Subsys sales and marketing capabilities. We utilize an incentive-based sales model similar to that employed by Sciele Pharma, Inc. and other companies previously led by members of our management and board, including our founder, Executive Chairman and principal stockholder. We are leveraging our capabilities in dronabinol formulation and manufacturing as well as our sublingual spray drug delivery technology to develop a portfolio of differentiated, wholly-owned product candidates. Our lead product candidate is Dronabinol Oral Solution, a proprietary orally administered liquid formulation of dronabinol, which would be our second branded supportive care product, if approved. We believe this product candidate may provide increased flexibility in dosing, more convenient delivery and an improved absorption profile in patients, which may ultimately increase patient compliance because of more rapid onset of action and less dose-to-dose variability and allow us to further penetrate and potentially expand the market for the use of dronabinol. We intend to market Dronabinol Oral Solution and any other future supportive care products, if approved, through our commercial organization.

Subsys is a proprietary, single-use product that delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue. We filed our New Drug Application, or NDA, in March 2011 and received marketing approval for Subsys from the U.S. Food and Drug Administration, or FDA, in January 2012 for the treatment of BTCP. BTCP is characterized by sudden, often unpredictable, episodes of intense pain which can peak in severity at three to five minutes despite background pain medication. We believe Subsys is an important, differentiated treatment option for patients and physicians relative to other transmucosal immediate-release fentanyl, or TIRF, products due to its rapid onset of action, improved bioavailability, most complete range of dosage strengths and ease of administration. Our product label includes data from our pivotal clinical trial demonstrating that Subsys provides pain relief at five minutes, which represents the most rapid onset of action in the TIRF class of products. Also, in a head-to-head study, Subsys demonstrated 76% bioavailability versus 51% for Actiq, which is the current market-leading TIRF product (including its generic equivalents). Further, Subsys offers the most complete range of dosage strengths in the TIRF class of products, consisting of 100 to 1,600 microgram, or mcg, doses. Patients can administer Subsys in less than one minute while Actiq and Fentora, the leading branded TIRF products, can require 14 to 30 minutes to administer.

We launched Subsys in March 2012. Subsys is the fourth new branded product in the TIRF market over the last four years. Within the first four weeks of product launch, Subsys realized greater market share than the previous three branded products combined at their respective peak market penetration levels to date according to Source Healthcare Analytics. In February 2013, Subsys was the second most prescribed branded TIRF product with 16.1% market share on a prescription basis according to Source Healthcare Analytics. Through our ongoing commercial initiatives, we believe we can continue to grow our market share and net revenue for this product. According to Source Healthcare Analytics, TIRF products generated $388.1 million in 2012 U.S. product sales. The physician prescriber base for TIRF products is concentrated with approximately 1,850 physicians writing 90% of all TIRF product prescriptions from the launch of Subsys through February 2013, according to Source Healthcare Analytics. As a result, our commercial organization is able to promote Subsys using a highly targeted approach designed to maximize impact with physicians.

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Subsys utilizes our proprietary sublingual spray technology consisting of a small single-unit device that delivers our proprietary formulation of drug particles via a fine mist disbursed across a broad surface area of the highly permeable membrane underneath the tongue. This delivery platform is suitable for other molecules for which there may be a benefit to a greater rate and extent of absorption, which could lead to a more rapid onset of action and enhanced bioavailability versus other oral preparations and routes of administration. We are developing our proprietary sublingual spray technology in other product applications in order to expand our portfolio of product candidates.

Dronabinol SG Capsule is a dronabinol soft gelatin capsule that is a generic equivalent to Marinol, an approved second-line treatment for CINV and anorexia associated with weight loss in patients with AIDS. Dronabinol, the active ingredient in Marinol, is a synthetic cannabinoid whose chemical name is delta-9-tetrahydrocannabinol, or THC. Dronabinol SG Capsule was the first approved product in our family of dronabinol product candidates that we are developing. We commercialize Marinol through our exclusive supply and distribution agreement with Mylan Pharmaceuticals Inc. We believe that Marinol and its generic equivalents have limitations in their current formulations. Marinol is characterized by a highly variable bioavailability and an onset of action that ranges from 30 minutes to one hour. We are developing additional proprietary formulations of dronabinol, the most advanced of which is Dronabinol Oral Solution, to address these limitations.

Dronabinol Oral Solution has demonstrated more rapidly detectable blood levels and a more reliable absorption profile than Marinol in our clinical studies. In 2012, we completed a pre-NDA meeting with the FDA and a pivotal bioequivalence study. Our pivotal bioequivalence study measured the pharmacokinetics, or PK, of Dronabinol Oral Solution versus Marinol. This PK study demonstrated that 100% of subjects receiving Dronabinol Oral Solution achieved detectable plasma levels at 15 minutes compared to less than 25% of subjects receiving Marinol. In this study, Dronabinol Oral Solution also demonstrated a 44% decrease in the patient coefficient of variation for area under the curve, or AUC, which is indicative of greater patient exposure to drug. We believe these product attributes could result in Dronabinol Oral Solution capturing a significant share of the existing U.S. market for dronabinol products, which was $134.7 million in 2012, according to IMS Health, and potential expanding the usage of dronabinol-based products.

The National Cancer Institute estimates that, as of January 1, 2009, there were approximately 12.5 million people in the United States who had been diagnosed or were living with cancer. According to the American Cancer Society, the number of patients with cancer continues to increase as the population ages and diagnosis, treatment and survival rates improve due to higher standards of care and greater patient access to health care. Cancer patients often suffer from symptoms such as pain, nausea, vomiting, fatigue, weight loss and anemia as a result of their cancer or radiation and chemotherapy treatments intended to eradicate or inhibit the growth of cancerous cells and tumors. Pain is a widely prevalent symptom of cancer patients, of whom it is estimated that between 50% to 90% also suffer from BTCP. We believe that the acute pain episodes of BTCP patients are not adequately managed by oncologists and pain specialists, creating an opportunity for us to educate these medical professionals and promote effective BTCP management using Subsys. According to a 2004 study by the American Society of Clinical Oncology, it is estimated that 60% to 80% of all cancer patients who receive chemotherapy experience nausea and vomiting associated with their therapy. We believe current therapies do not adequately address the needs of many of these patients. Supportive care is an important component in the treatment of cancer patients, as suggested by an August 2010 article in the New England Journal of Medicine indicating that improved supportive care in cancer patients prolonged median survival by over two months. By focusing on supportive care products, we believe we can contribute to the improvement of cancer patient outcomes and survival rates.

We are led by a management team and board of directors with substantial experience founding and managing pharmaceutical and related companies. Our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, has held executive management and board positions at Sciele Pharma and OptionCare, Inc., among others. Dr. Kapoor has also had significant experience with supportive

care products, including Marinol while he was Chairman of Unimed Pharmaceuticals, Inc. Our President and Chief Executive Officer, Michael L. Babich, has been involved with our company since its inception in various roles. He was appointed as our President in November 2010 and as our Chief Executive Officer in March 2011. Prior to that, he served as the Chief Operating Officer since 2007 and as a board member since inception. He has worked with Dr. Kapoor for over 11 years, including at EJ Financial Enterprises, Inc., Dr. Kapoor s venture capital firm, and Alliant Pharmaceuticals, Inc. where he served on the board. Our Chief Medical Officer, Dr. Larry Dillaha, served as the Chief Medical Officer of Sciele Pharma until its acquisition by Shionogi and Co., Ltd. in 2008 where he designed and managed the clinical development and regulatory filings of six products that were approved by the FDA through the 505(b)(2) regulatory pathway. Our Chief Financial Officer, Darryl S. Baker, has previously served as Chief Financial Officer of iGo, Inc. and an audit manager for Ernst & Young LLP. He is a Certified Public Accountant. We intend to leverage the experience of our management team to build Insys into a leading specialty pharmaceutical company focused on commercializing innovative therapies that address unmet medical needs of supportive care.

Strategy

Grow Subsys market share and revenues. We launched Subsys in March 2012. In February 2013, we had a 16.1% share of the overall TIRF market, according to Source Healthcare Analytics. We believe that we can continue to increase Subsys net product revenue through further market penetration and by working with physicians to ensure that patients are titrated to an effective dose of Subsys and have access to Subsys. In addition, we may conduct post-marketing clinical trials to seek to establish incremental uses for Subsys in the supportive care market or other advantages that Subsys may have over existing fentanyl products.

Leverage our cost-efficient commercial organization to market Subsys and, if approved, Dronabinol Oral Solution and other complementary products. We commercialize Subsys through a cost-efficient commercial organization of approximately 67 sales professionals utilizing an incentive-based sales model similar to that employed by Sciele Pharma and other companies previously led by members of our board of directors, including our founder and Executive Chairman. Applying this approach, in the fourth quarter of 2012 our sales and marketing expenses were $3.1 million (during which quarter our commercial organization consisted of approximately 50 sales professionals), and we generated Subsys net revenue of $4.8 million. We intend to market Dronabinol Oral Solution and other proprietary supportive care products, if approved, using the same approach and our commercial organization. We target our product detailing efforts primarily towards oncologists, pain specialists and centers that focus on supportive care. We may also pursue opportunities to acquire commercial products or product candidates that could further leverage our supportive care commercial organization.

Achieve FDA approval for Dronabinol Oral Solution and advance our proprietary dronabinol product pipeline. We believe there is an unmet patient need for a more reliable synthetic THC for treating CINV and anorexia associated with weight loss in patients with AIDS. In a pivotal bioequivalence study, our Dronabinol Oral Solution product candidate has demonstrated rapid and more reliable absorption, which we believe represents an attractive product profile relative to Marinol. We are also evaluating proprietary sublingual spray, inhaled and intravenous formulations of dronabinol in preclinical testing.

Leverage and expand our dronabinol manufacturing capabilities. Since dronabinol is difficult to import, procure and produce, we have a U.S.-based, state-of-the-art dronabinol manufacturing facility, which we anticipate will be able to supply the active pharmaceutical ingredient, or API, for Dronabinol SG Capsule and initial launch quantities of Dronabinol Oral Solution, if approved. For our long-term needs, we plan to use a portion of the net proceeds from this offering to build a second facility that 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.

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Develop additional sublingual spray product candidates. We believe that the delivery of certain pharmaceutical products using our sublingual spray platform technology could have significant advantages over other methods of delivery. Our technology delivers drug product directly to the sublingual mucosa for rapid and efficient absorption into the bloodstream. This process is accomplished by delivering a ready-to-be absorbed formulation across the sublingual mucosa. The sublingual mucosa is an efficient medium for the delivery of certain drugs because this membrane is highly permeable with a high density of blood vessels, which allows for the portion of the drug absorbed to bypass first-pass metabolism in the liver. As such, certain drug products delivered utilizing our sublingual spray technology can be absorbed quickly and take effect more rapidly than many other forms of administration. We are developing several product candidates where we believe our proprietary sublingual spray technology has the potential to provide a clinically meaningful therapeutic advantage over existing delivery methods.

Our Products and Product Candidates

The following table summarizes certain information regarding our marketed products and most advanced product candidates:

Franchise	Product or Product Candidate	Regulatory Pathway	Indication	Status
Spray	Subsys	505(b)(2)	BTCP in Opioid-Tolerant Patients	Marketed
Dronabinol	Dronabinol SG Capsule	ANDA	CINV and Anorexia Associated with Weight Loss in Patients with AIDS	Marketed[1]
	Dronabinol Oral Solution	505(b)(2)[2]		Pre-NDA[3]
	Dronabinol Line Extensions	505(b)(2)[2]		Preclinical

(1) Marketed in the United States under an exclusive distribution agreement with Mylan Pharmaceuticals Inc.
(2) Anticipated regulatory pathway. A 505(b)(2) New Drug Application (NDA) relies for its approval upon studies that were not conducted by or for the applicant, and for which the applicant has not obtained a right of reference. The applicant may rely on the FDA s findings of safety and/or effectiveness for a previously approved drug (the reference drug). However, the applicant must still provide any additional preclinical or clinical data necessary to ensure that differences from the reference drug do not compromise safety and effectiveness. For Dronabinol Oral Solution and our Dronabinol Line Extensions, we expect to use Marinol as the reference drug.
(3) Completed a pre-NDA meeting and pivotal bioequivalence study in 2012 and expect to submit an NDA in the second half of 2013.

Subsys Sublingual Fentanyl Spray

Subsys is a proprietary, single-use product that delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue. We received marketing approval for Subsys from the FDA on January 4, 2012 for the treatment of BTCP. BTCP is characterized by sudden, often unpredictable, episodes of intense pain which can peak in severity at three to five minutes despite background pain medication. We believe Subsys is an important, highly differentiated treatment option for patients and physicians relative to other TIRF products due to its rapid onset of action, improved bioavailability, most complete range of dosage strengths and ease of administration. According to Source Healthcare Analytics, TIRF products generated $388.1 million in U.S. sales in 2012.

Fentanyl is an opioid analgesic approved in the United States for acute and chronic pain management. Depending upon the type of pain, physicians currently prescribe fentanyl in three forms of administration: injectable, transmucosal, or delivery by diffusion through the mucous membranes of the mouth, and transdermal, or delivery through the skin. Fentanyl imitates natural biochemicals found in the body that moderate pain and block the transmission of pain signals that travel along nerves to the brain. We believe these properties make fentanyl a potent and effective therapy for use in patients with cancer who suffer from acute or breakthrough episodes of pain.

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Subsys is a proprietary, single-use product developed to treat BTCP through the delivery of a liquid fentanyl formulation in 100, 200, 400, 600, 800, 1,200 and 1,600 mcg dosages. The 1,200 and 1,600 mcg doses of Subsys are achieved by administering two 600 and 800 mcg doses, respectively. The mechanism by which the liquid is delivered is a highly consistent, one-step process in which a plume of fentanyl is generated by the actuation of the device. The plume disperses a small volume of liquid across the surface area of the sublingual mucosa and facilitates rapid absorption by the body.

Cancer Pain Market Overview

Cancer pain can occur as a result of tumors pressing on nerves, damage caused by cancer cells in bone and treatments for cancer such as chemotherapy, radiation therapy or surgery. Many cancer patients experiencing pain suffer from two types of pain: (1) persistent or continuous pain, which is typically managed by long-acting or sustained-release drugs taken by patients on a regular schedule, and (2) breakthrough pain, which can be severe and sudden, and may require a stronger, fast-acting medication. Opioids are the most widely-prescribed treatment for cancer pain followed by medications commonly used to treat inflammatory pain, such as corticosteroids, anesthetics, non-steroidal anti-inflammatory drugs, anticonvulsants and antidepressants. A report published by Worldwide Marketing Research estimated that the value of the U.S. cancer pain market was $3.1 billion in 2008 and will increase to $5.3 billion by 2018.

Following rapid onset that peaks in three to five minutes, BTCP episodes can last several minutes to an hour, and usually occur several times per day. Pain is a widely prevalent symptom of cancer patients, of whom it is estimated that between 50% to 90% suffer from BTCP, which is particularly difficult to treat due to its severity, rapid onset and the often unpredictable nature of its occurrence. Physicians typically treat BTCP with a variety of short-acting opioid medications, including morphine, morphine and codeine derivatives and fentanyl.

Morphine and morphine and codeine derivatives have been available for decades in immediate-release forms of tablets, capsules or liquids that are ingested by the patient. More recently approved short-acting opioid-based fentanyl formulations utilize transmucosal delivery in an attempt to improve upon existing fentanyl therapies. Teva Pharmaceutical Industries Ltd. s Actiq, approved by the FDA in 1998 and currently available in several generic options, is an oral transmucosal lozenge, and Fentora, the leading branded TIRF product, approved by the FDA in 2006, is a fentanyl buccal tablet. Three other companies have received approval for branded TIRF products since 2009 including BioDelivery Sciences International, Inc. s Onsolis, a soluble film placed on the buccal area after wetting the inside of the cheek with saliva or water, Orexo AB s Abstral, an immediate-release transmucosal sublingual tablet, and Archimedes Pharma Ltd. s Lazanda, a nasal spray. According to Source Healthcare Analytics, TIRF products generated $388.1 million in 2012 U.S. sales. Although these existing therapies provide improvements over oral opioids, we believe that Subsys market adoption to date demonstrates that the current treatment options have limitations and that there remains a significant unmet need for therapies that provide faster pain relief, more convenient dose administration and a better PK profile.

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Limitations of Competing TIRF Therapies

We believe that the BTCP market is underserved due to the limitations of the current market-leading TIRF therapies, which include:

Time until statistically significant pain relief: Patients suffering from BTCP require rapid pain relief as peak intensity of episodic breakthrough pain can occur between three and five minutes from the onset of pain symptoms. The peak effect of Actiq and Fentora may be delayed as it may take up to 14 to 30 minutes for the lozenge or tablet to fully dissolve and be absorbed. In addition, oral immediate-release opioids are metabolized in the liver and consequently may take up to 30 to 45 minutes to become effective.

Pharmacokinetic profile: Actiq and its generic equivalents achieve bioavailability of approximately 50% and require 15 to 30 minutes for absorption. Up to half of the delivered dose of competing TIRF treatments is swallowed and is absorbed slowly through the gastrointestinal, or GI, tract, which we believe may delay the onset of pain relief and contribute to side effects.

Inconvenient delivery: We believe competing commercially available therapies do not adequately address patient ease of use and convenience needs. Competing TIRF therapies can require an administration period of several minutes, disrupt daily activities and cause patient discomfort. For example, Actiq requires patients to place a lozenge between their cheeks and lower gums and rub the lozenge from side to side over a 15-minute period. In addition, patients with dry mouth and oral mucositis may experience difficulty in using Actiq and other commercially available therapies.

Limited dosage forms: Actiq and its generic equivalents are available in six dosage strengths ranging from 200 to 1,600 mcg. No other commercially available TIRF therapies are offered in the 1,200 and 1,600 mcg dosage range. According to Source Healthcare Analytics, approximately 47% of the U.S. dollar sales of Actiq in 2012 were in the 1,200 and 1,600 mcg doses.

Our Solution

We believe Subsys proprietary formulation and sublingual delivery mechanism offer several advantages over other FDA-approved TIRF products, and these advantages may lead to improved patient compliance and expanded medical use of fentanyl for BTCP. Such advantages include:

Statistically significant pain relief in five minutes: Subsys is the only product to show statistically significant pain relief when measuring the sum of pain intensity difference, SPID, at five minutes in a Phase 3 BTCP clinical trial using fentanyl. We believe that Subsys is able to achieve this rapid delivery of fentanyl through sublingual delivery because there is a high density of blood vessels beneath the tongue and the thin layer in the mucosa enables higher absorption. The product sprays in a manner that is designed to maximize the area covered by the product.

One-step administration: Subsys is administered in one step using a small handheld delivery system that sprays fentanyl beneath the patient s tongue. This delivery mechanism allows for administration in less than one minute, rather than the 14 to 30 minutes required for Actiq and Fentora. Further, Subsys can be administered without moistening the tongue or cheek, allowing for administration in cancer patients suffering from dry mouth and oral mucositis.

Superior pharmacokinetic profile. As compared to Actiq s PK profile, Subsys PK profile is characterized by higher peak blood concentrations, which are achieved at a more rapid rate. This profile is, in part, due to greater than 85% absorption occurring transmucosally, resulting in higher bioavailability. Because a small volume of liquid is sprayed on to the sublingual mucosa, we believe this method of administration reduces the amount of liquid swallowed and subsequently absorbed via the digestive system. As a result, we believe that less fentanyl is exposed to first-pass metabolism in the liver.

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Broad spectrum of dosage strengths allows for proper titration and better pain relief. Subsys is available in the most complete range of dosage strengths in the TIRF market, at 100, 200, 400, 600, 800, 1,200 and 1,600 mcg. We believe it is important to offer a product in all dose ranges for the treatment of BTCP, as all branded products without generic equivalents, and, to our knowledge, all product candidates currently in development, are not, or will not be, available in the 1,200 and 1,600 mcg dosage strengths.

Subsys Market Experience to Date

Prescription Trends: Monthly prescription data through February 2013 shows that nearly 9,200 prescriptions of Subsys have been dispensed since launch in March 2012. Subsys total prescription share of the TIRF market has increased each month since launch, as illustrated in the following chart. In February 2013, Subsys was the second most prescribed branded TIRF product with 16.1% market share.

Subsys TIRF Prescription Market Share Analysis[(1)]

(1) Source Healthcare Analytics

Physician Prescriber Base: Approximately 1,850 physicians were responsible for 90% of all TIRF prescriptions dispensed from the launch of Subsys through February 2013, according to Source Healthcare Analytics. We have targeted our initial commercialization efforts towards the majority of these high prescribers. As of February 2013, there were approximately 620 unique physician prescribers of Subsys, according to the TIRF risk evaluation mitigation strategy, or REMS, database. As of February 2013, approximately 66% of the top 135 TIRF prescribers had prescribed Subsys. These physicians accounted for 30% of TIRF prescriptions, according to Source Healthcare Analytics.

Patient Use: Patient data generated by the TIRF REMS database demonstrates that the number of Subsys-experienced patients has increased steadily since launch with over 3,200 unique patients as of February 2013. Importantly, the proportion of Subsys prescriptions written for repeat Subsys patients has continued to increase since July 2012 from 50% of prescriptions to over 70% of prescriptions as of February 2013. Generally, repeat Subsys patients receive 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 REMS protocol.

Patient Access: Subsys is a Tier 3 medication available under nearly all major commercial health insurance plans. Some third-party payors require usage and failure on cheaper generic versions of Actiq prior to providing reimbursement for Subsys and other branded TIRF products. We believe that physicians and payors will develop greater familiarity with both the differentiated features of Subsys and the process to achieve patient access to the product from continued and broader usage of Subsys by their patients. We offer patients a free trial of Subsys to allow for titration to their effective dose and bridge the prior authorization process. Once third-party payor reimbursement is in place, we offer patients coupons to reduce out of pocket costs.

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Clinical Trial History

We have completed two Phase 3 clinical trials and two Phase 1 clinical trials involving an aggregate of over 500 patients for Subsys.

Phase 3 Clinical Trials

Our Phase 3 clinical program for Subsys was comprised of a 130-patient safety and efficacy trial and a 300-patient safety trial. Our Phase 3 safety and efficacy trial was a randomized, double-blind, placebo-controlled study conducted at 27 U.S. clinical sites. Patients enrolled in the study experienced one to four BTCP episodes during a four-day screening period and were opioid-tolerant, defined as actively using long-acting oral opioids or transdermal fentanyl as a background analgesic and short-acting solid oral opioids to manage breakthrough episodes. Prior to entering the treatment period, patients were titrated to establish the optimal dose of Subsys to relieve their BTCP. Patients could receive 100, 200, 400, 600, 800, 1,200 (2 x 600 mcg) and 1,600 mcg (2 x 800 mcg) doses of Subsys. Of the 130 patients enrolled in the safety and efficacy trial, 92 were evaluated in the efficacy analysis. The primary endpoint of this study was pain relief at 30 minutes using SPID at 30 minutes for Subsys versus placebo. We also evaluated the secondary endpoints of SPID across time periods ranging from five minutes to 60 minutes post-administration as well as safety, tolerability and acceptability. Subsys met all primary and secondary endpoints with statistical significance and, notably, demonstrated statistically significant pain relief at five minutes. Statistical significance is a measure of the strength of a conclusion that can be drawn from the data. Clinical trial results are considered statistically significant when the probability of the results occurring by chance, rather than from the efficacy of the drug candidate, is sufficiently low. Statistical significance is measured by the probability value, or p-value. A clinical trial result with a p-value of less than 0.05 means that the probability of the same trial results occurring randomly or by chance is less than 5%, and is generally considered to be statistically significant. For our efficacy study, our primary endpoint had a p-value of <0.0001 and all secondary endpoints had p-values of <0.05. The results of this study are presented below.

Our Phase 3 safety trial was a three-month open-label study conducted at 46 sites in the United States and ten sites in India. Patients enrolled in the study included those rolled-over from the Phase 3

safety and efficacy study as well as new patients that met the same major inclusion criteria. The new patients were also titrated to the optimal dose of Subsys for the study period. The primary endpoint of this study was safety over a three-month treatment period. We enrolled 300 patients in this study, of which 150 completed 90 days on the treatment. No serious adverse events were reported in this study. The most common adverse events observed in this trial were principally those identified as typical of fentanyl products, including sleepiness, dizziness, nausea, vomiting and shortness of breath.

Phase 1 Clinical Trials

We have conducted two Phase 1 clinical trials evaluating the absorption rate, bioavailability and PK of Subsys. The results of our Phase 1 open-label trial in 21 healthy, normal volunteers, completed in April 2007, compared the rate of absorption and availability of the active drug to the patients on Subsys relative to patients receiving Actiq and a fentanyl intravenous injection, or fentanyl IV.

In the trial, we observed Subsys reaching higher peak blood concentration, or C_{max}, than Actiq, as well as a more rapid rate of absorption, or T_{max}. Subsys had a mean C_{max} of 0.813 nanograms per milliliter, or ng/mL, versus 0.607 ng/mL for Actiq. In addition, Subsys reached maximum concentration in the body in approximately 1.3 hours versus 1.7 hours for Actiq. We also observed that Subsys remained in the body at higher levels when compared to the same dose of Actiq. As expected, we observed that fentanyl IV achieved a higher C_{max} more rapidly than Subsys, but that its plasma concentration in the body declined much more rapidly than Actiq and Subsys. C_{max} for fentanyl IV was 0.929 ng/mL and time to maximum plasma concentration was 0.16 hours.

Data from our Phase 1 clinical trial relative to PK results supports our belief in the relatively rapid absorption of fentanyl using Subsys. The data further illustrates that the duration of action of Subsys is comparable to Actiq, providing support for our belief that Subsys may be a faster and more convenient alternative to existing treatment options. A second Phase 1 single-site trial was completed in 49 patients evaluating PK data across five different doses of Subsys. The results suggest that the administration of fentanyl using a sublingual spray is dose-proportional over a 100 to 800 mcg range.

The final Phase 1 study was conducted in 18 patients with Grade 1 and Grade 2 mucositis. The results of this study showed no statistically significant variation in plasma blood levels in patients with mucositis compared to those without mucositis.

Dronabinol Product Family

We have one approved dronabinol product and are developing several innovative dronabinol product candidates for the second-line treatment of CINV and anorexia associated with weight loss in patients with AIDS. We received FDA approval for Dronabinol SG Capsule in 2011, and we currently commercialize this product in the United States through our exclusive distribution agreement with Mylan. We believe a significant unmet medical need exists for formulations of dronabinol that act more rapidly, are subject to less variable patient absorption and allow for more flexible dosing. Our lead proprietary dronabinol product candidate is Dronabinol Oral Solution. We completed a pivotal bioequivalence study for Dronabinol Oral Solution in 2012. In addition, we are evaluating proprietary sublingual spray, inhaled and intravenous formulations of dronabinol in preclinical studies.

Dronabinol, the active ingredient in Marinol, is a synthetic form of THC. THC is an orally active cannabinoid which, like other cannabinoids, has complex effects on the central nervous system. Approved by the FDA in 1985, Marinol is indicated for the treatment of CINV in patients who have failed to respond adequately to conventional treatments, as well as for the treatment of anorexia associated with weight loss in patients with AIDS. Marinol is formulated in sesame oil and encapsulated in soft gelatin capsules and must be stored in cool storage conditions or in a refrigerator.

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Market Overview

CINV is a commonly known side effect of chemotherapy that can have a significant negative impact on quality of patient life. CINV is classified into five categories:

Acute: Occurs within 24 hours of chemotherapy administration.

Delayed: Occurs more than 24 hours after chemotherapy administration, with peak intensity two to three days post-administration and duration of up to one week.

Anticipatory: Occurs prior to treatment.

Breakthrough: Occurs after use of antiemetic agents.

Refractory: Occurs after failed use of breakthrough therapy.

The majority of chemotherapy patients experience at least one type of CINV. The National Comprehensive Cancer Network estimates that 70% to 80% of patients undergoing chemotherapy experience vomiting, with 10% to 44% experiencing anticipatory vomiting. Predictive factors for developing CINV can include: age of less than 50 years, female gender, vomiting during previous chemotherapy, pregnancy-induced nausea/vomiting, history of motion sickness and anxiety. In addition to generally affecting patient quality of life, CINV can result in weakness, weight loss, electrolyte imbalance, dehydration or anorexia. According to a study published by Ballatori, et al in 2007, 90% of patients who experienced CINV reported an impact on daily activities.

Although the pathophysiology of CINV is not clearly understood, it is thought that chemotherapeutic agents cause vomiting by activating neurotransmitter receptors located in the chemoreceptor trigger zone, GI tract, and vomiting center, or VC. Activation of the VC directly or through the chemoreceptor trigger zone results in stimulation of the salivation and respiratory centers as well as control of the pharyngeal, GI and abdominal muscles. This stimulation can trigger the body to retch and vomit.

Treatment of CINV is highly patient-specific and is based on the emetogenic potential of the chemotherapy regimen. According to IMS Health, U.S. sales for drugs treating CINV were $1.1 billion in 2012, though published reports suggest that current therapies are not entirely effective. A 2004 report published in Cancer estimated that approximately 35% of patients treated with CINV therapies continue to experience acute nausea, with 13% of CINV patients experiencing acute vomiting after first-line treatment.

Limitations of Existing Therapies

We believe that the synthetic cannabinoid market is underserved due to the limitations of existing therapies, which include:

Delayed absorption: Marinol is only available in a capsule formulation, which must be dissolved and digested before it is metabolized in the patient s liver, where the drug is broken down by enzymes. We believe that this capsule formulation and digestion process delays onset of action and relief of nausea and vomiting. After oral administration, Marinol has an onset of action of approximately 30 minutes to one hour and peak effect at two to four hours.

Lower level of efficacy: Due to the capsule formulation and digestion process of Marinol, only 10% to 20% of an administered dose of Marinol reaches the systemic circulation in the body. This poor absorption profile significantly reduces the bioavailability of the API in patients using its capsule formulation which may result in lower efficacy.

Lack of flexibility in dosing: Marinol and its generic equivalents are only available in 2.5, 5.0 and 10.0 milligram, or mg, soft-gelatin capsules. The fixed dosage amounts may cause patients to ingest more or less drug than necessary, which can result in increased side effects and/or a lower level of efficacy.

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Variable patient absorption: The uptake of Marinol into systemic circulation varies widely from dose-to-dose and patient-to-patient. In general, this level of variability is atypical relative to approved pharmaceutical products. As such, physicians are unable to predict the level of efficacy or side effects that an individual patient might experience relative to other patients or even to a patient s own last dose of dronabinol.

Our Solutions

We believe our proprietary dronabinol product candidates have the potential to address many of the limitations that exist in synthetic cannabinoid products by providing a number of key advantages, including:

Faster absorption: Dronabinol Oral Solution is a liquid solution and is absorbed faster than a capsule formulation which has to dissolve in the GI tract. We believe that quicker absorption may lead to faster onset of action for an oral solution product. Separately, we believe that our proprietary sublingual spray, inhalation and intravenous dronabinol formulations, currently in preclinical studies, may further accelerate dronabinol s onset of action due to their route of delivery bypassing first-pass metabolism in the liver.

Level of efficacy: By bypassing first-pass metabolism in the liver, we believe our proprietary sublingual spray, inhalation and intravenous dronabinol formulations may demonstrate lower dose-to-dose variability compared to Marinol and, as a result, more reliable efficacy.

Flexibility in dosing: Dronabinol Oral Solution allows for greater flexibility across the dosing range versus the fixed dosing necessitated by Marinol. We believe that offering physicians and patients an improved formulation with the opportunity to more precisely titrate may increase market acceptance of dronabinol.

Reduced dose-to-dose variability: Based on our pivotal bioequivalence and PK studies, we believe Dronabinol Oral Solution has lower dose-to-dose variability which could lead to more consistent intra-patient responses in each successive dose. Due to the higher anticipated absorption rates for our dronabinol inhalation formulation, we believe that lower dosages of this formulation may be required as compared to Marinol.

Dronabinol SG Capsule

Dronabinol SG Capsule is our generic version of Marinol approved by the FDA in August 2011. Dronabinol SG Capsule is a simple solution of dronabinol in sesame oil that is encapsulated in soft gelatin. Dronabinol SG Capsule is supplied in 2.5, 5.0 and 10.0 mg dosage strengths. We launched Dronabinol SG Capsule in the United States through our exclusive distribution partner, Mylan, in December 2011.

Dronabinol Oral Solution

Dronabinol Oral Solution is a proprietary synthetic THC in an oral liquid formulation, which contains ingredients to enhance absorption. We believe that this product candidate may provide increased flexibility in dosing, more convenient delivery and an improved absorption profile in patients. 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 on April 17, 2012 and subsequently in 2012 completed a pivotal bioequivalence study for Dronabinol Oral Solution. Our pivotal bioequivalence study was a 52-patient crossover bioavailability and PK clinical trial comparing Dronabinol Oral Solution with Marinol. In the study, 100% of subjects receiving Dronabinol Oral Solution achieved detectable plasma levels at 15 minutes compared to less than 25% of the subjects receiving Marinol, and Dronabinol Oral Solution demonstrated a more than 60% decrease in dose-to-dose drug exposure variability as measured by patient coefficient of variation for AUC. We will manufacture one additional registration lot and generate adequate stability data prior to submission of an NDA for Dronabinol Oral Solution, which we expect to submit in the second half of 2013.

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Other Product Candidates

Our other product candidates include other dronabinol line extensions and sublingual spray product candidates.

Future Dronabinol Line Extensions. As described above, we plan to develop additional dronabinol delivery systems, including proprietary sublingual spray, inhalation and intravenous dronabinol formulations. All of these product candidates are in preclinical development. We have also submitted a supplemental Abbreviated New Drug Application, or ANDA, for a room temperature stable version of our dronabinol soft gel capsule, which we refer to as Dronabinol RT Capsule.

Sublingual Spray Product Candidates. We are conducting preclinical development for multiple well-known, approved molecules for delivery through our sublingual drug delivery technology. We intend to evaluate these and other products that we believe could have a differentiated efficacy and/or safety profile if formulated by us and delivered via a sublingual spray.

Sales and Marketing

Key members of our management and board have extensive experience in building and implementing cost-efficient, incentive-based commercial organizations as well as commercializing supportive care products, including dronabinol. We currently market Subsys and intend to commercialize Dronabinol Oral Solution and future supportive care products, if approved, through our U.S.-based commercial organization focused on supportive care. Specifically, we currently market Subsys in the United States through a commercial organization comprised of approximately 67 sales professionals. We have built this commercial organization utilizing an incentive-based model similar to that employed by Sciele Pharma and other companies previously led by members of our board, including our founder, Executive Chairman and principal stockholder. This model employs a pay structure where a significant component of the compensation paid to sales representatives comes in the form of potential bonuses based on sales performance. In the fourth quarter of 2012, our sales and marketing expenses were $3.1 million and we generated Subsys net revenue of $4.8 million. Our product detailing efforts focus primarily on oncologists, pain specialists and centers that cater to supportive care. We do not currently have sales and marketing capabilities outside of the United States. 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 believe some of the key factors in generating continued growth in Subsys usage include taking market share from leading TIRF products and expanding the usage of Subsys for BTCP by building awareness among oncologists of its rapid onset of action, improved bioavailability, most complete range of dosage strengths and ease of administration relative to other TIRF products. To successfully commercialize our family of proprietary dronabinol products, we intend to focus our commercial efforts on taking market share from Marinol and its generic alternatives as well as further expanding into a broader segment of the CINV market by developing awareness of our product attributes relative to currently available dronabinol products.

As of February 28, 2013, there were approximately 8,400 physicians enrolled in the TIRF REMS program. Enrollment in this class-wide REMS program is required by the FDA as of March 2012 in order to prescribe TIRF products. Approximately 1,850 physicians comprise 90% of TIRF prescriptions dispensed from the launch of Subsys through February 2013, according to Source Healthcare Analytics. Our sales and marketing efforts have primarily targeted approximately 90% of these top 1,850 prescribing physicians with a focus on the highest prescribers. As of February 2013, 66% of the top 135 physician prescribers had prescribed Subsys. These physicians accounted for 30% of all U.S. TIRF prescriptions. We believe that key factors for driving future Subsys growth include increasing the number of prescriptions written by those physicians who currently prescribe Subsys, increasing the number of physicians who prescribe Subsys, and allowing sufficient time for physicians and patients to identify their effective Subsys dose among our broad spectrum of dosage strengths.

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We entered into a supply and distribution agreement effective as of May 20, 2011 with Mylan, pursuant to which we engaged Mylan to exclusively distribute our Dronabinol SG Capsule within the United States. The agreement has a seven-year term which commenced in December 2011 upon the first commercial sale of the Dronabinol SG Capsule product which will automatically renew for an additional one-year term, following the initial term, unless we or Mylan give the other party 180 days prior written notice of its desire to terminate the agreement. Pursuant to the terms of the agreement, which was amended on March 13, 2012, we are required to order Dronabinol SG Capsule from Catalent Pharma Solutions, LLC for shipment to Mylan in accordance with certain specifications, and ensure that Catalent uses commercially reasonable efforts to maintain enough Dronabinol SG Capsule inventory to satisfy Mylan s purchase orders. Under the terms of the agreement, we are obligated to pay Mylan a royalty between 10% and 20% on Mylan s net Dronabinol SG Capsule sales, and a single digit percentage fee on such sales for distribution and storage services. The parties have agreed to technical protocols and specific responsibilities for handling quality complaints related to Dronabinol SG Capsule. If during the term of the agreement, we obtain FDA approval for Dronabinol RT Capsule, then it will be subject to the agreement to the same extent as Dronabinol SG Capsule. Mylan may terminate the agreement in the event of a negative outcome of a quality audit of our and/or Catalent s manufacturing facilities. Additionally, we or Mylan may terminate the agreement effective 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 such breach within the 45-day period or effective upon notice if the other party becomes insolvent.

Manufacturing and Supply

We produce dronabinol, the API in our dronabinol product family, including Dronabinol SG Capsule and our proprietary dronabinol product candidates, internally at our U.S.-based, state-of-the-art manufacturing facility. We believe that this facility has the capacity to supply sufficient commercial quantities of dronabinol API for 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 believe this investment gives us a significant competitive advantage since dronabinol API is a Schedule I material and consequently is subject to annual production limits set by quota for each individual facility, cannot be readily procured, is difficult to import into the United States and has a limited number of suppliers domestically.

For our long-term needs, 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. The chemical materials for dronabinol API are sourced from independent suppliers and are manufactured utilizing well-established chemical techniques. Our manufacturing facility utilizes these chemical materials to produce dronabinol through a series of synthetic reactions and purification cycles. We believe that our suppliers are equipped to meet our current and future chemical material needs for the continued commercialization of Dronabinol SG Capsule and the development and commercialization of our dronabinol-based product candidates. On March 21, 2011, we entered into a commercial manufacturing and packaging agreement with Catalent pursuant to which we engaged Catalent on an exclusive basis to provide processing and packaging services with respect to our Dronabinol SG Capsule. Pursuant to the terms of the agreement, which was amended on March 5, 2012, we are required to supply Catalent with the API for our Dronabinol SG Capsule and are required to purchase a minimum number of units of our Dronabinol SG Capsule pursuant to annual purchase orders. For units ordered, we are required to pay Catalent a per-unit fee, plus annual product maintenance fees. We are also required to pay a testing fee for post-packaging analysis testing for each batch of product. The initial term of the agreement is five years, unless earlier terminated, and automatically renews for additional periods of two years, unless we or Catalent give the other party at least 12 months prior written notice of its desire to terminate the agreement. Additionally, we or Catalent may terminate the agreement effective upon 60 days prior written notice to the other party if the other party commits a material breach of the agreement and fails to cure such breach within the 60-day period, if the other party becomes insolvent or

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upon 24 months prior written notice to the other party. Catalent has been selected for its specific competencies in manufacturing processes and materials.

Subsys is manufactured by contract manufacturers and sub-component fabricators. AptarGroup, Inc., a dispensing system company based in Illinois, developed the sublingual spray device we use for Subsys. We entered into a supply agreement effective as of March 7, 2011 with Aptar pursuant to which Aptar supplies us with the delivery system to administer Subsys. We also granted Aptar the exclusive option to supply us with all of our requirements for Subsys drug delivery systems, and all other drug delivery systems for drugs we may develop in the future. In addition, under the agreement, Aptar is required to supply us exclusively with devices to administer Subsys, which obligation is dependent on several factors, including exclusivity payments to Aptar of less than $1.0 million, purchase order levels and our efforts to seek market approval for Subsys in Europe. We are required to provide Aptar with rolling quarterly forecasts of our requirement for Subsys drug delivery systems. Under certain circumstances, such forecasts are non-binding; however, some portions of such forecasts may constitute a firm commitment to purchase delivery systems to administer Subsys. The agreement has a term of five years from the effective date; however, either party may terminate the agreement (1) immediately if the other party makes an assignment for the benefit of its creditors or a receiver or custodian is appointed for it or its business is placed under attachment, garnishment or other process involving a significant portion of its business, (2) after written notice if the other party commits a material breach of the agreement and fails to commence and diligently pursue a remedy for any such material breach, or (3) immediately if the other party becomes insolvent.

We entered into a manufacturing agreement effective as of May 24, 2011 with DPT Lakewood, LLC pursuant to which we engaged DPT on an exclusive basis to provide processing and packaging services with respect to Subsys. Pursuant to the terms of the agreement, which was amended on April 23, 2012, we are obligated to provide DPT a written, non-binding rolling 18-month forecast on a monthly basis, with the first four-month forecast constituting a firm purchase order regardless of receipt of our actual purchase order. We are also required to supply DPT with the API for Subsys, and to pay manufacturing and materials fees related to the production, packaging, administration and carrying cost of Subsys. DPT is required to manufacture Subsys in accordance with certain specifications and to conduct product testing prior to delivery. Unless terminated earlier, the initial term of the agreement will continue until December 31, 2017. Thereafter, the agreement will automatically renew for 24-month periods unless either party provides notice at least 24 months prior to the expiration of the initial term or any renewal term. We or DPT may terminate the agreement effective upon 60 days prior written notice to the other party if the other party commits a material breach of the agreement and fails to cure such breach within the 60-day period or effective upon notice to the other party if the other party becomes insolvent.

Aptar and DPT have been selected for their specific competencies in manufacturing, product design and materials. FDA regulations require that materials be produced under current Good Manufacturing Practices, or cGMPs, or quality system regulations, as required for the respective unit operation within the manufacturing process. We believe both key suppliers have sufficient capacity to meet our projected product requirements.

Competition

Our industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary products. We face competition from many different sources, such as pharmaceutical companies, including generic drug companies, biotechnology companies, drug delivery companies and academic and research institutions. We believe the key competitive factors that will affect the commercial success of our products and the development of our product candidates include, but are not limited to, onset of action, bioavailability, efficacy, cost, convenience of dosing, safety, and tolerability profile. Many of our potential competitors have substantially greater financial, scientific, technical, intellectual property, regulatory and human resources than we do, and greater experience than we do commercializing products and developing product candidates, including obtaining FDA and other regulatory approvals for product candidates. Consequently, our competitors

may develop products for the treatment of BTCP, CINV and anorexia associated with weight loss in patients with AIDS, or other indications we pursue that are more effective, better tolerated, more widely-prescribed or accepted, more useful and less costly, and they may also be more successful in manufacturing and marketing their products. We also face competition from third parties in obtaining allotments of fentanyl and dronabinol under applicable U.S. Drug Enforcement Administration, or DEA, quotas, recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients for clinical trials and in identifying and acquiring or in-licensing new products and product candidates.

Subsys

Subsys competes against numerous branded and generic products already being marketed and potentially those which are or will be in development. Subsys is the fourth new product in the TIRF market over the last four years. In the BTCP market, physicians often treat patients 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 s Fentora and Actiq, Orexo AB s Abstral, Archimedes, Lazanda and BioDelivery Science International, Inc. s Onsolis. Some generic fentanyl products against which Subsys competes are marketed by Mallinckrodt, Inc., Par Pharmaceutical Companies 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, inhaled delivery systems and sublingual delivery systems, among others.

Dronabinol Product Family

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 which we encounter, or will encounter with respect to our dronabinol product candidates, 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 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, Inc. markets an authorized generic version of Marinol. 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 agents prior to initiating chemotherapy, such as Sanofi s Anzemet, Eisai Inc./Helsinn Group s Aloxi, Roche Holding AG s Kytril, Par Pharmaceutical Companies s 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 a broader segment of the CINV market, we will also face competition from these products.

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Additionally, we are aware of companies in late stage development for CINV product candidates, including A.P. Pharma, Inc. s APF530, which is in Phase 3 development, Aphios Corp. s Zindol, which is in Phase 2/3 development, Tesaro, Inc. 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.

Intellectual Property

The success of most of our product candidates will depend in large part on our ability to:

- obtain and maintain patent and other legal protections for the proprietary technology, inventions and improvements we consider important to our business;
- prosecute our patent applications and defend our issued patents;
- preserve the confidentiality of our trade secrets; and
- operate without infringing the patents and proprietary rights of third parties.

We intend to continue to seek appropriate patent protection for certain of our product candidates, drug delivery systems, molecular modifications, as well as other proprietary technologies and their uses by filing patent applications in the United States and selected other countries. We intend for these patent applications to cover, where possible, claims for medical uses, processes for preparation, processes for delivery and formulations.

As of March 31, 2013, we owned or licensed from third parties a total of ten issued U.S. utility patents and seven pending U.S. utility patent applications. These U.S. patents and patent applications will expire in 2015 through 2033. Some of the issued patents and pending applications, if issued, may also be eligible for patent term adjustment and patent term restoration, thereby extending their patent terms.

Subsys

Our Subsys patent portfolio currently consists of two U.S. pending patent applications and 17 foreign counterparts. We do not currently have any issued U.S. patents in our Subsys patent portfolio. The claims of these applications currently cover at least formulations and methods of use relating to Subsys. Any patents that issue from our pending patent applications will expire in 2027 and 2028.

Dronabinol

Our dronabinol patent portfolio currently consists of one issued patent and four U.S. pending patent applications and nine foreign counterparts. The claims of the patent and these applications currently cover at least formulations of dronabinol, codrug of opioid-cannabinoid compositions and methods of manufacturing and packaging dronabinol to provide for room temperature stability. Our one issued dronabinol patent will expire in 2028. Any patents that issue from our pending patent applications will expire between 2025 and 2033.

Other

The rest of our patent portfolio relates to patents and applications owned or licensed by us and directed to other potential product candidates.

Although we believe our rights under these patents and patent applications provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to obtain issued patents from pending applications. Even if patents are granted, the allowed claims may not be sufficient to adequately protect the technology owned by or licensed to us. Any patents or patent rights that we obtain carry some risk of being circumvented, challenged or invalidated by our competitors. As described in the section entitled Business Legal Proceedings, a former officer of Insys Pharma has

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sought to rescind his assignment of his inventions concerning fentanyl and dronabinol patent applications described above. Ownership and inventorship disputes may arise for other patents and applications that we own or license.

We also rely on trade secrets, proprietary know-how and continuing innovation to develop and maintain our competitive position, especially when we do not believe that patent protection is appropriate or can be obtained. We require each of our employees, consultants and advisors to execute proprietary information and inventions assignment agreement before they begin providing services to us. Among other things, this agreement obligates each employee, consultant or advisor to refrain from disclosing any of our confidential information received during the course of providing services and, with some exceptions, to assign to us any inventions conceived or developed during the course of these services. We also require confidentiality agreements from third parties that receive our confidential information.

The biotechnology and biopharmaceutical industries are characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. As our current and potential product candidates and others based upon our proprietary technologies progress toward commercialization, the possibility of an infringement claim against us increases. While we attempt to be certain that our products and proprietary technologies do not infringe other parties patents and other proprietary rights, competitors or other parties may assert that we infringe on their proprietary rights.

We have conducted certain clearance searches of issued U.S. patents for our fentanyl formulations and have not conducted extensive clearance searches for our other product candidates, and cannot guarantee that the searches we have done were comprehensive and, therefore, whether Subsys or any of our product candidates, delivery devices, or methods of using, making or delivering our product candidates infringe the patents searched, or that other patents do not exist that cover Subsys or product candidates, delivery devices or these methods. Interpreting patent claims involves complex legal and scientific questions and it is difficult to assess whether or not our product candidates would infringe any patent. Likewise, it is difficult to predict whether or not third-party patent applications will issue and what claim scope they may obtain. If we conclude that any identified patents, or patent applications once they issue as patents cover Subsys or our product candidates, we cannot guarantee that we will be able to formulate around such patents at all or without material delay or whether we can obtain reasonable license terms from the patent owners, if at all. There may also be other pending patent applications that are unknown to us and, if granted, may prevent us from making, using or selling Subsys or our product candidates. Other product candidates that we may develop, either internally or in collaboration with others, could be subject to similar uncertainties. If a product is found to infringe a third-party patent, we could be prevented from developing and selling that product. Please see the section entitled Risk Factors Risks Relating to Our Intellectual Property.

Environmental and Safety Matters

We use hazardous materials, including chemicals, biological agents and compounds that could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern, among other things, the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts.

In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. If one of our employees was accidentally injured as a result of the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment is within the coverage terms of our workers compensation insurance policy. However, we do not carry specific 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. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

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Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending investigational New Drug Applications, or INDs, and NDAs or issue warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. Pharmaceutical product development in the United States typically involves, among other things, preclinical laboratory and animal tests, the submission to the FDA of an IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease indicated for treatment.

Preclinical tests include laboratory evaluation of product chemistry, stability, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Certain nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may be conducted after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has not placed a clinical hold on the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal regulations, good clinical practices, or GCP, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial, as well as under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing in U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human volunteers, the drug is tested to assess safety, metabolism, PK, pharmacological actions, side effects associated with increasing doses and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to evaluate the effectiveness of the drug for a particular

indication or indications, dosage tolerance and optimum dosage, and identify possible adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In some cases, the FDA may condition approval on the sponsor s agreement to conduct additional clinical trials to further assess the drug s safety and effectiveness after approval. Such post-approval studies are typically referred to as Phase 4 studies.

The current FDA standards for approving new pharmaceutical products are more stringent than those that were applied in the past. These standards were not applied to many established products currently on the market, including certain opioid products. As a result, the FDA does not have as extensive safety databases on these products as on some products developed more recently. We believe the FDA has recently expressed an intention to develop safety data for certain products, including many opioids. In particular, the FDA has expressed interest in specific impurities that may be present in a number of opioid narcotic APIs, such as oxycodone. Based on certain structural characteristics, these impurities may have the potential to cause mutagenic effects. If, after testing, such effects are ultimately demonstrated to exist, more stringent controls on the levels of these impurities may be required for FDA approval of products containing these impurities, such as oxymorphone. Any additional testing or remedial measures that may be necessary could result in increased costs for, or delays in, obtaining approval for certain of our products in development.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture and controls, and proposed labeling, among other things. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA are also subject to annual product and establishment fees per product and per establishment. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the Prescription Drug User Fee Act the FDA has agreed to certain performance goals in the review of NDAs. The FDA has a goal of reviewing applications for non-priority drug products within 12 months of NDA submission. The review process may be extended by the FDA for three additional months to consider certain information or clarification regarding information already provided in the submission. The FDA may also refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless the facility demonstrates compliance with current cGMPs and the NDA contains data that provides substantial evidence that the drug is safe and effective for the indication sought in the proposed labeling. Additionally, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCPs before approving an NDA.

After the FDA evaluates the NDA and the manufacturing facilities, it may issue an approval letter, or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two to six months depending on the type of information included.

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An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require substantial post-approval testing and surveillance to monitor the drug s safety or efficacy and may impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms which can materially affect the potential market and profitability of the drug. Further, if there are any modifications to the drug, including changes in indications, labeling, or manufacturing processes or facilities, a new or supplemental NDA may need to be submitted, which may require additional data or additional nonclinical studies and clinical trials. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The FDA may require sponsors of investigational drugs to submit proposed REMS in order to ensure that the benefits of the drugs continue to outweigh the risks. Sponsors of certain drug applications approved without a REMS program may also be required to submit a proposed REMS program if the FDA becomes aware of new safety information and makes a determination that a REMS program is necessary.

The Hatch-Waxman Act

Abbreviated New Drug Applications (ANDAs)

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. ANDA applicants are not required to conduct or submit results of preclinical or clinical tests to prove the safety or effectiveness of their drug product, but are required to conduct bioequivalence testing, which compares the bioavailability of their drug product to that of the listed drug to confirm chemical and therapeutic equivalence. Drugs approved in this way are commonly referred to as generic versions of the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product s listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant does not challenge the listed patents via a Paragraph IV certification, the FDA will not approve the ANDA application until all the listed patents claiming the referenced product have expired.

If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the ANDA until the earlier of 30 months from the date of the lawsuit, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant. As an incentive for the rapid development of generic drug products, the first ANDA(s) filed that challenges a listed patent by filing a Paragraph IV certification may be granted a 180-day marketing exclusivity

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period during which the FDA may not approve another ANDA for the same product. There may be multiple such first filers. The 180-day marketing exclusivity period is triggered either by commercial launch of any first-filed ANDA approved product or from the date of a court decision finding the challenged patent to be invalid, unenforceable or not infringed, whichever is first. The 180-day exclusivity can be forfeited, among other reasons, if the first filed and approved ANDA is not marketed, does not obtain tentative approval or the challenged patent expires.

The ANDA application also will not be approved until any non-patent market exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired. Federal law provides an exclusive period of five years following approval of a drug containing no previously approved active ingredients, during which ANDAs for generic versions of those drugs cannot be submitted unless the submission contains a Paragraph IV challenge to a listed patent, in which case the submission may be made four years following the original product approval. Federal law additionally provides for a period of three years of exclusivity following approval of a drug that contains previously approved active ingredients but is approved in a new dosage form, route of administration or combination, or for a new use, the approval of which was required to be supported by new clinical trials conducted by or for the sponsor. The FDA cannot grant effective approval of an ANDA based on that listed drug during this three-year period.

Section 505(b)(2) Regulatory Pathway

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA. Section 505(b)(2) of the FDCA enables the applicant to rely, in part, on the FDA s findings of safety and efficacy for an existing product, or published literature, in support of its application.

505(b)(2) NDAs often provide an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved products. Specifically, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA s findings from preclinical or clinical studies conducted for an approved product. The FDA may also require 505(b)(2) applicants to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant. To the extent that the Section 505(b)(2) applicant is relying on findings of safety or efficacy for an already approved product, the applicant is subject to existing exclusivity for the reference product and is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would. Thus approval of a Section 505(b)(2) NDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the Section 505(b)(2) applicant.

Post-Approval FDA Requirements

Once an NDA is approved, a product is subject to extensive and ongoing post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. FDA post-market regulations also include, among other things, requirements relating to drug listing, recordkeeping, periodic reporting, product sampling and distribution, manufacturing and reporting of adverse events arising from use of the product. Failure to comply with these regulatory requirements

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may result in restrictions on the marketing or manufacturing of the product, recall or market withdrawal, fines, warning letters, refusal to approve pending applications, suspension or revocation of approvals, product seizure or detention, injunctions and/or the imposition of civil or criminal penalties.

Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, a REMS program and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product.

In addition, quality control as well as drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMPs. The FDA and comparable state regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The distribution of prescription pharmaceutical products is also subject to the Prescription Drug Marketing Act, or PDMA, which governs the distribution of drugs and drug samples at the federal level, and sets minimum standards for the licensing and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

Risk Evaluation and Mitigation Strategies (REMS)

On Dec 29, 2011, the FDA approved a single shared REMS for TIRF products. TIRF products, which include the brand-name drugs Abstral, Actiq, Fentora, Lazanda, Onsolis and Subsys, are narcotic pain medicines called opioids used to manage pain in adults with cancer who routinely take other opioid pain medicines around-the-clock. The program officially began in March 2012.

The goals of the TIRF REMS Access Program are to ensure patient access to important medications and mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors by:

- prescribing and dispensing TIRF products only to appropriate patients, including use only in opioid-tolerant patients;
- preventing inappropriate conversion between fentanyl products;
- preventing accidental exposure to children and others for whom TIRF products were not prescribed; and
- educating prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose.

Health care professionals who prescribe TIRF products that will only be used in an inpatient setting (hospitals, hospices, or long-term care facilities) are not be required to enroll in the TIRF REMS

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Access Program. Similarly, patients who receive TIRF products in an inpatient setting are not required to enroll in the program. Long term care and hospice patients who obtain their medications from outpatient pharmacies must still be enrolled.

Controlled Substances; Drug Enforcement Administration

We sell products that are controlled substances as defined in the federal Controlled Substances Act of 1970, or CSA, which establishes registration, security, recordkeeping, reporting, storage and other requirements administered by the DEA. States impose similar requirements. The DEA regulates entities that handle controlled substances and the equipment and raw materials used in their manufacture and packaging, in order to prevent loss and diversion into illicit channels of commerce.

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, the active ingredient in one of our products, is listed by the DEA as a Schedule II substance under the CSA. Consequently, its manufacture, shipment, storage, sale and use are subject to a high degree of regulation. For example, manufacturing of fentanyl is subject to a DEA regulated quota system. In addition, generally all Schedule II drug prescriptions must be signed by a physician and physically presented to a pharmacist before filling and may not be refilled without a new prescription.

Dronabinol is listed by the DEA as a Schedule I substance, but when formulated in sesame oil, encapsulated in a soft gelatin capsule, and in a product approved by FDA, it is listed as a Schedule III substance. 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. Dronabinol SG Capsule is classified as a Schedule III substance. There is a concern 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 pending ANDAs under review by the FDA.

DEA registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized to be handled under that registration.

The DEA typically inspects certain facilities to review their security controls, recordkeeping and reporting prior to issuing a registration. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II substances. Security measures required by the DEA include background checks on employees and physical control of inventory through measures such as vaults, cages, surveillance cameras and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances, Schedule III substances that are narcotics, and other designated substances. Reports must also be made for thefts or losses of any controlled substance, suspicious orders, and to obtain authorization to destroy any controlled substance. In addition, special authorization and notification requirements apply to imports and exports.

A DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. This includes manufacturing of the API and production of dosage forms. Distributions of

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any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Absent the Marinol-like formulation and encapsulation exception, dronabinol is a Schedule I controlled substance and, therefore, subject to the DEA s production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much total dronabinol 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 manufacturing and procurement quotas. We or our partners, including our contract manufacturers, must obtain an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II substance, including dronabinol and fentanyl. The DEA may adjust aggregate production quotas and individual manufacturing quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments. Our, or our contract manufacturers , quota of the active ingredient may not be sufficient to meet commercial demand or complete clinical trials. Any delay or refusal by the DEA in establishing our, or our contract manufacturers , quota for controlled substances could delay or stop our clinical trials or product launches which could have a material adverse effect on our business, financial position and results of operations.

The DEA conducts periodic inspections of certain registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in enforcement action that could have a material adverse effect on our business, results of operations and financial condition. 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 result in criminal proceedings.

Individual states also regulate controlled substances, and we and our contract manufacturers will be subject to state regulation on distribution of these products, including licensing, recordkeeping and security.

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.

Anti-Kickback and False Claims Laws

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback and false claims statutes. The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. The term remuneration has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for

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statutory exemptions or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor. Several courts have interpreted the statute s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The reach of the Anti-Kickback Statute was also broadened by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the PPACA, which amends the intent requirement of the federal Anti-Kickback Statute such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below) or the civil monetary penalties statute, which imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal False Claims Act prohibits any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes any request or demand for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal healthcare programs for the product. In addition, certain marketing practices, including off-label promotion, may also lead to violates of the False Claims Act. Many states also have statutes or regulations similar to the federal Anti-Kickback Statute and False Claims Act, which state laws apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Also, the federal Health Insurance Portability and Accountability Act of 1996 created new federal criminal statutes that prohibit knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payers and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services.

To the extent that any of our product candidates are ultimately sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Coverage and Reimbursement

The commercial success of our products and our ability to commercialize any approved product candidates successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for our products, product candidates, and related treatments.

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Government health administration authorities, private health insurers and other organizations generally decide which drugs they will pay for and establish reimbursement levels for health care. In particular, in the U.S., private health insurers and other third-party payers often provide reimbursement for products and services based on the level at which the government (through the Medicare or Medicaid programs) provides reimbursement for such treatments. In the U.S., the European Union and other potentially significant markets for our product candidates, government authorities and third-party payers are increasingly attempting to limit or regulate the price of medical products and services, particularly for new and innovative products and therapies, which has resulted in lower average selling prices. Further, the increased emphasis on managed healthcare in the U.S. and on country and regional pricing and reimbursement controls in the European Union will put additional pressure on product pricing, reimbursement and usage, which may adversely affect our future product sales and results of operations. These pressures can arise from rules and practices of managed care groups, judicial decisions and governmental laws and regulations related to Medicare, Medicaid and healthcare reform, pharmaceutical reimbursement policies and pricing in general. The cost containment measures that healthcare payors and providers are instituting and the effect of any healthcare reform could significantly reduce our revenues from the sale of any products or approved product candidates. We cannot provide any assurances that we will be able to obtain and maintain third-party coverage or adequate reimbursement for our product candidates in whole or in part.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, imposed new requirements for the distribution and pricing of prescription drugs for Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities which provide coverage of outpatient prescription drugs. Part D plans include both stand-alone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for our products for which we receive marketing approval. However, any negotiated prices for our future products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from Medicare Part D may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. A plan for the research will be developed by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of any product, if any such product or the condition that it is intended to treat is the subject of a study. It is also possible that comparative effectiveness research demonstrating benefits in a competitor s product could adversely affect the sales of our products or product candidates. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our products on a profitable basis.

The U.S. and some foreign jurisdictions are considering enacting or have enacted a number of additional legislative and regulatory proposals to change the healthcare system in ways that could affect

our ability to sell our products profitably. Among policy makers and payers in the U.S. and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the U.S., the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives, including, most recently, PPACA, which became law in the U.S. in March 2010 and substantially changes the way healthcare is financed by both governmental and private insurers.

Healthcare Privacy and Security Laws

We may be subject to various privacy and security regulations, including but not limited to the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013. HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions, as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. Among other things, HITECH makes HIPAA s privacy and security standards directly applicable to business associates independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent then HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Approval Outside the United States

In order to market any product outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales and distribution of our products. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, and may be otherwise complicated by our product candidates being controlled substances such as synthetic cannabinoids and fentanyl. The time required to obtain approval in other countries might differ from and be longer than that required to obtain FDA approval and DEA classification. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others.

To date, we have not initiated any discussions with the European Medicines Agency or any other foreign regulatory authorities with respect to seeking regulatory approval for any indication in Europe or in any other country outside the United States. As in the United States, the regulatory approval process in Europe and in other countries is a lengthy, challenging and inherently uncertain process.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

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Employees

As of March 31, 2013, we employed 119 full-time employees, including ten manufacturing employees, 82 sales and marketing employees (including approximately 67 sales professionals), 17 employees in research and development, and ten employees in administration. As of the same date, eight of our employees had a Ph.D. or M.D. degree. None of our employees is subject to a collective bargaining agreement and we consider our relationship with our employees to be good.

Scientific Advisory Board

We have established a scientific advisory board consisting of industry experts with knowledge of our target markets. Our scientific advisors generally meet twice a year as a group to assist us in formulating our research, development, clinical and sales and marketing strategies. Some individual scientific advisors consult with and meet informally with us on a more frequent basis. Our scientific 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 scientific advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

Properties

We lease a total of approximately 22,600 square feet of office and lab space in Chandler, Arizona under a lease agreement that expires in December 2017. We have an option to extend this lease for an additional five years. In addition, we are responsible for expenses associated with the use and maintenance of our Arizona facility, such as utility and common area maintenance expenses. We believe that the Chandler, Arizona facility is adequate to meet our current needs, and that suitable additional or alternative space will be available in the future on commercially reasonable terms. Additionally, we lease our U.S.-based, state-of-the-art dronabinol manufacturing facility, which is located in Texas and housed ten employees as of March 31, 2013.

Legal Proceedings

In September 2009, Insys Pharma, Inc. 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 brought 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 we own 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. We do not expect a trial

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of this action to take place before the second half of 2013, if not later, although an earlier date is possible. Although there has been some discovery into the range of potential loss or any potential recovery from the counter-claims, that range is very broad and we are not able to provide a reasonable estimate of these figures at this time, nor are we able to predict the outcome of this litigation. If the patent assignments are successfully rescinded, we may not have exclusive patent rights covering our fentanyl and dronabinol product candidates, and such patent rights may not be available to us on acceptable terms, if at all, which would have a material adverse effect on our business. We intend to vigorously defend against the plaintiffs claims and pursue our counter-claims.

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MANAGEMENT

Executive Officers and Directors

The following table sets forth certain information regarding our executive officers and directors as of April 4, 2013:

Name	Age	Position(s)
Michael Babich	36	President, Chief Executive Officer and Director
Darryl S. Baker	44	Chief Financial Officer
Larry Dillaha, M.D.	49	Chief Medical Officer
John N. Kapoor, Ph.D.	69	Director and Executive Chairman of the Board
Patrick P. Fourteau[1][2]	65	Director
Pierre Lapalme[2][3]	72	Director
Steven Meyer[1]	56	Director
Theodore H. Stanley, M.D.[2][3]	73	Director
Brian Tambi[1]	67	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Michael Babich has served as our President since November 2010 and was appointed as our Chief Executive Officer in March 2011. From March 2007 until November 2010, Mr. Babich served as the Chief Operating Officer and a director of Insys Pharma, our wholly-owned subsidiary, which was responsible for the initial development of Dronabinol SG Capsule and many of our product candidates, including Subsys and our other dronabinol product candidates. Prior to that, from 2001 to 2007, Mr. Babich worked at EJ Financial Enterprises, a venture capital firm specializing in early stage and startup investments primarily in the healthcare sector. During his time at EJ Financial Enterprises, Mr. Babich held various roles and worked on various projects, including private equity transactions, asset management and strategic consulting for both public and private companies. Prior to his work at EJ Financial Enterprises, Mr. Babich worked at the Northern Trust Corporation managing mid- to large-cap portfolios for high net worth individuals. Mr. Babich also has served as a director and in management roles at Alliant Pharmaceuticals, Mr. Babich received an MBA from the Kellogg School of Management at Northwestern University and a B.A. from the University of Illinois at Urbana-Champaign. The board of directors believes that Mr. Babich s business expertise, including his experience working with the investment community, provides him the operational expertise, breadth of knowledge and valuable understanding of our industry to qualify him to serve on our board of directors and as our President and Chief Executive Officer.

Darryl S. Baker has served as our Chief Financial Officer since October 2012. From 2001 to 2012, Mr. Baker served as Chief Financial Officer and Corporate Controller for iGo, a developer of power management solutions and accessories for mobile electronic devices. From 2000 to 2001, Mr. Baker served as the Corporate Controller for Integrated Information Systems, Inc., a provider of secure integrated information technology solutions. From 1997 to 1999, Mr. Baker served as the Corporate Controller for SkyMall, Inc., an integrated specialty retailer. Prior to 1997, Mr. Baker was an audit manager for Ernst & Young. Mr. Baker has extensive experience in accounting, SEC compliance for smaller public companies, merger and acquisition transactions, and small business financing and frequently serves as a panelist and lecturer for the Center for Professional Education on various topics including SEC compliance, share-based compensation, revenue recognition, fair value and lease accounting. Mr. Baker earned his B.S. in Accountancy from the Marriott School of Management at Brigham Young University and is a Certified Public Accountant in the states of California and Arizona and is also a Chartered Global Management Accountant.

Larry Dillaha, M.D. has served as our Chief Medical Officer since March 2011. Prior to joining our company, he served as Executive Vice-President and Chief Medical Officer for Shionogi (formerly

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Sciele Pharma, Inc. and First Horizon Pharmaceutical Corp.) from 2006 to 2010. While at Shionogi/Sciele, Dr. Dillaha oversaw the development and successful FDA filings of numerous compounds integral to the success of the company. He has extensive experience interacting with the FDA and designing successful drug development plans. Prior to serving as an officer of Shionogi/Sciele, Dr. Dillaha served as Medical Director for Sanofi, a multinational pharmaceutical company, where he was involved in several major clinical studies for the company s lead compounds. Dr. Dillaha also serves as a member of the board of directors of New Haven Pharma, Inc, a pharmaceutical company. Dr. Dillaha earned his M.D. degree as well as a B.A. in Biology from the University of Tennessee.

John N. Kapoor, Ph.D. has served on our board of directors since our formation in 1990 and has served as Executive Chairman since June 2006 and was Chairman from 1990 to 2004. Dr. Kapoor also served as a director of Insys Pharma from its inception in 2002. Dr. Kapoor has served as the President and chairman of the board of directors of EJ Financial Enterprises since forming the company in 1990. Dr. Kapoor is also the Managing Partner of Kapoor-Pharma Investments, an investment company that he founded in 2000. Dr. Kapoor serves as the chairman of the board of directors of Akorn, Inc., a publicly traded specialty pharmaceutical company, where he previously served as the Chief Executive Officer from March 2001 to December 2002 and from May 1996 to November 1998. Dr. Kapoor also served as the chairman of the board of directors of Sciele Pharma and OptionCare, a specialty pharmaceutical services company, where he served as Chief Executive Officer from August 1993 to April 1996. Dr. Kapoor received his Ph.D. in Medicinal Chemistry from the State University of New York at Buffalo and a B.S. in Pharmacy from Bombay University in India. We believe that Dr. Kapoor s leadership experience in the biopharmaceutical industry and his success as a venture capitalist add valuable expertise and insight to our board of directors and uniquely qualify him to serve as our Executive Chairman.

Patrick P. Fourteau has served on our board of directors since March 2011. Mr. Fourteau served as President and Chief Executive Officer of Shionogi from 2008 until 2010. Prior to the acquisition of Sciele Pharma by Shionogi, Mr. Fourteau served as President and CEO of Sciele Pharma from 2003 until 2008 and served on the board of directors of Sciele from 2004 until 2008. Mr. Fourteau served as President of Worldwide Sales of inVentiv Health, Inc. from 2000 to 2002. Mr. Fourteau served as President of various divisions of St. Jude Medical, Inc. from 1995 to 2000 and as an Executive of Eli Lilly and Company prior to 1995. Mr. Fourteau earned his MBA from Harvard University and a B.A. and M.A. in Mathematics from the University of California, Berkeley. We believe that Mr. Fourteau s leadership experience in the pharmaceutical industry adds valuable expertise and insight to our board of directors.

Steven Meyer has served on our board of directors since November 2010. From August 2007 until November 2010, Mr. Meyer served as a director of Insys Pharma. Since November 2005, Mr. Meyer has served as the Chief Financial Officer of JVM Realty Corporation, a private investment firm specializing in the acquisition, re-positioning and management of real estate for investors. Prior to that, Mr. Meyer was employed by Baxter International Incorporated, a global healthcare company, where he served as Corporate Treasurer from January 1997 to July 2004. Mr. Meyer earned his MBA in finance and accounting from the Kellogg Graduate School of Management at Northwestern University and his B.A. in Economics from the University of Illinois in Champaign-Urbana. He is an Illinois Certified Public Accountant. We believe that Mr. Meyer s management experience and his knowledge of the finance and healthcare industries give him a valuable understanding of our industry which qualifies him to serve as a member of our board of directors.

Theodore H. Stanley, M.D., has served on our board of directors since March 2013. Since July 2009, Dr. Stanley has served as a managing director of UpStart Ventures, a venture capital fund focusing on investments in life sciences companies, and since 1978, Dr. Stanley has been a full time professor in the Department of Anesthesiology at the University of Utah, School of Medicine. In 1985, Dr. Stanley co-founded Anesta Corp., a publicly held pharmaceutical company focusing on the development of transmucosal drug products, including its lead product, Actiq, which was co-invented by Dr. Stanley in 1983. From 1985 to December 1997, Dr. Stanley served as chairman of the board of Anesta and served

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as Anesta s Medical Director until April 1994, following which he served as founding chairman from January 1998 until the sale of Anesta to Cephalon in October 2000. In 1996, Dr Stanley co-founded ZARS Pharma, Inc., a privately held specialty pharmaceutical company that focused on the development and commercialization of topically administered drugs primarily in the area of pain management. Dr. Stanley served as chairman of the board of directors of ZARS Pharma until its acquisition in May 2011 by Nuvo Research Inc., a publicly held Canadian pharmaceutical company, of which Dr. Stanley currently serves as a director. Dr. Stanley also serves on the board of directors of seven privately held life sciences companies, four of which he serves as chairman of the board. Dr. Stanley earned his M.D. degree from Columbia University, College of Physicians and Surgeons (Medical Science), as well as an A.B. from Columbia College. The board of directors believes that Dr. Stanley s extensive operational and leadership experience in the pharmaceutical industry, including his experience in the development and commercialization of transmucosal drug products, brings valuable expertise and insight to our board of directors.

Brian Tambi has served on our board of directors since November 2010. Mr. Tambi currently serves as a member of the board of directors of Akorn. From August 2007 until the November 2010, Mr. Tambi served as a director of Insys Pharma. Since forming the company in January 2006, Mr. Tambi has served as the Chairman of the Board, President and Chief Executive Officer of BrianT Laboratories LLC, a pharmaceutical company currently focused on developing, manufacturing and marketing combinations of leading single agent drugs and delivery systems. From 1995 to January 2007, Mr. Tambi served as the Chairman, President and Chief Executive Officer of Morton Grove Pharmaceuticals, Inc. Prior to Morton Grove, Mr. Tambi served as President of Ivax North American Pharmaceuticals and as a member of the board of directors of Ivax Corporation (acquired by Teva), a publicly traded pharmaceutical company. Mr. Tambi also served as Chief Operating Officer of Fujisawa USA, Inc., a subsidiary of Fujisawa Pharmaceutical Company, Ltd. Mr. Tambi also held executive positions at Lyphomed, Inc. and Bristol-Myers Squibb. Mr. Tambi earned his MBA in International Finance & Economics and his B.S. in Corporate Finance from Syracuse University. We believe that Mr. Tambi s drug development and commercialization expertise as well as his experience in the finance sector brings important strategic insight to our board of directors.

Pierre Lapalme has served on our board of directors since March 2011. Mr. Lapalme joined BioMarin Pharmaceutical Inc. s Board in January 2004. From 1995 until his retirement in 2003, he served as the President and Chief Executive Officer of North America Ethypharm, Inc., a drug delivery company. Throughout his career, Mr. Lapalme held numerous senior management positions in the pharmaceutical industry, including Chief Executive Officer and Chairman of the Board of Rhône-Poulenc Pharmaceuticals, Inc., in Canada, from 1979 to 1994, and Senior Vice President and General Manager of North America Ethicals, a division of Rhône-Poulenc Rorer, Inc. (now known as Sanofi) where he oversaw the development of the ethical pharmaceutical business in the United Sates, Canada, Mexico, and Central America. Mr. Lapalme served on the board of the National Pharmaceutical Council and was a board member of the Pharmaceutical Manufacturers Association of Canada, where he played a leading role in reinstituting certain patent protection for pharmaceuticals. Mr. Lapalme previously served on the board of directors of two public companies during the past five years: Sciele Pharmaceuticals Inc. from 2000 to 2008 and Bioxel Pharma from 2004 to 2009. He also serves on the board of three private biotech companies and was appointed to the board Aeterna Zentaris, a biopharmaceutical company, in December 2009. Mr. Lapalme studied at the University of Western Ontario and INSEAD France. We believe that Mr. Lapalme s experience in the pharmaceutical industry gives him a valuable understanding of our industry which qualifies him to serve as a member of our board of directors.

BOARD COMPOSITION

Our business and affairs are organized under the direction of our board of directors, which currently consists of seven members. The primary responsibilities of our board of directors are to

provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that five of our seven directors, Patrick P. Fourteau, Pierre Lapalme, Steven Meyer, Theodore H. Stanley and Brian Tambi, are independent directors, as defined by Rule 5605(a)(2) of the NASDAQ Listing Rules.

Effective upon the closing of this offering, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of Steven Meyer and Brian Tambi, whose terms will expire at our annual meeting of stockholders to be held in 2014;
- Class II, which will consist of Pierre Lapalme and Michael Babich, whose terms will expire at our annual meeting of stockholders to be held in 2015; and
- Class III, which will consist of Patrick P. Fourteau, John N. Kapoor and Theodore H. Stanley, whose terms will expire at our annual meeting of stockholders to be held in 2016.

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently seven members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management. Our directors may be removed for cause by the affirmative vote of the holders of at least 66-2/3% of our voting stock.

Board Leadership Structure

Our board of directors is currently chaired by our Executive Chairman, Dr. Kapoor. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages objective oversight of management s performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Babich serves as our President and Chief Executive Officer while Dr. Kapoor serves as our Executive Chairman of the board of directors but is not an officer. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to be held by two individuals in the future as well.

Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

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Board Committees

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee.

Audit Committee

Our audit committee consists of Patrick P. Fourteau, Steven Meyer and Brian Tambi. Our board of directors has determined that each of the members of our audit committee satisfies the NASDAQ Stock Market and SEC independence requirements. Mr. Meyer serves as the chair of our audit committee. The functions of this committee include, among other things:

evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;

reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;

monitoring the rotation of partners of our independent auditors on our engagement team as required by law;

prior to engagement of any independent auditors, and at least annually thereafter, reviewing relationships that may reasonably be thought to bear on their independence, and assessing and otherwise taking the appropriate action to oversee the independence of our independent auditors;

reviewing our annual and quarterly consolidated financial statements and reports, including the disclosures contained in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations, and discussing the statements and reports with our independent auditors and management;

reviewing with our independent auditors and management significant issues that arise regarding accounting principles and financial statement presentation, and matters concerning the scope, adequacy and effectiveness of our financial controls;

reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;

establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;

preparing the audit committee report that the SEC requires in our annual proxy statement;

reviewing and providing oversight of any related-person transactions in accordance with our related-person transaction policy and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;

reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented;

reviewing on a periodic basis our investment policy; and

evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter. Our board of directors has determined that Mr. Meyer qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the NASDAQ Listing Rules. In making this determination, our board has considered Mr. Meyer s formal education and the nature and scope of experience that he has previously had with public companies. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

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Compensation Committee

Our compensation committee consists of Patrick P. Fourteau, Pierre Lapalme and Theodore H. Stanley, M.D. Mr. Fourteau serves as the chair of our compensation committee. Each member of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Code and satisfies the NASDAQ Stock Market independence requirements. The functions of this committee include, among other things:

reviewing, modifying and approving (or if it deems appropriate, making recommendations to the full board of directors regarding) our overall compensation strategy and policies;

reviewing and approving the compensation and other terms of employment of our executive officers;

reviewing and approving performance goals and objectives relevant to the compensation of our executive officers and assessing their performance against these goals and objectives;

reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;

evaluating risks associated with our compensation policies and practices and assessing whether risks arising from our compensation policies and practices for our employees are reasonably likely to have a material adverse effect on us;

reviewing and approving (or if it deems it appropriate, making recommendations to the full board of directors regarding) the type and amount of compensation to be paid or awarded to our non-employee board members;

establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;

selecting and receiving advice from compensation consultants, legal counsel and other advisors, only after considering the factors set forth in Section 10C of the Exchange Act, with respect to markets within the compensation committee s purview;

administering our equity incentive plans;

establishing policies with respect to equity compensation arrangements;

reviewing the competitiveness of our executive compensation programs and evaluating the effectiveness of our compensation policy and strategy in achieving expected benefits to us;

reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

reviewing the adequacy of its charter on a periodic basis;

reviewing with management and approving our disclosures in the section entitled Compensation Discussion and Analysis in our periodic reports or proxy statements to be filed with the SEC, to the extent such section is included in any such report or proxy statement;

preparing the compensation committee report that the SEC requires in our annual proxy statement; and

reviewing, discussing, and assessing on an annual basis the performance of the compensation committee.

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Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Pierre Lapalme and Theodore H. Stanley, M.D. Our board of directors has determined that each of the members of this committee satisfies the NASDAQ Stock Market independence requirements. Mr. Lapalme serves as the chair of our nominating and corporate governance committee. The functions of this committee include, among other things:

identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;

identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;

determining the minimum qualifications for service on our board of directors;

evaluating director performance on the board and applicable committees of the board and determining whether continued service on our board is appropriate;

evaluating, nominating and recommending individuals for membership on our board of directors;

evaluating nominations by stockholders of candidates for election to our board of directors;

considering and assessing the independence of members of our board of directors;

developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application, and recommending to our board of directors any changes to such policies and principles;

considering questions of possible conflicts of interest of directors as such questions arise;

reviewing the adequacy of its charter on an annual basis; and

reviewing, discussing and assessing on an annual basis the performance of the nominating and corporate governance committee.

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EXECUTIVE COMPENSATION

Summary Compensation Table for the Years ended December 31, 2012 and 2010

The following table provides information regarding the compensation earned during the years ended December 31, 2012 and 2010 by our (1) principal executive officer and (2) our next two highest compensated executive officers other than the principal executive officer, who we collectively refer to as our named executive officers.

Name and Principal Position	Year	Salary ($)[1]	Bonus ($)[2]	Option Awards ($)[3]	All Other Compensation ($)[4]	Total ($)
Michael L. Babich	2012	365,168	365,000	2,236,356	956	2,967,480
President and Chief Executive Officer	2010	181,773[6]		446,109[7]		627,880
Darryl S. Baker[5][8]	2012	36,070	21,000	884,435	159	941,664
Chief Financial Officer	2010					
Larry Dillaha, M.D.[8]	2012	225,168	135,000	619,104	956	980,228
Chief Medical Officer	2010					

(1) For Mr. Babich and Dr. Dillaha, 2012 salary amounts shown above include $175,000 and $50,000, respectively that we expect to pay upon the earlier of (i) the completion of this offering or (ii) the date we achieve profitability as determined by our board of directors.

(2) Amounts shown represent discretionary cash bonuses that were approved by our board of directors for 2012 as described below in the section entitled Annual Bonus Opportunity. The awards will be paid upon the earlier to occur of (i) the completion of this offering or (ii) the date we achieve profitability as determined by our board of directors.

(3) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2012 computed in accordance with FASB ASC Topic 718, or ASC 718. Assumptions used in the calculation of these amounts are included in Note 11 to our audited consolidated financial statements appearing elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying the stock options.

(4) Represents amounts paid for life insurance and long-term disability insurance premiums.

(5) Mr. Baker became our Chief Financial Officer on October 15, 2012.

(6) Represents salary paid to Mr. Babich by both Insys Pharma and us. Of this amount, $154,407 was paid by Insys Pharma prior to the NeoPharm merger.

(7) Upon closing of the NeoPharm merger in November 2010, we assumed outstanding options to purchase shares of common stock of Insys Pharma and converted these options into options to purchase shares of our common stock. The value of Mr. Babich s stock options shown represent the conversion of an option to purchase up to an aggregate of 32,786 shares of common stock of Insys Pharma into an option to purchase up to an aggregate of 121,876 shares of our common stock and the conversion of an option to purchase up to an aggregate of 59,803 shares of common stock of Insys Pharma into an option to purchase up to an aggregate of 222,303 shares of our common stock.

(8) Neither Mr. Baker nor Dr. Dillaha was a named executive officer in 2010.

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Base Salary

Base salaries for our executive officers are established based on seniority, position and functional role and level of responsibility. The base salary of each executive officer is initially established in the executive officer s employment agreement or offer letter with us, and may be increased from time to time in the sole discretion of the board of directors. We do not apply specific formulas to determine any increases. The following represents the base salaries in effect in 2012 for our named executive officers during 2012. Mr. Baker s salary became effective in connection with his commencement of employment in October 2012.

Name	2012 Base Salary ($)
Michael Babich	365,000(1)
Darryl S. Baker	170,000(2)
Larry Dillaha, M.D.	225,000(1)

(1) $175,000 and $50,000 of the annual salary payable to Mr. Babich and Dr. Dillaha, respectively, are expected to be paid upon the earlier of (i) the completion of this offering or (ii) the date we achieve profitability, as determined by our board of directors.

(2) In accordance with his offer letter agreement, Mr. Baker s base salary will be increased to $210,000 per year upon the closing of this offering or upon the date we achieve profitability, subject in each case to his satisfactory performance, as determined by our board of directors.

Annual Bonus Opportunity

Our executive officers annual bonuses are discretionary and may from time to time be tied to the achievement of corporate objectives, functional area objectives and/or individual performance objectives and a thorough review of the applicable performance results of the company, business, function and/or individual during the applicable period. Our named executive officers were not entitled to any minimum or target bonuses for 2012. Our board of directors did not establish specific performance goals for 2012 bonuses, but instead determined the following amounts of 2012 bonuses in its sole discretion, based on the amounts our board of directors considered appropriate for each executive officer s level of responsibility, base salary, period of employment during 2012 (with respect to Mr. Baker) In addition, the board of directors considered the following factors in approving the specific bonus amounts: for Mr. Babich, market penetration of Subsys, revenue growth and the overall performance of our management team; for Mr. Baker, his prompt management of financial matters and establishment of a finance team; and for Dr. Dillaha, our clinical performance, including FDA approval for Subsys.

Name	2012 Bonus ($)
Michael L. Babich	365,000
Darryl S. Baker	21,000
Larry Dillaha, M.D.	135,000

In approving the bonus amounts, our board of directors considered Mr. Babich s recommendations other than for his own bonus award. Our board of directors determined that no bonuses would be paid to our named executive officers unless and until the earlier of the completion of (i) this offering or (ii) the date we achieve profitability, as determined by our board of directors. At such time, each named executive officer will receive their 2012 bonus payments.

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Long-Term Equity-Based Compensation

Our long-term compensation program consists solely of stock option grants. Stock option grants made to executive officers are designed to provide them with incentives to execute their responsibilities in such a way as to generate long-term benefit to us and our stockholders. Through possession of stock options, our executive officers participate in the long-term results of their efforts, whether by appreciation of our company s value or the impact of business setbacks, either company-specific or industry-based. Additionally, stock options provide a means of retaining our executive officers, in that they are in almost all cases subject to vesting over an extended period of time.

Upon joining us, an executive officer may be granted an initial option award that is primarily based on competitive conditions applicable to such officer s specific position. Periodic awards to executive officers are made based on an assessment of their sustained performance over time, their ability to impact results that drive value to our stockholders and their organization level. Option awards are not granted at regular intervals or automatically to our executive officers. Our Chief Executive Officer periodically reviews the performance of our executive officers on the bases noted above and recommends to our board of directors and compensation committee any option awards deemed appropriate.

In December 2012, our board of directors granted stock options covering 177,000, 70,000 and 49,000 shares of our common stock to Mr. Babich, Mr. Baker and Dr. Dillaha, respectively, which our board of directors, based upon input from our Chief Executive Officer, believed provided the named executive officers with sufficient incentive to execute their responsibilities in such a way as to generate long-term benefit to us and our stockholders. The 2012 stock options were granted under our 2006 equity incentive plan, or the 2006 plan, and vest as further described in the table below entitled Outstanding Equity Awards as of December 31, 2012.

Benefits

We provide the following benefits to our executive officers on the same basis as the benefits provided to all employees:

- health, dental and vision insurance;
- life insurance;
- long-term disability; and
- defined contribution employee retirement plan, or 401(k) plan.

Employment Agreements

Employment agreements or written offer letters are used from time to time on a case by case basis, to attract and/or to retain executives. We currently maintain written employment agreements with Mr. Babich and Dr. Dillaha.

Employment Agreement with Mr. Babich. We entered into an employment agreement with Mr. Babich in April 2011 setting forth the terms of Mr. Babich s employment as our President and Chief Executive Officer, which was amended in April 2013. Pursuant to the agreement, Mr. Babich is paid an annual salary of $365,000 and is eligible to receive a performance bonus of up to 80% of his base salary for 2011. Beginning in 2011, Mr. Babich agreed to defer $175,000 of his annual $365,000 base salary to be paid upon the earlier of (i) the completion of this offering or (ii) the date we achieve profitability or otherwise, as determined by our board of directors. Mr. Babich s employment is at-will, and either we or Mr. Babich may terminate the agreement at any time without cause and without notice. However, if we terminate Mr. Babich without cause, or if Mr. Babich resigns for good reason, and Mr. Babich signs a release in our favor, Mr. Babich will be entitled to receive salary continuation for a period of 12 months following his termination date, as well as an additional severance payment equal to his prorated target bonus for the year in which he is terminated, and all of Mr. Babich s unvested stock options and equity awards will immediately vest in full.

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Employment Agreement with Dr. Dillaha. We entered into an employment agreement with Dr. Dillaha in April 2011 setting forth the terms of Dr. Dillaha s employment as our Chief Medical Officer, which was amended in April 2013. Pursuant to the agreement, Dr. Dillaha is paid an annual salary of $225,000 and is eligible to receive a performance bonus of up to 60% of his base salary for 2011. Beginning in 2011, Dr. Dillaha agreed to defer $50,000 of his annual $225,000 base salary to be paid upon the earlier of (i) the completion of this offering or (ii) the date we achieve profitability or otherwise, as determined by our board of directors. Dr. Dillaha s employment is at-will, and either we or Dr. Dillaha may terminate the agreement at any time without cause and without notice. However, if we terminate Dr. Dillaha without cause, or if Dr. Dillaha resigns for good reason, and Dr. Dillaha signs a release in our favor, Dr. Dillaha will be entitled to receive salary continuation for a period of 12 months following his termination date, as well as an additional severance payment equal to his prorated target bonus for the year in which he is terminated, and all of Dr. Dillaha s unvested stock options and equity awards will immediately vest in full.

Offer Letter Agreement with Mr. Baker. We entered into an offer letter agreement with Mr. Baker in October 2012 setting forth the terms of Mr. Baker s employment as our Chief Financial Officer. Pursuant to the agreement, Mr. Baker is paid an annual salary of $170,000, which will be increased to $210,000 upon the closing of this offering or upon the date we achieve profitability, subject in each case to his satisfactory performance, as determined by our board of directors. Mr. Baker was also entitled to a stock option grant covering at least 50,000 shares. Mr. Baker s employment is at-will, and either we or Mr. Baker may terminate employment at any time without cause and without notice. In April 2013, we entered into an employment agreement with Mr. Baker pursuant to which he is entitled to the same benefits upon a termination without cause or resignation for good reason as Mr. Babich and Dr. Dillaha.

For purposes of each of the named executive officer s employment agreements, cause generally means the executive s (i) conviction of a felony of crime involving fraud or dishonesty; (ii) participation in a fraud, act of dishonesty or misconduct; (ii) conduct constituting gross unfitness to serve as determined by our board of directors; (iii) violation of a statutory duty, fiduciary duty or duty of loyalty to us; (iv) breach of a material term of any material contract with the us; (v) repeated violation of any material company policy; or (v) repeated failure to adequately perform job duties. For purposes of each of the named executive officer s employment agreements, good reason generally means, with respect to the executive, (A) a material reduction of base salary (unless in connection with a company-wide decrease); (B) our material breach of the employment agreement; (C) a material adverse change in the executive s duties, authority or responsibilities or (D) a relocation of executive s principal place of employment to a location outside the greater Phoenix metropolitan area.

Termination-Based Compensation

Payments Made Upon Termination. Regardless of the manner in which a named executive officer s employment terminates, the named executive officer is entitled to receive amounts earned during his term of employment, including salary and, to the extent required by state law, unused vacation pay.

Potential Termination-Based Payments. In April 2011, we entered into employment agreements with Mr. Babich and Dr. Dillaha and in April 2013, we entered into an employment agreement with Mr. Baker providing for certain termination-based payments described in the section entitled Employment Agreements. For more information regarding accelerated vesting of stock options under our equity incentive plans in the event of certain corporate transactions, please see the section entitled Employee Benefit Plans below.

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Outstanding Equity Awards as of December 31, 2012

The following table sets forth certain information regarding equity awards granted to our named executive officers that were outstanding as of December 31, 2012.

	Option Awards			
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Option Exercise Price ($)[1]	Option Expiration Date ($)
Michael L. Babich	56,876		1.83	2/22/2020
	210,958		1.83	2/22/2020
	43,085	55,395[2]	4.88	3/28/2021
		177,000[3]	3.54	12/27/2022
Darryl S. Baker	3,889	66,111[4]	3.54	12/27/2022
Larry Dillaha, M.D.	112,126		1.83	2/22/2020
	22,665	29,142[5]	4.88	3/28/2021
		49,000[6]	3.54	12/27/2022

(1) At the time of grant, all of the stock options had a per share exercise price equal to the fair market value of one share of our common stock on the date of grant, except for the stock options with an expiration date of 2/22/2020, as determined in good faith by our board of directors with the assistance of a third-party valuation expert. The stock options with an expiration date of 2/22/2020 were assumed in connection with the NeoPharm merger and have a per share exercise price that was determined based on the mean between the lowest and highest reported sales prices of our common stock on the OTC market as of the grant date. Vesting for all stock options is subject to the applicable named executive officer s continued service with us through each of the vesting dates and with respect to Mr. Babich and Dr. Dillaha, subject to acceleration in connection with certain types of terminations as further described above in the section entitled Employment Agreements.

(2) The option vests at the rate of 2,052 shares on the 28th day of the month over a remaining period of 27 months.

(3) The option vests at the rate of 4,917 shares on the 27th day of the month over a remaining period of 36 months.

(4) The option vests at the rate of 1,836 shares on the 27th day of the month over a remaining period of 36 months.

(5) The option vests at the rate of 1,079 shares on the 28th day of the month over a remaining period of 27 months.

(6) The option vests at the rate of 1,361 shares on the 27th day of the month over a remaining period of 36 months.

Pension Benefits

Our named executive officers did not participate in or have account balances in qualified or nonqualified defined benefit plans sponsored by us. Our board of directors or compensation committee may elect to adopt qualified or nonqualified benefit plans in the future if it determines that doing so is in our best interests.

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Nonqualified Deferred Compensation

Our named executive officers did not participate in or have account balances in nonqualified defined contribution plans or other nonqualified deferred compensation plans maintained by us. Our board of directors or compensation committee may elect to provide our executive officers and other employees with nonqualified defined contribution or other nonqualified deferred compensation benefits in the future if it determines that doing so is in our best interests.

Director Compensation

From time to time we may in our discretion choose to provide cash or equity compensation to our non-employee directors. We do not have any compensation arrangements in place for and did not provide any compensation to our non-employee directors in 2012. The aggregate number of shares subject to each director s outstanding option awards as of December 31, 2012 was as follows: Mr. Fourteau: 24,590 shares; Dr. Kapoor: 3,994 shares; Mr. Meyer: 40,835 shares; Mr. Lapalme: 24,590 shares; and Mr. Tambi: 40,835 shares. Mr. Babich was an employee director during 2012 and his compensation is fully reflected in the Summary Compensation Table above.

In April 2013, our board of directors adopted a compensation program for our non-employee directors, or the Non-Employee Director Compensation Policy. The Non-Employee Director Compensation Policy will be effective on the effective date of the underwriting agreement for this offering. The Non-Employee Director Compensation Policy will apply to each of our non-employee directors who is eligible to receive compensation under the policy and may be amended by our board of directors or the compensation committee at any time. Pursuant to the Non-Employee Director Compensation Policy, each eligible non-employee member of our board of directors will receive the following cash compensation for board services, as applicable:

- $35,000 per year for service as the chairman of our board;
- $25,000 per year for service as a board member;
- $3,000 per year for service as the chairman of each of the audit committee, compensation committee and nominating and corporate governance committee; and
- $2,500 per year for service as a member of each of the audit committee and compensation committee and $1,500 per year for service as a member of the nominating and corporate governance committee.

In addition, our eligible non-employee directors will receive initial and annual, automatic, non-discretionary grants of nonqualified stock options under the terms and provisions of the 2013 plan. Each eligible non-employee director joining our board after the closing of this offering will automatically be granted a non-statutory stock option to purchase 20,000 shares of common stock with an exercise price equal to the then fair market value of our common stock. Each of these initial grants will vest over a three year period; one-third of the stock will vest upon the first anniversary of the date of grant and the remainder will vest in a series of 24 successive equal monthly installments thereafter. On the date of each annual meeting of our stockholders beginning in 2014, each continuing non-employee director will automatically be granted a non-statutory stock option to purchase 10,000 shares of common stock with an exercise price equal to the then fair market value of our common stock. The annual grants will vest in equal monthly installments over 12 months following the date of grant. All stock options granted will have a maximum term of ten years and will vest in full upon the closing of a change of control transaction.

For a more detailed description of the 2013 plan, see the section entitled Equity Benefit Plans below.

Equity Benefits Plans

2006 Equity Incentive Plan

The 2006 plan was adopted by our board of directors and stockholders in April 2006 and June 2006, respectively, and has been subsequently amended, most recently in December 2012. As of March 31,

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2013, 7,006 shares of common stock have been issued upon the exercise of options granted under the 2006 plan, options to purchase 1,139,158 shares of common stock were outstanding and 40,147 shares remained available for future grant. Upon the effective date of this offering, no further option grants will be made under the 2006 plan. We intend to grant all future equity awards under the 2013 plan. However, all stock options granted under our 2006 plan will continue to be governed by the terms of the 2006 plan.

Eligibility. The 2006 plan permits us to grant stock awards, including stock options, restricted stock, stock appreciation rights, performance units, performance shares and other stock awards to our employees, directors and consultants. Our board of directors has granted only stock options under the 2006 plan. A stock option may be an incentive stock option within the meaning of Section 422 of the Code, or an ISO, or a nonstatutory stock option, or an NSO.

Administration. A duly authorized committee of our board of directors administers the 2006 plan and the stock options granted under it. The committee has the authority to amend stock option agreements, prevent a stock option from being treated as an ISO and cancel any outstanding stock options in exchange for new stock awards. The committee, however, may not reprice options without stockholder approval.

Stock option provisions generally. In general, the duration of a stock option granted under the 2006 plan cannot exceed ten years. No later than the grant date of any option, the exercise price of such stock option is required to be determined; provided, however, that our board of directors may elect to determine the exercise price as of the date the grantee is hired or promoted (or similar event), if the grant date occurs not more than 90 days after the date of hiring, promotion or other event. The exercise price of a stock option (other than an ISO) shall not be less than 85% of the fair market value of our common stock on the grant date. If, and to the extent deemed necessary by our board of directors with respect to a NSO granted to a named executive officer, the price to be paid for each share of our common stock upon exercise of such stock option shall in no event be less than 100% of the fair market value of a share of our common stock on the date such stock option is granted, unless the exercisability of such stock option is subject to one or more of the performance goals set forth in the 2006 plan that will enable such stock option to qualify as performance-based compensation under regulations promulgated under Section 162(m) of the Code.

ISOs may be granted only to our employees or employees of any designated subsidiary of ours as permitted under the applicable provisions of the Code. The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to which ISOs are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power unless (a) the option exercise price is at least 110% of fair market value of the stock subject to the option on the date of grant and (b) the term of the ISO does not exceed five years from the date of grant.

Effect on stock options of certain change in control events. Unless otherwise provided in the plan or an award agreement, if we experience a change in control, stock options held by individuals whose service has not terminated prior to the change in control will be accelerated in full and shall be immediately exercisable in full on the date of such change in control. A change in control generally means (i) one person or more than one person as a group acquires 30% or more of the outstanding common stock or combined voting power of our company; (ii) members of the incumbent board cease to constitute a majority of the members of the board; or (iii) approval by our stockholders of: (A) a merger, reorganization or consolidation of our company, unless the holders of the company s voting stock immediately prior to such transaction continue to hold 60% of the surviving or successor s outstanding common stock or voting power immediately after the transaction; (B) our liquidation or dissolution; or (C) the sale or disposition of all or substantially all of our assets.

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In addition, if our stockholders receive capital stock of another corporation in exchange for their shares of stock in any transaction involving a merger, consolidation, acquisition of property or stock, separation or reorganization, all outstanding stock options will be converted into stock options to purchase shares of the other corporation s stock unless our board of directors determines that such options will instead terminate, in which case, the option holders will be notified in writing or electronically of their right to exercise their outstanding options in full.

Other provisions. Our board of directors will appropriately adjust the class and the maximum number of shares subject to the 2006 plan in the event of a consolidation of shares, stock dividend or stock split.

Insys Pharma, Inc. Amended and Restated Equity Incentive Plan

In connection with the NeoPharm merger, on November 8, 2010, we assumed all of the outstanding stock options granted under Insys Pharma, Inc s amended and restated equity incentive plan, or the Insys Pharma plan. Subsequent to the NeoPharm merger, these stock options were adjusted to cover shares of our common stock at the exchange ratios set forth in the applicable merger agreement. As of March 31, 2013, options to purchase an aggregate of 944,537 shares of our common stock under the Insys Pharma plan were outstanding. The Insys Pharma plan was terminated and we will not grant additional equity awards under the Insys Pharma plan.

Share Reserve. Except with respect to the outstanding options referenced above, no shares of our common stock remain reserved or available for issuance under the Insys Pharma plan.

Administration. Our board of directors administers the Insys Pharma plan, but the board may delegate authority to administer the Insys Pharma plan to a committee that complies with applicable law. Our board of directors has broad authority to administer the Insys Pharma plan.

Eligibility. The Insys Pharma plan permitted the grant of NSOs to key employees, non-employee directors and consultants, and permitted the grant of ISOs to employees.

Stock option provisions generally. In general, the duration of a stock option granted under the Insys Pharma plan cannot exceed ten years. An ISO may be transferred only on death, but an NSO may be transferred as permitted by our board of directors or other permitted plan administrator. In addition, our board of directors may amend, modify, extend, cancel or renew any outstanding option or may waive any restrictions or conditions applicable to any outstanding option.

The aggregate fair market value, determined at the time of grant, of shares of our common stock with respect to which ISOs are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. An ISO granted to a person who at the time of grant owns or is deemed to own more than 10% of the total combined voting power of all classes of our outstanding stock or any of our affiliates must have a term of no more than five years and an exercise price that is at least 110% of fair market value at the time of grant.

Other provisions. If there is a transaction or event which changes our stock that does not involve our receipt of consideration, such as a merger, consolidation, reorganization, stock dividend or stock split, our board of directors will appropriately adjust the class and the maximum number of shares subject to the Insys Pharma plan.

2013 Equity Incentive Plan

Our board of directors adopted the 2013 plan in April 2013, and we expect our stockholders will approve the plan prior to this offering and that the 2013 plan will become effective upon the execution and delivery of the underwriting agreement for this offering. Once the 2013 plan is effective, no further grants will be made under the 2006 plan.

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Stock Awards. The 2013 plan provides for the grant of ISOs, NSOs, stock appreciation rights, restricted stock awards, restricted stock unit awards, performance-based stock awards, and other forms of equity compensation (collectively, stock awards), all of which may be granted to employees, including officers, non-employee directors and consultants of us and our affiliates. Additionally, the 2013 plan provides for the grant of performance cash awards. ISOs may be granted only to employees. All other awards may be granted to employees, including officers, and to non-employee directors and consultants.

Share Reserve. Initially, the aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2013 plan after the 2013 plan becomes effective is the sum of (i) 1,500,000 shares, plus (ii) the number of shares reserved for issuance under the 2006 plan at the time the 2013 plan becomes effective, plus (iii) any shares subject to stock options or other stock awards granted under the 2006 plan or the Insys Pharma plan, or the prior plans, that expire or terminate for any reason without being exercised in full or otherwise are not issued. Additionally, the number of shares of our common stock reserved for issuance under the 2013 plan will automatically increase on January 1 of each year, beginning on January 1, 2014 and continuing through and including January 1, 2023, by 4.0% of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. The maximum number of shares that may be issued upon the exercise of ISOs under the 2013 plan is 7,200,000 shares.

No person may be granted stock awards covering more than 1,000,000 shares of our common stock under the 2013 plan during any calendar year pursuant to stock options, stock appreciation rights and other stock awards whose value is determined by reference to an increase over an exercise or strike price of at least 100% of the fair market value on the date the stock award is granted. Additionally, no person may be granted in a calendar year a performance stock award covering more than 1,000,000 shares or a performance cash award having a maximum value in excess of $3,000,000. Such limitations are designed to help assure that any deductions to which we would otherwise be entitled with respect to such awards will not be subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to any covered executive officer imposed by Section 162(m) of the Code.

If a stock award granted under the 2013 plan or the prior plans expires or otherwise terminates without being exercised in full, or is settled in cash, the shares of our common stock not acquired pursuant to the stock award again will become available for subsequent issuance under the 2013 plan. In addition, the following types of shares under the 2013 plan or the prior plans may become available for the grant of new stock awards under the 2013 plan: (i) shares that are forfeited to or repurchased by us prior to becoming fully vested; (ii) shares withheld to satisfy income or employment withholding taxes; or (iii) shares used to pay the exercise or purchase price of a stock award. Shares issued under the 2013 plan may be previously unissued shares or reacquired shares bought by us on the open market. As of the date hereof, no awards have been granted and no shares of our common stock have been issued under the 2013 plan.

Administration. Our board of directors, or a duly authorized committee thereof, has the authority to administer the 2013 plan. Our board of directors may also delegate to one or more of our officers the authority to (i) designate employees (other than other officers) to be recipients of certain stock awards, and (ii) determine the number of shares of common stock to be subject to such stock awards. Subject to the terms of the 2013 plan, our board of directors or the authorized committee, referred to herein as the plan administrator, determines recipients, dates of grant, the numbers and types of stock awards to be granted and the terms and conditions of the stock awards, including the period of their exercisability and vesting schedule applicable to a stock award. Subject to the limitations set forth below, the plan administrator will also determine the exercise price, strike price or purchase price of awards granted and the types of consideration to be paid for the award.

The plan administrator has the authority to modify outstanding awards under the 2013 plan. Subject to the terms of the 2013 plan, the plan administrator has the authority to reduce the exercise, purchase

or strike price of any outstanding stock award, cancel any outstanding stock award in exchange for new stock awards, cash or other consideration, or take any other action that is treated as a repricing under GAAP, with the consent of any adversely affected participant.

Stock Options. ISOs and NSOs are granted pursuant to stock option agreements adopted by the plan administrator. The plan administrator determines the exercise price for a stock option, within the terms and conditions of the 2013 plan, provided that the exercise price of a stock option generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2013 plan vest at the rate specified by the plan administrator.

The plan administrator determines the term of stock options granted under the 2013 plan, up to a maximum of ten years. Unless the terms of an option holder s stock option agreement provide otherwise, if an option holder s service relationship with us, or any of our affiliates, ceases for any reason other than disability, death or cause, the option holder may generally exercise any vested options for a period of three months following the cessation of service. The option term may be extended in the event that exercise of the option following such a termination of service is prohibited by applicable securities laws or our insider trading policy. If an optionholder s service relationship with us or any of our affiliates ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or a beneficiary may generally exercise any vested options for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, options generally terminate immediately upon the termination of the individual for cause. In no event may an option be exercised beyond the expiration of its term.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the plan administrator and may include (i) cash, check, bank draft or money order, (ii) a broker-assisted cashless exercise, (iii) the tender of shares of our common stock previously owned by the optionholder, (iv) a net exercise of the option if it is an NSO and (v) other legal consideration approved by the plan administrator.

Unless the plan administrator provides otherwise, options generally are not transferable except by will, the laws of descent and distribution, or pursuant to a domestic relations order. An optionholder may designate a beneficiary, however, who may exercise the option following the optionholder s death.

Tax Limitations On Incentive Stock Options. The aggregate fair market value, determined at the time of grant, of our common stock with respect to ISOs that are exercisable for the first time by an optionholder during any calendar year under all of our stock plans may not exceed $100,000. Options or portions thereof that exceed such limit will generally be treated as NSOs. No ISO may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (i) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant, and (ii) the term of the ISO does not exceed five years from the date of grant.

Restricted Stock Awards. Restricted stock awards are granted pursuant to restricted stock award agreements adopted by the plan administrator. Restricted stock awards may be granted in consideration for (i) cash, check, bank draft or money order, (ii) services rendered to us or our affiliates, or (iii) any other form of legal consideration. Common stock acquired under a restricted stock award may, but need not, be subject to a share repurchase option in our favor in accordance with a vesting schedule to be determined by the plan administrator. Rights to acquire shares under a restricted stock award may be transferred only upon such terms and conditions as set by the plan administrator. Except as otherwise provided in the applicable award agreement, restricted stock unit awards that have not vested will be forfeited upon the participant s cessation of continuous service for any reason.

Restricted Stock Unit Awards. Restricted stock unit awards are granted pursuant to restricted stock unit award agreements adopted by the plan administrator. Restricted stock unit awards may be granted in consideration for any form of legal consideration. A restricted stock unit award may be settled by cash, delivery of stock, a combination of cash and stock as deemed appropriate by the plan

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administrator, or in any other form of consideration set forth in the restricted stock unit award agreement. Additionally, dividend equivalents may be credited in respect of shares covered by a restricted stock unit award. Except as otherwise provided in the applicable award agreement, restricted stock units that have not vested will be forfeited upon the participant s cessation of continuous service for any reason.

Stock Appreciation Rights. Stock appreciation rights are granted pursuant to stock appreciation grant agreements adopted by the plan administrator. The plan administrator determines the strike price for a stock appreciation right, which generally cannot be less than 100% of the fair market value of our common stock on the date of grant. Upon the exercise of a stock appreciation right, we will pay the participant an amount equal to the product of (i) the excess of the per share fair market value of our common stock on the date of exercise over the strike price, multiplied by (ii) the number of shares of common stock with respect to which the stock appreciation right is exercised. A stock appreciation right granted under the 2013 plan vests at the rate specified in the stock appreciation right agreement as determined by the plan administrator.

The plan administrator determines the term of stock appreciation rights granted under the 2013 plan, up to a maximum of ten years. Unless the terms of a participant s stock appreciation right agreement provides otherwise, if a participant s service relationship with us or any of our affiliates ceases for any reason other than cause, disability or death, the participant may generally exercise any vested stock appreciation right for a period of three months following the cessation of service. The stock appreciation right term may be further extended in the event that exercise of the stock appreciation right following such a termination of service is prohibited by applicable securities laws. If a participant s service relationship with us, or any of our affiliates, ceases due to disability or death, or a participant dies within a certain period following cessation of service, the participant or a beneficiary may generally exercise any vested stock appreciation right for a period of 12 months in the event of disability and 18 months in the event of death. In the event of a termination for cause, stock appreciation rights generally terminate immediately upon the occurrence of the event giving rise to the termination of the individual for cause. In no event may a stock appreciation right be exercised beyond the expiration of its term.

Performance Awards. The 2013 plan permits the grant of performance-based stock and cash awards that may qualify as performance-based compensation that is not subject to the $1,000,000 limitation on the income tax deductibility of compensation paid to a covered executive officer imposed by Section 162(m) of the Code. To help assure that the compensation attributable to performance-based awards will so qualify, our compensation committee can structure such awards so that stock or cash will be issued or paid pursuant to such award only after the achievement of certain pre-established performance goals during a designated performance period.

The performance goals that may be selected will include one or more of the following: (1) earnings (including earnings per share and net earnings); (2) earnings before interest, taxes and depreciation; (3) earnings before interest, taxes, depreciation and amortization; (4) earnings before interest, taxes, depreciation, amortization and legal settlements; (5) earnings before interest, taxes, depreciation, amortization, legal settlements and other income (expense); (6) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense) and stock-based compensation; (7) earnings before interest, taxes, depreciation, amortization, legal settlements, other income (expense), stock-based compensation and changes in deferred revenue; (8) total stockholder return; (9) return on equity or average stockholder s equity; (10) return on assets, investment, or capital employed; (11) stock price; (12) margin (including gross margin); (13) income (before or after taxes); (14) operating income; (15) operating income after taxes; (16) pre-tax profit; (17) operating cash flow; (18) sales or revenue targets; (19) increases in revenue or product revenue; (20) expenses and cost reduction goals; (21) improvement in or attainment of working capital levels; (22) economic value added (or an equivalent metric); (23) market share; (24) cash flow; (25) cash flow per share; (26) share price performance; (27) debt reduction; (28) implementation or completion of projects or processes;

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(29) user satisfaction; (30) stockholders equity; (31) capital expenditures; (32) debt levels; (33) operating profit or net operating profit; (34) workforce diversity; (35) growth of net income or operating income; (36) billings; (37) bookings; (38) the number of users, including but not limited to unique users; (39) employee retention; and (40) to the extent that an award is not intended to comply with Section 162(m) of the Code, other measures of performance selected by our board of directors.

The performance goals may be based on a company-wide basis, with respect to one or more business units, divisions, affiliates, or business segments, and in either absolute terms or relative to the performance of one or more comparable companies or the performance of one or more relevant indices. Unless specified otherwise (i) in the award agreement at the time the award is granted or (ii) in such other document setting forth the performance goals at the time the goals are established, we will appropriately make adjustments in the method of calculating the attainment of performance goals as follows: (A) to exclude restructuring and/or other nonrecurring charges; (B) to exclude exchange rate effects; (C) to exclude the effects of changes to GAAP; (D) to exclude the effects of any statutory adjustments to corporate tax rates; (E) to exclude the effects of any extraordinary items as determined under GAAP; (F) to exclude the dilutive effects of acquisitions or joint ventures; (G) to assume that any business divested by us achieved performance objectives at targeted levels during the balance of a performance period following such divestiture; (H) to exclude the effect of any change in the outstanding shares of our common stock by reason of any stock dividend or split, stock repurchase, reorganization, recapitalization, merger, consolidation, spin-off, combination or exchange of shares or other similar corporate change, or any distributions to common stockholders other than regular cash dividends; (I) to exclude the effects of stock-based compensation and the award of bonuses under our bonus plans; (J) to exclude costs incurred in connection with potential acquisitions or divestitures that are required to be expensed under GAAP; (K) to exclude the goodwill and intangible asset impairment charges that are required to be recorded under GAAP; and (L) to exclude the effect of any other unusual, non-recurring gain or loss or other extraordinary item. In addition, we retain the discretion to reduce or eliminate the compensation or economic benefit due upon attainment of the goals and to define the manner of calculating the criteria for achievement of such goals. The performance goals may differ from participant to participant and from award to award.

Other Stock Awards. The plan administrator may grant other awards based in whole or in part by reference to our common stock. The plan administrator will set the number of shares under the stock award and all other terms and conditions of such awards.

Changes to Capital Structure. In the event that there is a specified type of change in our capital structure, such as a stock split or recapitalization, appropriate adjustments will be made to (i) the class and maximum number of shares reserved for issuance under the 2013 plan, (ii) the class and maximum number of shares by which the share reserve may increase automatically each year, (iii) the class and maximum number of shares that may be issued upon the exercise of ISOs, (iv) the class and maximum number of shares subject to stock awards that can be granted in a calendar year (as established under the 2013 plan pursuant to Section 162(m) of the Code) and (v) the class and number of shares and exercise price, strike price, or purchase price, if applicable, of all outstanding stock awards.

Corporate Transactions. In the event of certain specified significant corporate transactions, the plan administrator has the discretion to take any of the following actions with respect to stock awards:

arrange for the assumption, continuation or substitution of a stock award by a surviving or acquiring entity or parent company;

arrange for the assignment of any reacquisition or repurchase rights held by us to the surviving or acquiring entity or parent company;

accelerate the vesting of the stock award and provide for its termination prior to the effective time of the corporate transaction;

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arrange for the lapse of any reacquisition or repurchase right held by us;

cancel or arrange for the cancellation of the stock award in exchange for such cash consideration, if any, as our board of directors may deem appropriate; or

make a payment equal to the excess of (a) the value of the property the participant would have received upon exercise of the stock award over (b) the exercise price otherwise payable in connection with the stock award.

Our plan administrator is not obligated to treat all stock awards, even those that are of the same type, in the same manner.

Under the 2013 plan, a corporate transaction is generally the consummation of (i) a sale or other disposition of all or substantially all of our consolidated assets, (ii) a sale or other disposition of at least 90% of our outstanding securities, (iii) a merger, consolidation or similar transaction following which we are not the surviving corporation, or (iv) a merger, consolidation or similar transaction following which we are the surviving corporation but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction.

Change of Control. The plan administrator may provide, in an individual award agreement or in any other written agreement between a participant and us that the stock award will be subject to additional acceleration of vesting and exercisability in the event of a change of control. Under the 2013 plan, a change of control is generally (i) the acquisition by a person or entity of more than 50% of our combined voting power other than by merger, consolidation or similar transaction; (ii) a consummated merger, consolidation or similar transaction immediately after which our stockholders cease to own more than 50% of the combined voting power of the surviving entity; (iii) a consummated sale, lease or exclusive license or other disposition of all or substantially of our consolidated assets; or (iv) a change in which the members of the incumbent board of directors (or persons appointed or elected by a majority of the incumbent board of directors) cease to constitute a majority of the board of directors.

Amendment and Termination. Our board of directors has the authority to amend, suspend, or terminate the 2013 plan, provided that such action does not materially impair the existing rights of any participant without such participant s written consent. No ISOs may be granted after the tenth anniversary of the date our board of directors adopted the 2013 plan.

2013 Employee Stock Purchase Plan

Our board of directors adopted the 2013 ESPP in April 2013 and we expect our stockholders will approve the 2013 ESPP prior to the closing of this offering. The 2013 ESPP will become effective immediately upon the signing of the underwriting agreement related to this offering. The purpose of the 2013 ESPP is to retain the services of new employees and secure the services of new and existing employees while providing incentives for such individuals to exert maximum efforts toward our success and that of our affiliates.

Share Reserve. Following this offering, the 2013 ESPP authorizes the issuance of 175,000 shares of our common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of our 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 (i) 1.0% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year, (ii) 200,000 shares, or (iii) a number determined by our board of directors that is less than (i) and (ii). The 2013 ESPP is intended to qualify as an employee stock purchase plan within the meaning of Section 423 of the Code. As of the date hereof, no shares of our common stock have been purchased under the 2013 ESPP.

Administration. Our board of directors has delegated its authority to administer the 2013 ESPP to our compensation committee. The 2013 ESPP is implemented through a series of offerings of purchase

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rights to eligible employees. Under the 2013 ESPP, we may specify offerings with duration of not more than 27 months, and may specify shorter purchase periods within each offering. Each offering will have one or more purchase dates on which shares of our common stock will be purchased for employees participating in the offering. An offering may be terminated under certain circumstances.

Payroll Deductions. Generally, all regular employees, including executive officers, employed by us or by any of our designated affiliates, may participate in the 2013 ESPP and may contribute, normally through payroll deductions, up to 15% of their earnings for the purchase of our common stock under the 2013 ESPP. Unless otherwise determined by our board of directors, common stock will be purchased for accounts of employees participating in the 2013 ESPP at a price per share equal to the lower of (i) 85% of the fair market value of a share of our common stock on the first date of an offering or (ii) 85% of the fair market value of a share of our common stock on the date of purchase.

Limitations. Employees may have to satisfy one or more of the following service requirements before participating in the 2013 ESPP, as determined by our board of directors: (i) customarily employed for more than 20 hours per week, (ii) customarily employed for more than five months per calendar year or (iii) continuous employment with us or one of our affiliates for a period of time (not to exceed two years). No employee may purchase shares under the 2013 ESPP at a rate in excess of $25,000 worth of our common stock based on the fair market value per share of our common stock at the beginning of an offering for each year such a purchase right is outstanding. Finally, no employee will be eligible for the grant of any purchase rights under the 2013 ESPP if immediately after such rights are granted, such employee has voting power over 5% or more of our outstanding capital stock measured by vote or value pursuant to Section 424(d) of the Code.

Changes to Capital Structure. In the event that there occurs a change in our capital structure through such actions as a stock split, merger, consolidation, reorganization, recapitalization, reincorporation, stock dividend, dividend in property other than cash, large nonrecurring cash dividend, liquidating dividend, combination of shares, exchange of shares, change in corporate structure or similar transaction, the board of directors will make appropriate adjustments to (i) the number of shares reserved under the 2013 ESPP, (ii) the maximum number of shares by which the share reserve may increase automatically each year and (iii) the number of shares and purchase price of all outstanding purchase rights.

Corporate Transactions. In the event of certain significant corporate transactions, including: (i) a sale or disposition of all our assets, (ii) the sale or disposition of 90% of our outstanding securities, (iii) the consummation of a merger or consolidation where we do not survive the transaction, and (iv) the consummation of a merger or consolidation where we do survive the transaction but the shares of our common stock outstanding immediately prior to such transaction are converted or exchanged into other property by virtue of the transaction, any then-outstanding rights to purchase our stock under the 2013 ESPP may be assumed, continued or substituted for by any surviving or acquiring entity (or its parent company). If the surviving or acquiring entity (or its parent company) elects not to assume, continue or substitute for such purchase rights, then the participants accumulated payroll contributions will be used to purchase shares of our common stock within ten business days prior to such corporate transaction, and such purchase rights will terminate immediately.

Plan Amendments, Termination. Our board of directors has the authority to amend or terminate the 2013 ESPP, provided that except in certain circumstances any such amendment or termination may not materially impair any outstanding purchase rights without the partipant s consent. We will obtain stockholder approval of any amendment to the 2013 ESPP to the extent required by applicable law or listing requirements.

401(k) Plans

We maintain a 401(k) plan for our full-time employees. Our executive officers are also eligible to participate in the 401(k) plan on the same basis as our other employees. The 401(k) plan is intended to

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qualify as a tax-qualified plan under Section 401(k) of the Code. The plan provides that each participant may contribute up to the lesser of 100% of his or her pre-tax compensation or the statutory limit, which is $17,000 for 2012. Participants that are 50 years or older can also make catch-up contributions, which in calendar year 2012 may be up to an additional $5,500 above the statutory limit. The 401(k) plan provides for us to make qualified non-elective contributions on behalf of all eligible participants. The 401(k) plan also permits us to make discretionary contributions and matching contributions, subject to established limits and a vesting schedule. In 2012, we did not made any discretionary or matching contributions to the 401(k) plan on behalf of participating employees. The 401(k) plan currently does not offer the ability to invest in our securities. Under the 401(k) plan, each participant is fully vested in his or her deferred salary contributions when contributed. Participant contributions are held and invested, pursuant to the participant s instructions, by the plan s trustee.

Insys Pharma also sponsors a 401(k) plan covering all full-time employees. Participants may contribute up to the legal limit. The 401(k) plan provides for employee contributions, but Insys Pharma does not make any matching contributions.

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CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2010 to which we have been a party, in which the amount involved in the transaction exceeded $120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described in the section entitled Executive Compensation.

Loan Transactions

Since January 1, 2010, we and Insys Pharma have entered into various loan arrangements with entities controlled by Dr. Kapoor, our founder, Executive Chairman and principal stockholder, pursuant to which we or Insys Pharma have issued secured promissory notes and secured demand notes. The notes carry interest at the prime rate plus 2.0% (5.25% as of December 31, 2012). Below is a summary of certain information relating to such notes as of and for the years ended December 31, 2012, 2011 and 2010:

	Years Ended December 31,		
	2012	2011	2010
		(in thousands)	
Principal amount of promissory and demand notes issued	$ 48,626	$ 45,640	$ 15,145
Largest aggregate principal amount outstanding	48,626	48,626	29,687
Interest expense accrued on notes payable	9,757	7,175	1,150
Principal and interest repaid			
Principal and interest converted to equity			

As of March 31, 2013, we and Insys Pharma had $59.0 million in outstanding indebtedness, including accrued interest, pursuant to these notes and other notes issued by us or Insys Pharma in prior years to trusts controlled by or affiliated with Dr. Kapoor. Immediately prior to the closing of this offering, all of the outstanding principal and interest under these notes will convert into shares of our common stock at the price to the public of the shares sold in this offering.

Employment Arrangements

We currently have written employment agreements with our President and Chief Executive Officer, Michael Babich, our Chief Medical Officer, Dr. Larry Dillaha, and our Chief Financial Officer, Darryl S. Baker. For more information, refer to the section entitled Executive Compensation Employment Agreements.

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Stock Options Granted to Executive Officers and Directors

We have granted stock options under the 2006 plan to our executive officers and directors. The table below summarizes the stock option grants made to such persons since January 1, 2010.

Name	Grant Date	Shares of Our Common Stock Subject to Option Grants	Exercise Price Per Share ($)
Michael L. Babich	March 28, 2011	98,480	4.88
	December 27, 2012	177,000	3.54
Director / President and Chief Executive Officer			
Darryl S. Baker	December 27, 2012	70,000	3.54
Chief Financial Officer			
Frank Becker	August 19, 2010	1,024	17.69
Former Director			
Larry Dillaha, M.D	March 28, 2011	51,807	4.88
Chief Medical Officer			
	December 27, 2012	49,000	3.54
Patrick P. Fourteau	March 28, 2011	24,590	4.88
Director			
Bernard Fox, M.D	August 19, 2010	1,024	17.69
Former Director			
Paul Freiman	August 19, 2010	1,024	17.69
Former Director			
John N. Kapoor, Ph.D	August 19, 2010	1,536	17.69
Executive Chairman			
Pierre Lapalme	March 28, 2011	24,590	4.88
Director			
Richard Mallery	March 28, 2011	24,590	4.88
Former Director			
Martin McCarthy	February 10, 2010	491	18.61
	March 28, 2011	40,491	4.88
Former Chief Financial Officer			
Steven Meyer	March 28, 2011	22,950	4.88
Director			

Aquilur Rahman, Ph.D *Former Director and Former President and Chief Executive Officer*	February 10, 2010	2,459	18.61
Brian Tambi *Director*	March 28, 2011	22,950	4.88

For further information regarding stock option grants to our executive officers and directors, see the section entitled Executive Compensation.

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Limitation on Liability and Indemnification Agreements

Our amended and restated certificate of incorporation and amended and restated bylaws, each to be effective upon the closing of this offering, will provide that we will indemnify our directors and officers, and may indemnify our employees and other agents, to the fullest extent permitted by the Delaware General Corporation Law. However, Delaware law prohibits our amended and restated certificate of incorporation from limiting the liability of our directors for the following:

- any breach of the director s duty of loyalty to us or to our stockholders;
- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or unlawful stock repurchases or redemptions; and
- any transaction from which the director derived an improper personal benefit.

If Delaware law is amended to authorize corporate action further eliminating or limiting the personal liability of a director, then the liability of our directors will be eliminated or limited to the fullest extent permitted by Delaware law, as so amended. Our amended and restated certificate of incorporation does not eliminate a director s duty of care and, in appropriate circumstances, equitable remedies, such as injunctive or other forms of non-monetary relief, remain available under Delaware law. This provision also does not affect a director s responsibilities under any other laws, such as the federal securities laws or other state or federal laws. Under our amended and restated bylaws, we will also be empowered to enter into indemnification agreements with our directors, officers, employees and other agents and to purchase insurance on behalf of any person whom we are required or permitted to indemnify.

In addition to the indemnification required in our amended and restated certificate of incorporation and amended and restated bylaws, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might benefit us and our stockholders. A stockholder s investment may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, executive officers and controlling persons pursuant to the foregoing provisions, or otherwise, we have been advised that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Policies and Procedures for Transactions with Related Persons

We have adopted a written related-person transactions policy that sets forth our policies and procedures regarding the identification, review, consideration and oversight of related-person transactions. For purposes of our policy only, a related-person transaction is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any related person are participants involving an amount that exceeds $120,000.

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Transactions involving compensation for services provided to us as an employee, consultant or director are not considered related-person transactions under this policy. A related person is any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors takes into account the relevant available facts and circumstances including, but not limited to:

the risks, costs and benefits to us;

the impact on a director s independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;

the terms of the transaction;

the availability of other sources for comparable services or products; and

the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

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PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our common stock outstanding as of March 31, 2013 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- each of our named executive officers; and
- all of our directors and executive officers as a group.

The percentage ownership information shown in the table is based upon 15,971,068 shares of common stock outstanding as of March 31, 2013, which assumes the conversion of all of our outstanding convertible preferred stock into 8,528,860 shares of common stock and the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, both of which will occur immediately prior to the closing of this offering. The percentage ownership information after this offering shown in the table also reflects the sale and issuance of 4,000,000 shares in this offering and assumes no exercise of the underwriters over-allotment option to purchase additional shares.

Information with respect to beneficial ownership has been furnished by each director, officer or beneficial owner of more than 5% of our common stock. We have determined beneficial ownership in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities. In addition, these rules require inclusion of shares of common stock issuable pursuant to the exercise of stock options or warrants that are either immediately exercisable or exercisable on or before May 30, 2013, which is 60 days after March 31, 2013. These shares are deemed to be outstanding and beneficially owned by the person holding those options or warrants for the purpose of computing the percentage ownership of that person, but they are not treated as outstanding for the purpose of computing the percentage ownership of any other person. Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

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Except as otherwise noted below, the address for each person or entity listed in the table is c/o Insys Therapeutics, Inc., 444 South Ellis Street, Chandler, Arizona 85224.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned Before Offering	Percentage of Shares Beneficially Owned After Offering
Greater than 5% Stockholders			
The John N. Kapoor Trust dated September 20, 1989[1]	13,328,549	83.5%	66.7%
1925 W. Field Ct., Ste. 300			
Lake Forest, IL 60045			
The Kapoor Children s 1992 Trust[1]	1,476,169	9.2%	7.4%
1925 W. Field Ct., Ste. 300			
Lake Forest, IL 60045			
Named Executive Officer and Directors			
John N. Kapoor, Ph.D.[2]	13,362,783	83.7%	66.9%
Michael Babich[3]	422,067	2.6%	2.1%
Darryl S. Baker[4]	13,611	*	*
Larry Dillaha, M.D.[5]	146,991	*	*
Patrick P. Fourteau[6]	13,319	*	*
Pierre Lapalme[7]	13,319	*	*
Steve Meyer[8]	32,548	*	*
Theodore H. Stanley, M.D.	0	*	*
Brian Tambi[9]	32,548	*	*
All executive officers and directors as a group (9 persons)[10]	14,037,186	84.7%	68.2%

* Represents beneficial ownership of less than 1%.

(1) John N. Kapoor, Ph.D., our founder, Executive Chairman and principal stockholder, is the sole trustee and sole beneficiary of The John N. Kapoor Trust, dated September 20, 1989 and is the grantor of The Kapoor Children s 1992 Trust.

(2) Includes 1,262 shares held by Dr. Kapoor in his individual capacity; 3,994 shares that Dr. Kapoor has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options; 13,328,549 shares held by The John N. Kapoor Trust, dated September 20, 1989, of which Dr. Kapoor is the sole trustee and sole beneficiary; 18,763 shares held by EJ Financial/NEO Management, L.P., of which Dr. Kapoor is Managing General Partner; and 6,221 shares held by The John and Editha Kapoor Charitable Foundation, or the Charitable Foundation, of which Dr. Kapoor is a joint trustee. The percentage of shares beneficially owned after the offering includes shares of common stock to be issued upon the conversion of $56.2 million in aggregate principal amount of notes and accrued interest thereon owed to The John N. Kapoor Trust dated September 20, 1989, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering.

(3) Includes 76,307 shares held by Mr. Babich and 345,760 shares that Mr. Babich has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

(4)

Represents 13,611 shares that Mr. Baker has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

(5) Represents 146,991 shares that Dr. Dillaha has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

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(6) Represents 13,319 shares that Mr. Fourteau has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

(7) Represents 13,319 shares that Mr. Lapalme has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

(8) Represents 32,548 shares that Mr. Meyer has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

(9) Represents 32,548 shares that Mr. Tambi has the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

(10) Includes 602,088 shares that our current executive officers and directors as a group have the right to acquire from us within 60 days of March 31, 2013 pursuant to the exercise of stock options.

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DESCRIPTION OF CAPITAL STOCK

Upon the closing of this offering and the filing of our amended and restated certificate of incorporation, our authorized capital stock will consist of 50,000,000 shares of common stock, par value $0.0002145 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share. The following is a summary of the rights of our common and preferred stock and some of the provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our amended and restated certificate of incorporation, amended and restated certificate of designations, as amended, and amended and restated bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

Common Stock

On March 31, 2013, there were 856,026 shares of our common stock outstanding, held of record by 74 stockholders, and there were 2,083,695 shares of our common stock subject to outstanding options. Based on (i) 856,026 shares of our common stock outstanding as of March 31, 2013, (ii) the conversion of 14,864,607 shares of convertible preferred stock into 8,528,860 shares of common stock immediately prior to the closing of this offering, (iii) the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering, and (iv) the issuance of 4,000,000 shares of common stock in this offering, there will be 19,971,068 shares of our common stock outstanding upon the closing of this offering.

Voting. Our common stock is entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, including the election of directors, and does not have cumulative voting rights. Accordingly, the holders of a majority of the shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election.

Dividends. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds.

Liquidation. In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Fully Paid and Nonassessable. All of our outstanding shares of common stock are, and the shares of common stock to be issued in this offering will be, fully paid and nonassessable.

Preferred Stock

On March 31, 2013, there were 14,864,607 shares of convertible preferred stock outstanding, held of record by 21 stockholders. Pursuant to our amended and restated certificate of designations, as amended, each share of convertible preferred stock will automatically convert into shares of our common stock immediately prior to the closing of this offering, at the then-applicable conversion ratio.

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Each share of our convertible preferred stock is convertible into approximately 0.57377 shares of our common stock. Accordingly, immediately prior to the closing of this offering, the outstanding shares of convertible preferred stock will automatically convert into 8,528,860 shares of our common stock.

Following this offering, under our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power, impair the liquidation rights of our common stock or otherwise adversely affect the rights of holders of our common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control and may adversely affect the market price of our common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Anti-Takeover Effects of Provisions of Our Amended and Restated Certificate of Incorporation, Our Bylaws and Delaware Law

Delaware Anti-Takeover Law. We are subject to Section 203 of the Delaware General Corporation Law, or Section 203. Section 203 generally prohibits a public Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66-2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction involving the corporation that has the effect of increasing the proportionate share of the stock of any class or series of the corporation beneficially owned by the interested stockholder;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; and

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the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with or controlling or controlled by the entity or person.

Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws. Provisions of our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the closing of this offering, may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);

provide that the authorized number of directors may be changed only by resolution of our board of directors;

provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

divide our board of directors into three classes;

require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner, and also specify requirements as to the form and content of a stockholder s notice;

do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose); and

provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by our board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then outstanding common stock.

NASDAQ Global Market Listing

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol INSY.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Shareowner Services LLC. The transfer agent and registrar s address is 250 Royall Street, Canton, MA 02021.

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SHARES ELIGIBLE FOR FUTURE SALE

Although our common stock was once traded on the NASDAQ Capital Market and our common stock is currently quoted on the Pink Sheets, immediately prior to this offering, we do not believe that there is currently a liquid public market on which our common stock is actively and readily traded. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since a relatively limited number of our outstanding shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market after these restrictions lapse could adversely affect the prevailing market price for our common stock as well as our ability to raise equity capital in the future.

Based on 856,026 shares of common stock outstanding as of March 31, 2013, the conversion of 14,864,607 shares of convertible preferred stock into 8,528,860 shares of common stock immediately prior to the closing of this offering, the conversion of $59.3 million in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with our founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of this offering, and the issuance of 4,000,000 shares of common stock in this offering, upon the closing of this offering, 19,971,068 shares of common stock will be outstanding, assuming no exercise of the underwriters over-allotment option and no exercise of outstanding stock options. All of the shares sold in this offering will be freely tradable unless held by an affiliate of ours. Immediately prior to the NeoPharm merger, there were 464,353 shares of our common stock outstanding, and we expect that substantially all of these shares will also be freely tradable after this offering unless held by an affiliate of ours. Except as set forth below, substantially all of the remaining 15,506,715 shares of common stock outstanding upon the closing of this offering will be restricted as a result of securities laws or lock-up agreements. These remaining shares will generally become available for sale in the public market under Rule 144 or Rule 701 upon expiration of lock-up agreements at least 180 days after the date of this offering, subject to volume limitations pursuant to Rule 144.

Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 199,711 shares immediately after this offering; or
- the average weekly trading volume of our common stock on the NASDAQ Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144

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also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

Rule 701

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

As of March 31, 2013, options to purchase a total of 2,083,695 shares of common stock were outstanding, of which 1,318,520 were vested. Of the total number of shares of our common stock issuable under these options, substantially all are subject to contractual lock-up agreements with us or the underwriters described below under the section entitled Underwriting Lock-Up Agreements and will become eligible for sale at the expiration of those agreements unless held by an affiliate of ours.

Lock-Up Agreements

As described under the section entitled Underwriting Lock-Up Agreements below, we, each of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering, other than shares outstanding prior to the NeoPharm merger, and the holders of substantially all of our options outstanding prior to this offering, have agreed, subject to specified exceptions, not to, directly or indirectly, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or any securities convertible into or exercisable or exchangeable for shares of our common stock, without the prior written consent of Wells Fargo Securities, LLC and JMP Securities LLC, for a period of 180 days from the date of the final prospectus for the offering.

Wells Fargo Securities, LLC and JMP Securities LLC, may, in their sole discretion, at any time or from time to time and without notice, release for sale in the public market all or any portion of the shares restricted by the terms of the lock-up agreements.

Equity Incentive Plans

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock reserved for issuance under the 2013 plan and the 2013 ESPP. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

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MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following summary describes the material U.S. federal income and estate tax consequences of the acquisition, ownership and disposition of our common stock acquired in this offering by Non-U.S. Holders (as defined below). This discussion does not address all aspects of U.S. federal income and estate taxes and does not deal with foreign, state and local consequences that may be relevant to Non-U.S. Holders in light of their particular circumstances, nor does it address U.S. federal tax consequences other than income and estate taxes. Special rules different from those described below may apply to certain Non-U.S. Holders that are subject to special treatment under the Code, such as financial institutions, insurance companies, tax-exempt organizations, broker-dealers and traders in securities, U.S. expatriates, controlled foreign corporations, passive foreign investment companies, corporations that accumulate earnings to avoid U.S. federal income tax, persons that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or integrated investment or other risk reduction strategy, partnership and other pass-through entities, and investors in such pass-through entities or an entity that is treated as a disregarded entity for U.S. federal income tax purposes (regardless of its place of organization or formation). Such Non-U.S. Holders are urged to consult their own tax advisors to determine the U.S. federal, state, local and other tax consequences that may be relevant to them. Furthermore, the discussion below is based upon the provisions of the Code, and Treasury regulations, rulings and judicial decisions thereunder as of the date hereof, and such authorities may be repealed, revoked or modified, perhaps retroactively, so as to result in U.S. federal income and estate tax consequences different from those discussed below. We have not requested a ruling from the U.S. Internal Revenue Service, or IRS, with respect to the statements made and the conclusions reached in the following summary, and there can be no assurance that the IRS will agree with such statements and conclusions. This discussion assumes that the Non-U.S. Holder holds our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment).

The following discussion is for general information only and is not tax advice. Persons considering the purchase of our common stock pursuant to this offering should consult their own tax advisors concerning the U.S. federal income and estate tax consequences of acquiring, owning and disposing of our common stock in light of their particular situations as well as any consequences arising under the laws of any other taxing jurisdiction, including any state, local or foreign tax consequences.

For the purposes of this discussion, a Non-U.S. Holder is, for U.S. federal income tax purposes, a beneficial owner of common stock that has not been excluded from this discussion and is not a U.S. Holder. A U.S. Holder means a beneficial owner of our common stock that is for U.S. federal income tax purposes (a) an individual who is a citizen or resident of the United States, (b) a corporation or other entity treated as a corporation created or organized in or under the laws of the United States, any state thereof or the District of Columbia, (c) an estate the income of which is subject to U.S. federal income taxation regardless of its source or (d) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

Distributions

Subject to the discussion below, distributions, if any, made on our common stock to a Non-U.S. Holder of our common stock to the extent made out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles) generally will constitute dividends for U.S. tax purposes and will be subject to withholding tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. To obtain a reduced rate of withholding under a treaty, a Non-U.S. Holder generally will be required to provide us with a properly executed IRS Form W-8BEN, or other appropriate form, certifying the Non-U.S. Holder s entitlement to benefits under that treaty. In the case

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of a Non-U.S. Holder that is an entity, Treasury Regulations and the relevant tax treaty provide rules to determine whether, for purposes of determining the applicability of a tax treaty, dividends will be treated as paid to the entity or to those holding an interest in that entity. If a Non-U.S. Holder holds stock through a financial institution or other agent acting on the holder s behalf, the holder will be required to provide appropriate documentation to such agent. The holder s agent will then be required to provide certification to us or our paying agent, either directly or through other intermediaries. If you are eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, you should consult with your own tax advisor to determine if you are able to obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim for a refund with the IRS.

We generally are not required to withhold tax on dividends paid to a Non-U.S. Holder that are effectively connected with the Non-U.S. Holder s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment that such holder maintains in the United States) if a properly executed IRS Form W-8ECI, stating that the dividends are so connected, is furnished to us (or, if stock is held through a financial institution or other agent, to such agent). In general, such effectively connected dividends will be subject to U.S. federal income tax, on a net income basis at the regular graduated rates, unless a specific treaty exemption applies. A corporate Non- U.S. Holder receiving effectively connected dividends may also be subject to an additional branch profits tax, which is imposed, under certain circumstances, at a rate of 30% (or such lower rate as may be specified by an applicable treaty) on the corporate Non-U.S. Holder s effectively connected earnings and profits, subject to certain adjustments.

To the extent distributions on our common stock, if any, exceed our current and accumulated earnings and profits, they will constitute a non-taxable return of capital and will first reduce your adjusted basis in our common stock, but not below zero, and then will be treated as gain and taxed in the same manner as gain realized from a sale or other disposition of common stock as described in the next section.

Gain on Disposition of Our Common Stock

Subject to the discussion below regarding backup withholding and foreign accounts, a Non-U.S. Holder generally will not be subject to U.S. federal income tax with respect to gain realized on a sale or other disposition of our common stock unless (a) the gain is effectively connected with a trade or business of such holder in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment that such holder maintains in the United States), (b) the Non-U.S. Holder is a nonresident alien individual and is present in the United States for 183 or more days in the taxable year of the disposition and certain other conditions are met, or (c) we are or have been a United States real property holding corporation within the meaning of Code Section 897(c)(2) at any time within the shorter of the five-year period preceding such disposition or such holder s holding period. In general, we would be a United States real property holding corporation if interests in U.S. real estate comprised (by fair market value) at least half of our business assets. We believe that we are not, and do not anticipate becoming, a United States real property holding corporation. Even if we are treated as a United States real property holding corporation, gain realized by a Non-U.S. Holder on a disposition of our common stock will not be subject to U.S. federal income tax so long as (1) the Non-U.S. Holder owned, directly, indirectly and constructively, no more than 5% of our common stock at all times within the shorter of (i) the five-year period preceding the disposition or (ii) the holder s holding period and (2) our common stock is regularly traded on an established securities market. There can be no assurance that our common stock will continue to qualify as regularly traded on an established securities market.

If you are a Non-U.S. Holder described in (a) above, you will be required to pay tax on the net gain derived from the sale at regular graduated U.S. federal income tax rates, unless a specific treaty exemption applies, and corporate Non-U.S. Holders described in (a) above may be subject to the additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable

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income tax treaty. If you are an individual Non-U.S. Holder described in (b) above, you will be required to pay a flat 30% tax on the gain derived from the sale, which gain may be offset by U.S. source capital losses (even though you are not considered a resident of the United States).

Information Reporting Requirements and Backup Withholding

Generally, we or certain financial middlemen must report information to the IRS with respect to any dividends we pay on our common stock including the amount of any such dividends, the name and address of the recipient, and the amount, if any, of tax withheld. A similar report is sent to the holder to whom any such dividends are paid. Pursuant to tax treaties or certain other agreements, the IRS may make its reports available to tax authorities in the recipient s country of residence.

Dividends paid by us (or our paying agents) to a Non-U.S. Holder may also be subject to U.S. backup withholding. U.S. backup withholding generally will not apply to a Non-U.S. Holder who provides a properly executed IRS Form W-8BEN or otherwise establishes an exemption. The current backup withholding rate is 28%.

Under current U.S. federal income tax law, U.S. information reporting and backup withholding requirements generally will apply to the proceeds from a disposition of our common stock effected by or through a U.S. office of any broker, U.S. or foreign, except that information reporting and such requirements may be avoided if the holder provides a properly executed IRS Form W-8BEN or otherwise meets documentary evidence requirements for establishing Non-U.S. Holder status or otherwise establishes an exemption. Generally, U.S. information reporting and backup withholding requirements will not apply to a payment of disposition proceeds to a Non-U.S. Holder where the transaction is effected outside the United States through a non-U.S. office of a non-U.S. broker. Information reporting and backup withholding requirements may, however, apply to a payment of disposition proceeds if the broker has actual knowledge, or reason to know, that the holder is, in fact, a U.S. person. For information reporting purposes, certain brokers with substantial U.S. ownership or operations will generally be treated in a manner similar to U.S. brokers.

If backup withholding is applied to you, you should consult with your own tax advisor to determine if you are able to obtain a tax benefit or credit with respect to such backup withholding.

Foreign Accounts

A U.S. federal withholding tax of 30% may apply to dividends paid after December 31, 2013 and the gross proceeds from a disposition of our common stock paid after December 31, 2016 to a foreign financial institution (as specifically defined for this purpose), including when the foreign financial institution holds our common stock on behalf of a non-U.S. Holder, unless such institution enters into an agreement with the U.S. government to withhold on certain payments and to collect and provide to the U.S. tax authorities substantial information regarding U.S. account holders of such institution (which includes certain equity and debt holders of such institution, as well as certain account holders that are foreign entities with U.S. owners). This U.S. federal withholding tax of 30% will also apply to dividends paid after December 31, 2013 and the gross proceeds from a disposition of our common stock paid after December 31, 2016 to a non-financial foreign entity unless such entity provides the withholding agent with either a certification that it does not have any substantial direct or indirect U.S. owners or provides information regarding direct and indirect U.S. owners of the entity. Under certain circumstances, a Non-U.S. Holder might be eligible for refunds or credits of such taxes. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this paragraph. Holders are encouraged to consult with their own tax advisors regarding the possible implications of the legislation on their investment in our common stock.

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Federal Estate Tax

An individual Non-U.S. Holder who is treated as the owner of, or has made certain lifetime transfers of, an interest in our common stock will be required to include the value thereof in his or her gross estate for U.S. federal estate tax purposes, and may be subject to U.S. federal estate tax unless an applicable estate tax treaty provides otherwise, even though such individual was not a citizen or resident of the United States at the time of his or her death.

THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME AND ESTATE TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW.

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UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement, we have agreed to sell to the underwriters named below, and the underwriters, for whom Wells Fargo Securities, LLC and JMP Securities LLC are acting as joint-book running managers and representatives, have severally agreed to purchase, the respective numbers of shares of common stock appearing opposite their names below:

Underwriter	Number of Shares
Wells Fargo Securities, LLC	
JMP Securities LLC	
Oppenheimer & Co. Inc	
Total	4,000,000

All of the shares to be purchased by the underwriters will be purchased from us.

The underwriting agreement provides that the obligations of the several underwriters are subject to various conditions, including approval of legal matters by counsel. The shares of common stock are offered by the underwriters, subject to prior sale, when, as and if issued to and accepted by them. The underwriters reserve the right to withdraw, cancel or modify the offer and to reject orders in whole or in part.

The underwriting agreement provides that the underwriters are obligated to purchase all the shares of common stock offered by this prospectus if any are purchased, other than those shares covered by the over-allotment option described below. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

Over-Allotment Option

We have granted a 30-day option to the underwriters to purchase up to a total of 600,000 additional shares of our common stock from us at the initial public offering price per share less the underwriting discounts and commissions per share, as set forth on the cover page of this prospectus, and less any dividends or distributions declared, paid or payable on the shares that the underwriters have agreed to purchase from us but that are not payable on such additional shares, to cover over-allotment, if any. If the underwriters exercise this option in whole or in part, then the underwriters will be severally committed, subject to the conditions described in the underwriting agreement, to purchase the additional shares of our common stock in proportion to their respective commitments set forth in the prior table.

Discounts and Commissions

Shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus and to certain dealers at that price less a concession of not more than $ per share, of which up to $ per share may be reallowed to other dealers. After the initial offering, the public offering price, concession and reallowance to dealers may be changed.

The following table summarizes the underwriting discounts and commissions and the proceeds, before expenses, payable to us, both on a per share basis and in total, assuming either no exercise or full exercise by the underwriters of their over-allotment option:

		Total	
	Per Share	Without Option	With Option
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses, to us	$	$	$

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We estimate that the expenses of this offering payable by us, not including underwriting discounts and commissions, will be approximately $3.3 million. We have also agreed to reimburse the underwriters for certain of their expenses in an amount up to $20,000 as set forth in the underwriting agreement.

Indemnification of Underwriters

The underwriting agreement provides that we will indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, or contribute to payments that the underwriters may be required to make in respect of those liabilities.

Lock-Up Agreements

We, each of our directors and officers, the holders of substantially all of the other shares of our common stock outstanding prior to this offering, other than shares outstanding prior to the NeoPharm merger, and the holders of substantially all of our options outstanding prior to this offering, have agreed, subject to specified exceptions, that, without the prior written consent of Wells Fargo Securities, LLC and JMP Securities LLC, we and they will not, during the period beginning on and including the date of this prospectus through and including the date that is the 180th day after the date of this prospectus, directly or indirectly:

- issue (in the case of us), offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock;

- in the case of us, file or cause the filing of any registration statement under the Securities Act with respect to any shares of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock, other than registration statements on Form S-8 filed with the SEC after the closing date of this offering; or

- enter into any swap or other agreement, arrangement, hedge or transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic consequences of ownership of our common stock or other capital stock or any securities convertible into or exercisable or exchangeable for our common stock or other capital stock,

whether any transaction described in any of the foregoing bullet points is to be settled by delivery of our common stock or other capital stock, other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing.

Wells Fargo Securities, LLC and JMP Securities LLC may, in their sole discretion and at any time or from time to time, without notice, release all or any portion of the shares or other securities subject to the lock-up agreements. Any determination to release any shares or other securities subject to the lock-up agreements would be based on a number of factors at the time of determination, which may include the market price of the common stock, the liquidity of the trading market for the common stock, general market conditions, the number of shares or other securities proposed to be sold or otherwise transferred and the timing, purpose and terms of the proposed sale or other transfer.

NASDAQ Global Market Listing

Our common stock has been approved for listing on the NASDAQ Global Market under the symbol INSY.

Stabilization

In order to facilitate this offering of our common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the market price of our common stock. Specifically, the underwriters may sell more shares of common stock than they are obligated to purchase under the

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underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares of common stock available for purchase by the underwriters under the over-allotment option. The underwriters may close out a covered short sale by exercising the over-allotment option or purchasing common stock in the open market. In determining the source of common stock to close out a covered short sale, the underwriters may consider, among other things, the market price of common stock compared to the price payable under the over-allotment option. The underwriters may also sell shares of common stock in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing shares of common stock in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after the date of pricing of this offering that could adversely affect investors who purchase in this offering.

As an additional means of facilitating this offering, the underwriters may bid for, and purchase, common stock in the open market to stabilize the price of our common stock, so long as stabilizing bids do not exceed a specified maximum. The underwriting syndicate may also reclaim selling concessions allowed to an underwriter or a dealer for distributing common stock in this offering if the underwriting syndicate repurchases previously distributed common stock to cover syndicate short positions or to stabilize the price of the common stock.

The foregoing transactions, if commenced, may raise or maintain the market price of our common stock above independent market levels or prevent or retard a decline in the market price of the common stock.

The foregoing transactions, if commenced, may be effected on the NASDAQ Global Market or otherwise. Neither we nor any of the underwriters makes any representation that the underwriters will engage in any of these transactions and these transactions, if commenced, may be discontinued at any time without notice. Neither we nor any of the underwriters makes any representation or prediction as to the direction or magnitude of the effect that the transactions described above, if commenced, may have on the market price of our common stock.

Discretionary Accounts

The underwriters have informed us that they do not intend to confirm sales to accounts over which they exercise discretionary authority in excess of five percent of the total number of shares of common stock offered by them.

Pricing of this Offering

Prior to this offering, there has been no public market for our common stock. Consequently, the initial public offering price for our common stock was determined between us and the representatives of the underwriters. The factors considered in determining the initial public offering price included:

- prevailing market conditions;
- our results of operations and financial condition;
- financial and operating information and market valuations with respect to other companies that we and the representatives of the underwriters believe to be comparable or similar to us;
- the present state of our development; and
- our future prospects.

An active trading market for our common stock may not develop. It is possible that the market price of our common stock after this offering will be less than the initial public offering price. In addition, the estimated initial public offering price range appearing on the cover of this preliminary prospectus is subject to change as a result of market conditions or other factors.

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Relationships

The underwriters and their respective affiliates are full-service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. Certain of the underwriters and their respective affiliates have, from time to time, performed various commercial banking and brokerage activities for us, for which they received customary fees and commissions. The underwriters and their respective affiliates may in the future perform these and other financial advisory and investment banking services for us, for which they will receive customary fees and commissions.

In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of instruments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve our securities and/or instruments. The underwriters and their respective affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Sales Outside the United States

No action has been taken in any jurisdiction (except in the United States) that would permit an initial public offering of the shares of our common stock that are the subject of the offering contemplated by this prospectus, or the possession, circulation or distribution of this prospectus or any other material relating to us or the shares in any jurisdiction where action for that purpose is required. Accordingly, the shares may not be offered or sold, directly or indirectly, and none of this prospectus or any other offering material or advertisements in connection with the shares may be distributed or published, in or from any country or jurisdiction except in compliance with any applicable rules and regulations of any such country or jurisdiction.

Each of the underwriters may arrange to sell shares offered hereby in certain jurisdictions outside the United States, either directly or through affiliates, where they are permitted to do so. In that regard, Wells Fargo Securities, LLC may arrange to sell shares in certain jurisdictions through an affiliate, Wells Fargo Securities International Limited, or WFSIL. WFSIL is a wholly-owned indirect subsidiary of Wells Fargo & Company and an affiliate of Wells Fargo Securities, LLC. WFSIL is a U.K. incorporated investment firm regulated by the Financial Services Authority. Wells Fargo Securities is the trade name for certain corporate and investment banking services of Wells Fargo & Company and its affiliates, including Wells Fargo Securities, LLC and WFSIL.

Notice to Prospective Investors in the European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a Relevant Member State), including each Relevant Member State that has implemented amendments to Article 3(2) of the Prospectus Directive introduced by the 2010 PD amending Directive (each, an Early Implementing Member State), an offer of the shares to the may not be made in that Relevant Member State and each underwriter represents and agrees that with effect from and including the date on which the Prospectus Directive is implemented in that Relevant Member State (the Relevant Implementation Date) it has not made and will not make an offer of the shares to the public in that Relevant Member State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the Prospectus Directive, except that an offer of the shares to the public in that Relevant Member State may be made at any time under the following

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exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to any legal entity which is a qualified investor as defined in the Prospectus Directive;

(b) to fewer than 100 (or, in the case of Early Implementing Member States, 150) natural or legal persons (other than qualified investors as defined in the Prospectus Directive) subject to obtaining the prior consent of the representatives of the underwriters; or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive, provided that no such offer of the shares referred to in (a) to (c) above shall require the Company or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive and each person who initially acquires any shares or to whom any offer is made will be deemed to have represented, warranted and agreed to and with the Company or any underwriter that it is a qualified investor within the meaning of the law in that Relevant Member State implementing Article 2(1)(e) of the Prospectus Directive.

For the purposes of this provision, the expression an offer to the public in relation to any shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe to the shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression Prospectus Directive means Directive 2003/71 EC of the European Parliament and of the Council of 4 November 2003 (and amendments thereto, including the 2010 PD Amending Directive to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

Notice to Prospective Investors in the United Kingdom

This prospectus and any other material in relation to the shares described herein is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2 (1) (e) of the Prospective Directive that also (i) have professional experience in matters relating to investments falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the Order), (ii) fall within Article 49(2)(a) to (d) of the Order and (iii) are persons to whom it may otherwise lawfully be communicated (all such persons together being referred to as relevant persons). The shares are only available to, and any invitation, offer or agreement to engage in investment activity with respect to such shares will be engaged in only with, relevant persons. This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other person in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this prospectus or any of its contents.

The distribution of this prospectus in the United Kingdom to anyone not falling within the above categories is not permitted and may contravene the United Kingdom Financial Services and Markets Act 2000. No person falling outside those categories should treat this prospectus as constituting a promotion to him, or act on it for any purposes whatever. Recipients of this prospectus are advised that we, the underwriters and any other person that communicates this prospectus are not, as a result solely of communicating this prospectus, acting for or advising them and are not responsible for providing recipients of this prospectus with the protections which would be given to those who are clients of any aforementioned entities that is subject to the rules and regulations of the Financial Services Authority.

Notice to Prospective Investors in France

We and the underwriters have not offered or sold and will not offer or sell, directly or indirectly, shares to the public in France, and have not distributed or caused to be distributed and will not

distribute or cause to be distributed to the public in France, this prospectus or any other offering material relating to the shares. Offers, sales and distributions that have been and will be made in France have been and will be made only to (a) providers of the investment service of portfolio management for the account of third parties, and (b) qualified investors (investisseurs qualifiés), other than individuals, all as defined in, and in accordance with, Articles L. 411-1, L. 411-2, and D. 411-1 of the French Code monétaire et financier.

Shares may be resold directly or indirectly only in compliance with Article L. 411-1, L. 411-2, L. 412-1 and L. 621-8 to L. 621-8-3 of the French Code monétaire et financier.

Neither this prospectus prepared in connection with the shares nor any other offering material relating to the shares has been submitted to the clearance procedures of the Autorité des marchés financiers or notified to the Autorité des marchés financiers by the competent authority of another member state of the European Economic Area.

Notice to Prospective Investors in Germany

The shares offered by this prospectus have not been and will not be offered to the public within the meaning of the German Securities Prospectus Act (Wertpapierprospektgesetz). No securities prospectus pursuant to the German Securities Prospectus Act has been or will be published or circulated in Germany or filed with the German Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht). This prospectus does not constitute an offer to the public in Germany, and it does not serve for public distribution of the shares in Germany. Neither this prospectus, nor any other document issued in connection with this offering, may be issued or distributed to any person in Germany except under circumstances that do not constitute an offer to the public under the German Securities Prospectus Act. Prospective Investors should consult with their legal and/or tax advisor before investing into the shares.

Notice to Prospective Investors in Ireland

This prospectus and any other material in relation to the shares described herein is only being distributed in Ireland:

(i) in circumstances which do not require the publication of a prospectus pursuant to Article 3(2) of Directive 2003/71/EC as amended by Directive 2010/73/EC;

(ii) in compliance with the provisions of the Irish Companies Acts 1963-2009; and

(iii) in compliance with the provisions of the European Communities (Markets in Financial Instruments) Regulations 2007 (S.I. No. 60 of 2007) (as amended), and in accordance with any codes or rules of conduct and any conditions or requirements, or any other enactment, imposed or approved by the Central Bank of Ireland with respect to anything done by them in relation to the shares.

Notice to Prospective Investors in Italy

The offering of the shares has not been registered pursuant to Italian securities legislation and, accordingly, no shares may be offered, sold or delivered, nor may copies of the prospectus or of any other document relating to the shares be distributed in the Republic of Italy, except:

(i) to qualified investors (investitori qualificati), as defined pursuant to Article 100 of Legislative Decree No. 58 of 24 February 1998, as amended (the Financial Services Act) and Article 34-ter, first paragraph, letter b) of CONSOB Regulation No. 11971 of 14 May 1999, as amended from time to time (Regulation No. 11971); or

(ii) in other circumstances which are exempted from the rules on public offerings pursuant to Article 100 of the Financial Services Act and Article 34-ter of Regulation No. 11971.

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Any offer, sale or delivery of the shares or distribution of copies of the prospectus or any other document relating to the shares in the Republic of Italy under (i) or (ii) above must be:

(a) made by an investment firm, bank or financial intermediary permitted to conduct such activities in the Republic of Italy in accordance with the Financial Services Act, CONSOB Regulation No. 16190 of 29 October 2007 (as amended from time to time) and Legislative Decree No. 385 of 1 September 1993, as amended (the Banking Act); and

(b) in compliance with Article 129 of the Banking Act, as amended, and the implementing guidelines of the Bank of Italy, as amended from time to time, pursuant to which the Bank of Italy may request information on the issue or the offer of shares in the Republic of Italy; and

(c) in compliance with any other applicable laws and regulations or requirement imposed by CONSOB or other Italian authority. Please note that in accordance with Article 100-bis of the Financial Services Act, where no exemption from the rules on public offerings applies under (i) and (ii) above, the subsequent distribution of the shares on the secondary market in Italy must be made in compliance with the public offer and the prospectus requirement rules provided under the Financial Services Act and Regulation No. 11971. Failure to comply with such rules may result in the sale of such shares being declared null and void and in the liability of the intermediary transferring the shares for any damages suffered by the investors.

Notice to Prospective Investors in the Netherlands

The shares will not be offered or sold, directly or indirectly, in the Netherlands, other than:

(i) with a minimum denomination of 50,000 or the equivalent in another currency per investor;

(ii) for a minimum consideration of 50,000 or the equivalent in another currency per investor;

(iii) to fewer than 100 individuals or legal entities other than Qualified Investors (see below); or

(iv) solely to Qualified Investors, all within the meaning of Article 4 of the Financial Supervision Act Exemption Regulation (Vrijstellingsregeling Wet op het financieel toezicht) and Article 1:12 and Article 5:3 of the Financial Supervision Act (Wet op het financieel toezicht, FSA).

Notice to Prospective Investors in Switzerland

This document as well as any other material relating to the shares of our common stock that are the subject of the offering contemplated by this prospectus do not constitute an issue prospectus pursuant to Article 652a or Article 1156 of the Swiss Code of Obligations. Our common stock will not be listed on the SWX Swiss Exchange and, therefore, the documents relating to our common stock, including, but not limited to, this document, do not claim to comply with the disclosure standards of the listing rules of SWX Swiss Exchange and corresponding prospectus schemes annexed to the listing rules of the SWX Swiss Exchange.

Our common stock is being offered in Switzerland by way of a private placement, i.e., to a small number of selected investors only, without any public offer and only to investors who do not purchase shares of our common stock with the intention to distribute them to the public. The investors will be individually approached by us from time to time.

This document as well as any other material relating to our common stock is personal and confidential and does not constitute an offer to any other person. This document may only be used by those investors to whom it has been handed out in connection with the offering described herein and may neither directly nor indirectly be distributed or made available to other persons without our express consent. It may not be used in connection with any other offer and shall in particular not be copied and/or distributed to the public in (or from) Switzerland.

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LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Cooley LLP, San Diego, California. The underwriters are being represented by Latham & Watkins LLP, San Diego, California.

EXPERTS

The consolidated financial statements of Insys Therapeutics, Inc. as of December 31, 2012 and 2011 and for the years then ended included in this prospectus have been so included in reliance on the report of BDO USA, LLP, an independent registered public accounting firm appearing elsewhere herein, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC s website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street NE, Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street NE, Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 444 South Ellis Street, Chandler, Arizona 85224 or telephoning us at (602) 910-2617.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.insysrx.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website incorporated by reference in, and is not part of, this prospectus.

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of

Insys Therapeutics, Inc.

Chandler, Arizona

We have audited the accompanying consolidated balance sheets of Insys Therapeutics, Inc. (the Company) as of December 31, 2012 and 2011 and the related consolidated statements of comprehensive loss, stockholders deficit, and cash flows for the years then ended. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Insys Therapeutics, Inc. as of December 31, 2012 and 2011, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ BDO USA, LLP

Phoenix, Arizona

February 26, 2013

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INSYS THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share data)

	Unaudited Pro forma Stockholders Deficit as of December 31, 2012	As of December 31, 2012	2011
ASSETS			
Current Assets:			
Cash and cash equivalents		$ 361	$ 11
Accounts receivable, net		3,089	
Inventories		7,095	6,735
Prepaid expenses and other assets		1,344	1,162
Total current assets		11,889	7,908
Property and equipment, net		6,791	7,479
Intangible assets			5,300
Goodwill			103
Other assets		61	170
Total assets		$ 18,741	$ 20,960
LIABILITIES AND STOCKHOLDERS DEFICIT			
Current Liabilities:			
Accounts payable and accrued expenses		$ 5,971	$ 7,902
Accrued compensation		1,392	476
Other current liabilities		508	508
Deferred patient discount program		1,540	
Deferred revenue		3,767	
Line of credit		11,858	
Notes payable to related party, including interest	$	58,383	52,815
Total current liabilities		83,419	61,701
Contingent payment obligation			2,114
Other long-term liabilities			358
Total liabilities		83,419	64,173
Commitments and contingencies (see Note 9)			
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 December 31, 2012, and 2011)		149	149
Common stock (par value $0.0002145 per share, 25,000,000 shares and 750,000,000 shares authorized as of December 31, 2012 and 2011, respectively; 856,026 shares and 784,020 shares issued and outstanding as of December 31, 2012 and 2011, respectively)	3		
Additional paid in capital	123,133	64,604	61,691
Notes receivable from stockholders	(21)	(21)	(21)

Accumulated deficit	(129,410)	(129,410)	(105,032)
Total stockholders deficit	$ (6,295)	(64,678)	(43,213)
Total liabilities and stockholders deficit		$ 18,741	$ 20,960

See accompanying notes to consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(in thousands, except share and per share data)

	Years Ended December 31,	
	2012	2011
Net revenue	$ 15,476	$
Cost of revenue	7,627	
Gross profit	7,849	
Operating expenses:		
Sales and marketing	11,411	
Research and development	6,305	8,334
General and administrative	8,170	9,039
Impairment of intangible assets and goodwill	5,403	
Total operating expenses	31,289	17,373
Loss from operations	(23,440)	(17,373)
Other income (expense), net	1,746	(25)
Interest expense	(2,684)	(1,963)
Loss before income taxes	(24,378)	(19,361)
Income tax benefit		
Net and comprehensive loss	$ (24,378)	$ (19,361)
Net loss allocable to preferred stockholders	$ (22,318)	$ (17,731)
Net loss allocable to common stockholders	$ (2,060)	$ (1,630)
Basic and diluted net loss per common share	$ (2.62)	$ (2.08)
Basic and diluted weighted average common shares outstanding	787,174	784,020
Pro forma basic and diluted net loss per share (unaudited)	$ (1.37)	
Pro forma basic and diluted weighted average shares outstanding (unaudited)	15,902,216	

See accompanying notes to consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT

(in thousands, except share amounts)

	Common Stock		Convertible Preferred Stock		Additional Paid-In Capital	Notes Receivable from Stockholders	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2010	784,020	$	14,864,607	$ 149	$ 60,026	$ (26)	$ (85,671)	$ (25,522)
Stock-based compensation expense					1,693			1,693
Shares repurchased					(28)			(28)
Repayment of employee loans						5		5
Net loss							(19,361)	(19,361)
Balance at December 31, 2011	784,020		14,864,607	149	61,691	(21)	(105,032)	(43,213)
Stock-based compensation expense					2,761			2,761
Exercise of stock options	72,006				152			152
Net loss							(24,378)	(24,378)
Balance at December 31, 2012	856,026	$	14,864,607	$ 149	$ 64,604	$ (21)	$ (129,410)	$ (64,678)

See accompanying notes to consolidated financial statements.

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INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31, 2012	2011
Cash flows from operating activities:		
Net loss	$ (24,378)	$ (19,361)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,662	1,385
Stock-based compensation	2,761	1,693
Impairment of intangible assets	5,300	
Impairment of goodwill	103	
Loss on disposal of assets	46	
Interest expense, accrued on notes payable	2,582	1,964
Accretion (re-valuation) of contingent payment obligation	(2,114)	285
Changes in assets and liabilities:		
Accounts receivable	(3,089)	
Inventories	(360)	(5,955)
Prepaid expenses and other assets	(73)	(1,090)
Accounts payable, accrued expenses, and other current liabilities	166	5,700
Deferred revenue	3,767	
Net cash used in operating activities	(13,627)	(15,379)
Cash flows from investing activities:		
Purchase of property and equipment	(1,020)	(599)
Net cash used in investing activities	(1,020)	(599)
Cash flows from financing activities:		
Proceeds from line of credit	11,858	
Proceeds from note payable to related party	2,987	15,953
Proceeds from exercise of stock options	152	
Repurchase of common stock		(28)
Net cash provided by financing activities	14,997	15,925
Net increase (decrease) in cash and cash equivalents	350	(53)
Cash and cash equivalents, beginning of year	11	64
Cash and cash equivalents, end of year	$ 361	$ 11
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 98	$

See accompanying notes to consolidated financial statements.

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Business

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 has two marketed products: Subsys, a proprietary sublingual fentanyl spray for breakthrough cancer pain in opioid-tolerant patients and Dronabinol SG Capsule, a generic equivalent to Marinol, an approved second-line treatment for chemotherapy-induced nausea and vomiting and anorexia associated with weight loss in patients with AIDS.

2. Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expense during the reporting period. Actual results could differ from those estimates.

Principles of Consolidation

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.

Since Insys Pharma, formerly known as Insys Therapeutics, Inc., was the acquiring entity for accounting purposes, the financial statements for all periods up to and including the November 8, 2010 NeoPharm merger date are the financial statements of the entity that is now the subsidiary, Insys Pharma. The financial statements for all periods subsequent to the November 8, 2010 NeoPharm merger date are the consolidated financial statements of Insys and Insys Pharma.

All significant intercompany balances and transactions have been eliminated in the accompanying consolidated financial statements. Certain reclassifications have been made to prior year amounts to conform to the current year presentation.

Unaudited Pro Forma Stockholders Deficit

The unaudited pro forma stockholders deficit as of December 31, 2012 reflects the automatic conversion of all outstanding shares of convertible preferred stock and $58,383,000 of notes payable from related parties as of December 31, 2012 into 8,528,860 and 6,487,000 shares of common stock, respectively, immediately prior to the closing of the public offering (offering) contemplated by the Company s filing of its registration statement on Form S-1 (the Registration Statement) with the Securities and Exchange Commission (SEC) in May 2013, assuming an offering price of $9.00 per share (the mid-point of the price range set forth on the cover page of this preliminary prospectus). The shares of common stock issued in the offering and the Company s estimated net proceeds are excluded in such pro forma information.

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 does not have financial assets or liabilities that are measured at fair value on a recurring basis as of December 31, 2012 and 2011.

Financial Accounting Standards Board (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.

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

INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

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

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents. The carrying value of those investments approximates their fair market value due to their short maturity and liquidity. Cash and cash equivalents include cash on hand and amounts on deposit with financial institutions.

Accounts Receivable, Net

Trade accounts receivable are recorded at the invoice amount net of allowances for cash discounts for prompt payment. The Company evaluates the collectability of its accounts receivable based on a variety of factors including the length of time the receivables are past due, the financial health of the customer and historical experience. Based upon the review of these factors, the Company did not record an allowance for doubtful accounts as of December 31, 2012. The need for an allowance for doubtful accounts is evaluated each reporting period.

Inventories

Inventories consist of raw materials, work-in-process and finished product and are valued at the lower of cost (first-in, first-out cost method) or market. Inventory costs are capitalized prior to regulatory approval and product launch based on management s judgment of probable future commercial use and net realizable value of the inventory. Such judgment incorporates the Company s knowledge and best estimate of where the relevant product is in the regulatory process, the Company s required investment in the product, market conditions, competing products and the Company s economic expectations for the product post-approval relative to the risk of manufacturing the product prior to approval. In evaluating the recoverability of inventories produced in preparation for product launches, the Company considers the probability that revenue will be obtained from the future sale of the related inventory together with the status of the product within the regulatory approval process, as well as the market for the product in its current state. The Company could be required to permanently write down previously

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

capitalized costs related to pre-approval or pre-launch inventory upon a change in such judgment, due to a denial or delay of approval by regulatory bodies, a delay in commercialization, or other potential factors including product expiration.

Property and Equipment, Net

Property and equipment are recorded at cost and depreciated using the straight-line method over their estimated useful lives. Maintenance and repairs that do not extend the life of assets are charged to expense when incurred. When properties are disposed of, the related costs and accumulated depreciation are removed from the accounts and any gain or loss is reported in the period the transaction takes place.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to estimated undiscounted cash flows expected to be generated by the asset. If the carrying amount exceeds its estimated future undiscounted cash flows, an impairment charge is recognized by the amount by which the carrying amount exceeds the fair value of the asset.

Intangible Assets

As described in Note 5, the Company s intangible assets were fully impaired in 2012. Prior to that impairment, intangible assets consisted of in-process research and development (IPR&D) acquired in the NeoPharm merger. The valuations and useful life assumptions were based on information available near the NeoPharm merger date and on expectations and assumptions that were considered reasonable by management.

The Company evaluates IPR&D, which has an indefinite useful life, for impairment on an annual basis as of October 1, or more frequently if an event occurs creating the potential for impairment, until such time as the research and development efforts are completed or abandoned. If the research and development efforts are abandoned, the related costs will be written off in the period of such determination. If the research and development efforts are completed successfully, the related assets will be amortized over the estimated useful life of the underlying products. The Company will amortize the cost of identified intangible assets using amortization methods that reflect the pattern in which the economic benefits of the intangible assets are consumed or otherwise realized. The Company reviews intangible assets that have finite useful lives when an event occurs creating the potential for impairment. The Company reviews for impairment by examining facts or circumstances, either external or internal, indicating that the Company may not recover the carrying value of the asset. The Company measures impairment losses related to indefinite-lived intangible assets based on the amount by which the carrying amounts of these assets exceed their fair values. The Company measures fair value generally based on the estimated future cash flows. The Company s analysis is based on available information and on assumptions and projections that it considers to be reasonable and supportable. If necessary, the Company will perform subsequent calculations to measure the amount of the impairment loss based on the excess of the carrying value over the fair value of the impaired assets.

Goodwill

As described in Note 6, the Company s goodwill was fully impaired in 2012. Prior to that impairment, goodwill represented the excess of the purchase price over the fair value of the net assets acquired in the NeoPharm merger. Goodwill was tested for impairment annually as of October 1, or more frequently if indications of impairment arose.

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Income Taxes

Prior to November 8, 2010, Insys Pharma was subject to taxation under the provisions of Subchapter S of the U.S. Internal Revenue Code of 1986, as amended (the Code), and, as a result, the federal and state income tax liabilities of this entity were the responsibility of its stockholders. Accordingly, no provision was made for federal or state income taxes, since it was the personal responsibility of the individual stockholders of this entity to separately report their proportionate share of its taxable income or loss. As of November 8, 2010, as a result of the NeoPharm merger, Insys Pharma became a Subchapter C Corporation and became subject to U.S. federal and state income tax at the corporate level. The effect of this change in the tax status was to recognize a one-time non-cash tax benefit of $3,000,000, to establish a $3,000,000 net deferred tax asset for the future tax consequences attributable to differences between the financial statement and income tax bases of its assets and liabilities as of November 8, 2010. The Company recorded a full valuation allowance against this net deferred tax asset.

The Company accounts for its deferred income tax assets and liabilities based on differences between the financial reporting and tax bases of assets and liabilities, and net operating loss carry forwards (the NOLs) and other tax credit carry forwards. These items are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The effect of a change in tax rates on deferred tax assets and liabilities is recognized in the period that includes the enactment date.

The Company records a valuation allowance to reduce the deferred income tax assets to the amount that is more likely than not to be realized. In making such determinations, management considers all available positive and negative evidence, including scheduled reversals of deferred tax liabilities, projected future taxable income, tax planning strategies and recent financial operations.

The Company recognizes a tax benefit from uncertain tax positions when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits of the position. The Company recognizes interest accrued on unrecognized tax benefits and penalties in income tax expenses.

Research and Development Expenses

Research and development (R&D) costs are expensed when incurred. These costs consist of external research and development expenses incurred under agreements with third-party contract research organizations and investigative sites, third-party manufacturing organizations 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 expense, depreciation and other allocated expenses; and equipment and laboratory supplies.

Stock-Based Compensation Expenses

Stock-based compensation cost is estimated at the grant date based on the fair value of the award, and the cost is recognized as expense ratably over the vesting period. The Company uses the Black-Scholes option pricing model for estimating the grant date fair value of stock options. Determining the assumptions that are inputs of the model is highly subjective and requires judgment. The exercise price is based on valuations using the best information available to management at the time of the valuations. Prior to the NeoPharm merger, the Company did not have a history of market prices for its common stock and since the NeoPharm merger, it does not have what it considers a sufficiently active and readily traded market for its common stock to use historical market prices for its common stock to estimate volatility. Accordingly, the Company estimates the expected stock price volatility for its common stock

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

by taking the median historical stock price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. The expected term is based on a simplified method which defines the life as the average of the contractual term of the options and the weighted-average vesting period for all open employee awards. The risk-free interest rate for the expected term of the option is based on the average market rate on U.S. treasury securities in effect during the quarter in which the options were granted. The dividend yield assumption is based on the Company s history and expectation of paying no dividends. Forfeitures are assumed to be insignificant.

Grant Income

The Company records income from grants in other income on a systematic and rational basis in the periods they are intended to benefit. For the years ended December 31, 2012 and 2011, the Company recorded approximately $0 and $245,000, respectively, of income related to grants.

Segment Information

FASB ASC No. 280, Segment Reporting establishes standards for reporting information about reportable segments. Operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group (CODM), in deciding how to allocate resources and in assessing performance. The CODM evaluates revenues and gross profits based on product lines and routes to market. Based on the Company s integration and management strategies, the Company operates in a single reportable segment.

Recent Accounting Pronouncements

In June 2011, the FASB issued an amendment to the existing guidance on the presentation of comprehensive income. Under the amended guidance, entities have the option to present the components of net income and other comprehensive income in either a single continuous statement of comprehensive income or in two separate but consecutive statements. Entities no longer have the option of presenting the components of other comprehensive income within the statement of changes in stockholders equity. For public entities, the amendment is effective on a retrospective basis for fiscal years, and interim periods within those years, beginning after December 15, 2011. Adoption of this amendment resulted in a change to the Company s presentation of comprehensive income.

3. 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.

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	As of December 31, 2012	2011
Finished goods	$ 2,221	$ 1,814
Work-in-process	1,731	2,961
Raw materials and supplies	2,597	1,960
Deferred costs	546	
Total Inventories	$ 7,095	$ 6,735

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

As of December 31, 2012 and 2011, 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.

4. Property and Equipment

Property and equipment are comprised of the following (dollars in thousands):

	Estimated Useful Life (in years)	As of December 31, 2012	2011
Computer equipment	3-5	$ 514	$ 231
Scientific equipment	5-7	4,931	4,701
Furniture	5-7	359	150
Manufacturing equipment	5	1,975	1,975
Leasehold improvements	*	3,641	3,485
Less accumulated depreciation and amortization		(4,629)	(3,063)
Property and equipment, net		$ 6,791	$ 7,479

* The estimated useful life of the leasehold improvements is the lesser of the lease term or five years.

Manufacturing equipment consists of tools, molds and dies owned by the supplier of the Subsys spray device that were funded by the Company. This equipment is amortized over the life of the supply agreement. Prior to commercialization of Subsys, amortization expense was included in research and development expense. Upon Subsys commercial launch in March 2012, the Company began including amortization expense in cost of revenue.

Total depreciation and amortization expense for the years ended December 31, 2012 and 2011 was $1,662,000 and $1,385,000, respectively.

5. Intangible Assets

In connection with the NeoPharm merger, the Company recorded IPR&D as an intangible long-lived asset with an indefinite useful life in the amount of $5,300,000, of which $4,200,000 related to LEP-ETU and $1,100,000 related to IL-13. The acquisition-date fair value of the IPR&D was determined primarily through the use of the cost approach, which is a Level 3 fair value measurement. The cost approach relies on historical costs incurred adjusted for estimated wasted efforts and taxes.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

LEP-ETU is a liposomal formulation of the widely used cancer drug, paclitaxel. At the time of the NeoPharm merger, a Phase 2 clinical trial for LEP-ETU was ongoing in India and approximately 75% of the patients had been enrolled for that trial. The Phase 2 clinical trial was completed in December 2011. However, a significant amount of additional work remains on this formulation and the chances of success at this point for a commercially viable product using the agent are low. The Company is currently evaluating next steps with respect to this drug product candidate.

IL-13 is a potential therapeutic agent for the treatment of idiopathic pulmonary fibrosis (IPF) and asthma. Prior to the NeoPharm merger, an investigational New Drug Application (IND) was submitted by NeoPharm for a Phase 1 study in IPF, and that submission was on hold by the FDA at the time of the NeoPharm merger and remains on hold as of December 31, 2012. IL-13 was also granted an orphan drug designation for this indication. All work done at the time of the NeoPharm merger was preclinical and no human clinical trials had been performed. The complexity and uniqueness of this project is quite extensive since the agent is a combination of a protein and an endotoxin and must be maintained at the right temperature in a solution. The planned delivery system for the agent is a nebulizer which is still in a state of refinement. Additionally, there are Chemistry, Manufacturing and Control (CMC) challenges that must be overcome in order to have a commercially viable product. A significant amount of additional work remains on this indication and the chances of success at this point for a commercially viable product using the agent are low. The Company is currently evaluating next steps with respect to this drug product candidate.

As of October 1, 2012, as a result of the Company s commercialization of Subsys and Dronabinol SG Capsule, and a product development strategy focused on expansion of the Subsys spray technology and dronabinol line of products (including Dronabinol Oral Solution), the Company determined that there was an indication that its recorded intangible assets associated with its acquisition of NeoPharm might be impaired. Accordingly, the Company performed an impairment analysis utilizing a discounted future cash flow approach, which is a Level 3 fair value measurement, and determined that the intangible assets associated with NeoPharm were fully impaired. As a result, during the quarter ended December 31, 2012, the Company recorded an impairment charge of $5,300,000. This impairment charge is included in the consolidated statements of comprehensive loss under the caption Impairment of intangible assets and goodwill.

6. Goodwill

The Company recorded goodwill in the amount of $103,000 in connection with its acquisition of NeoPharm in November 2010.

As of October 1, 2012, as a result of the Company s commercialization of Subsys and Dronabinol SG Capsule, and a product development strategy focused on expansion of the Subsys spray technology and dronabinol line of products (including Dronabinol Oral Solution), the Company determined that there was an indication that its goodwill recorded in connection with its acquisition of NeoPharm might be impaired. Accordingly, the Company performed an impairment analysis utilizing a discounted future cash flow approach, which is a Level 3 fair value measurement, and determined that the goodwill associated with NeoPharm was fully impaired. As a result, during the quarter ended December 31, 2012, the Company recorded an impairment charge of $103,000. This impairment charge is included in the consolidated statements of comprehensive loss under the caption Impairment of intangible assets and goodwill.

The Company evaluated goodwill for impairment as of October 1, 2011 and determined its recorded goodwill was not impaired as of that date.

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7. 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 December 31, 2012) 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 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 $11,858,000 against the line of credit as of December 31, 2012. The line of credit is subject to covenants. The Company is currently in compliance with the covenants. In February 2013, the Facility was amended to extend its maturity date to February 2014.

8. 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. The Company draws on the Kapoor Notes as needed to pay its expenses. In general, unless otherwise noted, the principal and interest are due upon maturity. The Kapoor Notes carry interest at the prime rate plus 2.0% (5.25% as of December 31, 2012). The following is a summary of the outstanding Kapoor Notes.

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 refer to Note 10. 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 December 31, 2012. The Company had not repaid the principal or interest accrued on the Kapoor Notes as of December 31, 2012 and they are currently payable on demand. Although by their terms the Kapoor Notes are payable on demand, the JNK Trust and the Kapoor Children 1992 Trust have each agreed not to require the Company to repay any outstanding indebtedness under the Kapoor Notes until March 31, 2014 and have further agreed to convert all outstanding indebtedness under the Kapoor Notes into shares of the Company s common stock at the initial public offering price immediately prior to the closing of the offering as described in Note 2.

In connection with one of these notes issued in February of 2008, the Company issued a warrant to The JNK Trust to purchase up to an aggregate of 18,917 shares of the Company s common stock, which expired in February 2011.

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 December 31, 2012 and it is currently payable on demand. Although by its terms this note is payable on demand, the JNK Trust agreed not to require the Company to repay any outstanding indebtedness under this note until March 31, 2014 and has further agreed to convert all outstanding indebtedness under this note into shares of the Company s common stock at the initial public offering price immediately prior to the closing of the offering as described in Note 2.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Total interest accrued on these notes approximated $9,757,000 and $7,175,000 as of December 31, 2012 and 2011, respectively. Interest expense was approximately $2,582,000 and $1,963,000 for the years ended December 31, 2012 and 2011, respectively.

The balance payable on these notes, including interest, was approximately $58,383,000 and $52,815,000 as of December 31, 2012 and 2011, respectively.

9. Commitments and Contingencies

Lease Commitments

The Company leases facilities under non-cancelable operating lease agreements. Future minimum commitments for these operating leases in place as of December 31, 2012, with a remaining non-cancelable lease term in excess of one year, are as follows (dollars in thousands):

Years Ending December 31,	
2013	$ 500
2014	431
2015	432
2016	428
2017	263
Thereafter	21
Total	$ 2,075

Dr. John N. Kapoor, the Company s founder, Executive Chairman and principal stockholder, guarantees the lease commitments under one of these operating leases totaling $724,000 as of December 31, 2012.

The terms of certain lease agreements provide for rental payments on a graduated basis. The Company recognizes rent expense on the straight-line basis over the lease period and has accrued for rent expense incurred but not paid. Rent expense under operating leases for the years ended December 31, 2012 and 2011 was approximately $586,000 and $604,000, respectively.

Defined Contribution Retirement Plans (401(k) Plans)

Insys and Insys Pharma each sponsor a 401(k) plan covering all full-time employees. Participants may contribute up to the legal limit. The 401(k) plans provide for employee contributions, but the Company and Insys Pharma do not make any matching contributions.

Contractual Commitments

Manufacture and Supply Agreements

DPT Lakewood, LLC (DPT) DPT is the Company s contractor which manufactures and packages Subsys. In May 2011, the Company entered into a manufacturing agreement with DPT on an exclusive basis to provide processing and packaging services with respect to Subsys. Unless terminated earlier, the agreement has an initial term continuing until December 31, 2017, followed by automatic 24-month renewal periods unless either party provides notice at least 24 months prior to the expiration of the initial term or any renewal term. Under the terms of the agreement, the Company is obligated to provide DPT a written, non-binding rolling 18-month forecast on a monthly basis, with the first four-month forecast constituting a firm purchase order regardless of receipt of the Company s actual purchase order.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Catalent Pharma Solutions, LLC (Catalent) In March 2011, the Company entered into a commercial manufacturing and packaging agreement with Catalent pursuant to which the Company engaged Catalent on an exclusive basis to provide processing and packaging services with respect to Dronabinol SG Capsule finished product. Under the terms of the agreement, which was amended on March 5, 2012, the Company is required to supply Catalent with the API for Dronabinol SG Capsule and obligated to make minimum annual purchases, pay annual product maintenance fees and pay post-packaging analysis testing fees for each batch of product tested. The initial term of the agreement is five years, unless earlier terminated, and automatically renews for additional periods of two years, unless the Company or Catalent gives the other party at least 12 months prior written notice of its desire to terminate the agreement. As of December 31, 2012, the Company s remaining estimated contractual obligation to be paid for product manufacturing through the end of the term of the agreement was approximately $1,833,000.

Clinical Trial and Research Agreements

Worldwide Clinical Trials (Worldwide) In 2010, the Company entered into an agreement with Worldwide, a clinical research organization, to conduct clinical studies and trials of Dronabinol Oral Solution. This agreement was subsequently amended in October 2011, and as of December 31, 2012, the estimated contractual obligation to be paid to Worldwide was approximately $189,000, which was paid in January 2013.

NeoPharm Contingent Consideration

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 were recorded in other expense.

In October 2012, in connection with its analysis of impairment of IPR&D (see Note 5), the Company determined it was not probable that the contingent consideration would be paid. Accordingly, a decrease in the estimated fair value of contingent consideration of $2,324,000 was recorded in the statement of comprehensive loss as 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

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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 May 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.

10. Equity

Convertible Preferred Stock

Pursuant to the NeoPharm merger, all of the outstanding common stock of Insys prior to the merger was exchanged for 319,667 shares of NeoPharm common stock and 14,864,607 shares of newly-created NeoPharm convertible preferred stock. The convertible preferred stock is convertible into common stock on a one-to-0.57377 basis and, until converted, will be entitled to the voting and dividend rights of the same number of shares of common stock into which it is convertible. Each share of convertible preferred stock will automatically convert into shares of the Company s common stock immediately prior to the closing of an offering of common stock at the conversion ratio.

Common Stock

The share data presented in the balance sheets and statements of stockholders deficit and the share and per share data presented in the statements of comprehensive loss have been retroactively adjusted to account for a one-for-2.35 reverse stock split on January 17, 2008, a one-for-1,500,000 reverse stock split on June 2, 2009, a 1,862,623-for-one stock split on February 22, 2010, a one-for-61 reverse stock split on July 14, 2011 and the NeoPharm merger.

On December 29, 2009, debt and accrued interest payable to The JNK Trust and Dr. John N. Kapoor totaling $11,549,000 was converted into 253,414 shares of the Company s common stock, which was based on the then existing fair market value per share of a minority, non-marketable interest in the Company. On July 25, 2008, The JNK Trust converted approximately $24,197,000 of debt and accrued interest into 38,112 shares of the Company s common stock. On July 25, 2008, the Company sold 13,559 shares of the Company s common stock to The JNK Trust for total proceeds of $8,609,000. Certain of these transactions were based on the then fair market value per share of a minority, non-marketable

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interest in the Company. Compensation expense of $3,160,000 and $3,942,000 was recognized in 2009 and 2008, respectively, for the conversions based on the difference between the fair market value per share of a 100% equity interest in the Company and the fair market value per share of the minority, non-marketable interest.

In connection with the one-for-1,500,000 reverse stock split in June 2009, the Company agreed to repurchase common shares from those stockholders which were left with only fractional shares after the reverse stock split. The Company recorded a liability of $547,000 to these stockholders as of December 31, 2010 and 2009 relating to this repurchase of 14,911 aggregate shares. The remaining liability is approximately $508,000 as of December 31, 2012 and 2011, and is included in Other current liabilities on the Company s consolidated balance sheets.

In March 2011, total authorized shares of the Company s common stock was increased from 50,000,000 shares to 750,000,000 shares. In May 2012, the total authorized shares of the Company s common stock was decreased from 750,000,000 shares to 25,000,000 shares.

11. Stock-based Compensation

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

2006 Equity Incentive Plan

The Company s 2006 Equity Incentive Plan (the 2006 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. The 2006 Plan was adopted in April 2006. Through December 2012, the Company amended the 2006 Plan to increase the total shares available for future grant to 1,186,311 shares. As of December 31, 2012, options to purchase 1,146,658 shares of common stock were outstanding and 32,647 shares remained available for future grant.

Awards under the 2006 Plan generally consist 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 vest ratably over four years, subject to continuous employment. Stock awards granted to the Company s non-employee directors under the 2006 Plan typically vest one year from the date of grant. Awards under the 2006 Plan vest immediately upon a change in control. Although the 2006 Plan provides for the issuance of performance units and performance shares, the Company has not made 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) provides 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 December 31, 2012, 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 December 31, 2012. 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

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typically have a ten-year life and vest within the first two years of the grant, subject to continuous employment. Option awards granted to Insys Pharma s non-employee consultants under the Plan typically vest within two years from the date of grant. These options are 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 loss with respect to the Company s stock-based compensation plans were as follows (dollars in thousands):

	Years Ended December 31,	
	2012	2011
Research and development	$ 1,055	$ 831
General and administrative	1,706	862
Total cost of stock-based compensation	$ 2,761	$ 1,693

The Company has never capitalized, or recognized an income tax benefit from, stock-based compensation.

The following table summarizes stock option activity during the years ended December 31, 2012 and 2011:

	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, 2011	1,195,422	$ 4.18	8.22	$ 15.1
Outstanding as of December 31, 2011	1,775,157	$ 4.18	8.57	$ 21.3
Granted	571,500	$ 3.54		
Cancelled	(183,456)	$ 13.94		
Exercised	(72,006)	$ 2.12		
Outstanding as of December 31, 2012	2,091,195	$ 3.22	8.24	$ 12.40
Vested and exercisable as of December 31, 2012	1,228,396	$ 2.78	7.43	$ 2.80

The aggregate intrinsic value for stock options outstanding and exercisable is defined as the positive difference between the fair market value of the Company s common stock and the exercise price of the stock options. As of December 31, 2012, the Company expects to recognize $11,167,000 of stock-based compensation for its outstanding options over a weighted-average period of 2.9 years.

Stock Option Valuation Information

The Company currently uses the Black-Scholes option pricing model to estimate the fair value of its stock-based payment awards. The determination of the fair value of stock-based payment awards utilizing the Black-Scholes model is affected by the Company s stock price and a number of assumptions, including expected volatility, risk-free interest rate, expected term, expected dividends yield and expected forfeiture rate. Prior to the NeoPharm merger, the Company did not have a history of market prices for its common stock and since the merger, it did not

have what it considered a sufficiently active and readily traded market for its common stock to use historical market prices for its common stock to estimate volatility. Accordingly, the Company estimates the expected stock price volatility for its common stock by taking the median historical stock price volatility for industry peers based on daily price observations over

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a period equivalent to the expected term of the stock option grants. Industry peers consist of other public companies in the pharmaceutical industry similar in size, stage of life cycle and financial leverage. The Company s industry peers for estimating stock price volatility changed for the year ended December 31, 2012 as compared to the year ended December 31, 2011 as a result of the Company s transition from a development stage company to a commercial stage company. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of the Company s awards. The risk-free interest rate assumption is based on the yields of U.S. Treasury securities with maturities similar to the expected term of the options for each option group. The expected term represents the period that the Company s stock-based awards are expected to be outstanding. The expected terms of the awards are based on a simplified method which defines the life as the average of the contractual term of the options and the weighted-average vesting period for all open tranches. The Company has never declared or paid any cash dividends and does not presently plan to pay cash dividends in the foreseeable future. Consequently, the Company used an expected dividend yield of zero. The Company estimates its forfeiture rate based on an analysis of its actual forfeitures and will continue to evaluate the appropriateness of the forfeiture rate based on actual forfeiture experience, analysis of employee turnover and other factors. Changes in the estimated forfeiture rate can have a significant impact on our stock-based compensation expense as the cumulative effect of adjusting the rate is recognized in the period the forfeiture estimate is changed. The weighted-average assumptions used to estimate the fair value of employee stock options granted during the periods presented are as follows:

	2012	2011
Expected volatility (range)	65.0%	108.1 109.2%
Expected volatility (weighted average)	65.0%	108.9%
Risk-free interest rate	1.15%	1.9 3.5%
Expected term (in years)	6.5 7.0	6.5 7.0
Expected dividend yield	0.0%	0.0%

For the year ended December 31, 2012, the weighted-average estimated fair value per option granted during that year was $12.70. The options to purchase 571,500 shares of common stock granted in December 2012 were issued with an exercise price of $3.54 per share. For the year ended December 31, 2011, the weighted-average estimated fair value per option granted during that year was $13.97. The options to purchase 157,000 shares of common stock granted in December 2011 were issued with an exercise price of $2.72 per share. The options to purchase 508,491 shares of common stock granted in March 2011 were issued with an exercise price of $4.88 per share. For each of these grants, the Company set the fair value of the underlying common stock for financial accounting purposes at $15.00 per share.

12. Income Taxes

From inception through November 8, 2010, Insys Pharma operated as a Subchapter S Corporation for income tax purposes. Losses incurred through November 7, 2010 were reported on the stockholders tax returns and are not available to the Company as NOLs. Since that time, losses incurred result in NOLs which can be used to offset possible future taxable income of the Company.

The NeoPharm merger was accounted for as a reverse acquisition and resulted in a change of 50% or more of the ownership of Insys on November 8, 2010. As of the NeoPharm merger date, Insys had approximately $274,000,000 of federal NOLs which were scheduled to expire in tax years 2011 to 2029. Under Section 382 of the Code, the Company s utilization of the pre-NeoPharm merger federal NOLs of Insys to offset the Company s post-NeoPharm merger federal taxable income is significantly limited due to the NeoPharm merger. The Company has estimated the amount of pre-NeoPharm merger federal

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NOLs of Insys that are available to offset post-NeoPharm merger income of the Company are limited to approximately $158,000 per year for 20 years, or cumulatively $3,000,000 as of December 31, 2012. In addition, prior to the NeoPharm merger, Insys had completed a partial analysis of ownership changes under Section 382 of the Code to determine if a change in control of Insys had occurred. Based on Insys partial analysis, no change in control was identified, based on the review of eight test dates covering a four-year period ended December 31, 2007. A complete formal analysis of ownership change would have to be performed in order to obtain certainty that a change in control of Insys had not occurred prior to the NeoPharm merger, which could further limit the utilization of the Insys pre-NeoPharm merger NOLs by the Company.

For state income tax purposes, NeoPharm had approximately $269,000,000 of Illinois state NOLs which are scheduled to expire in tax years 2017 to 2029 which are available to offset future Illinois taxable income of the Company.

As of December 31, 2012, the Company has federal NOLs available to offset future income of the Company of approximately $27,000,000, which are scheduled to expire in tax years 2030 to 2032.

As of December 31, 2012, the Company has state NOLs available to offset future state income of the Company of approximately $288,000,000, which are scheduled to expire in tax years 2017 to 2032.

The Company has placed a full valuation allowance on its net deferred tax assets, as it is not more likely than not that such amounts will be realized.

Deferred Income Taxes:

The tax effects of temporary differences and carry forwards that give rise to the deferred tax assets and liabilities are comprised of the following as of December 31 (dollars in thousands):

	2012	2011
Deferred Tax Assets:		
NOLs and credit	$ 37,865	$ 33,072
Start-up expenditures	3,954	4,102
Stock based compensation	1,613	1,252
Deferred revenue and allowances	2,823	
Expenses not currently deductible for tax purposes	727	456
Property and equipment		43
Gross deferred tax assets	46,982	38,925
Deferred tax asset valuation allowance	(46,924)	(36,827)
Deferred tax assets	58	2,098
Deferred Tax Liabilities:		
In-process research and development		(2,098)
Property and equipment	(58)	
Net deferred tax assets	$	$

In assessing the realization of deferred tax assets, the Company considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company also considers the scheduled reversal of deferred tax

liabilities, projected future taxable income or losses, and tax planning strategies in making this assessment. Based upon the Company s history of tax losses and projections

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for future taxable income over the periods in which the deferred tax assets are deductible, the Company does not believe realization of these tax assets is more likely than not. As such, a full valuation allowance for the deferred tax assets has been established.

Effective Tax Rate Reconciliation:

The Company s federal statutory tax rate is 35.0%, while its effective tax rate was 0% in 2012 and 2011.

	2012	2011
U.S. statutory tax rate	35.00%	35.00%
Increase (reduction) in income taxes resulting from:		
Non-deductible and includible items and credits	(1.65)%	2.62%
Revalue of contingent payment obligation	3.04%	
Other	(1.95)%	
Change in federal valuation allowance	(34.44)%	(37.62)%
Total benefit	%	%

As of December 31, 2012 and 2011, the Company had not recorded any reserves for uncertain tax positions and has not recorded any interest and penalties. The Company s tax years subsequent to 2008 remain open to examination by federal and state taxing authorities. In addition, Insys pre-NeoPharm merger NOLs remain open to examination. In 2011, the Internal Revenue Service began and completed an audit for tax year 2009 of Insys Pharma, a year in which Insys Pharma was a Subchapter S Corporation. The audit did not result in any significant changes.

13. Net Loss per Share

The Company computes the net 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 loss for the years ended 2012 and 2011 was 91.5% and 91.6%, respectively. Basic net loss per common share is computed by dividing the net loss allocable to the common stockholders by the weighted average number of common shares outstanding during the period. The diluted 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 calculations for unaudited pro forma net loss per common share assume the conversion of (i) the Company s convertible preferred stock outstanding as of the date presented into 8,528,860 shares of the Company s common stock, which will occur automatically immediately prior to the closing of this offering, and (ii) $59,276,000 in aggregate principal amount of notes and accrued interest thereon owed to trusts controlled by or affiliated with the Company s founder, Executive Chairman and principal stockholder into 6,586,182 shares of common stock, assuming a conversion date of May 6, 2013 and an initial public offering price of $9.00 per share, the mid-point of the price range set forth on the cover page of this prospectus, immediately prior to the closing of the offering as described in Note 2, as if they had occurred as of the beginning of the period presented.

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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

	Years Ended December 31, 2012	2011
Historical net loss per share:		
Numerator:		
Total net loss	$ (24,378)	$ (19,361)
Net loss allocable to participating securities	22,318	17,731
Net loss allocable to common stockholders	$ (2,060)	$ (1,630)
Denominator:		
Weighted average shares outstanding	787,174	784,020
Basic and diluted net loss per common share	$ (2.62)	$ (2.08)

	2012
Unaudited pro forma net loss per share:	
Numerator:	
Total net loss	$ (24,378)
Pro forma adjustment related to interest expense on convertible notes payable	2,582
Net loss used to compute pro forma net loss per share	$ (21,796)
Denominator:	
Weighted average shares outstanding	787,174
Pro forma adjustment to reflect assumed weighted average effect of conversion of convertible preferred stock	8,528,860
Pro forma adjustment to reflect assumed weighted average effect of conversion of convertible notes payable	6,586,182
Weighted average pro forma shares outstanding	15,902,216
Pro forma basic and diluted net loss per share	$ (1.37)

As the Company has incurred a net loss for all periods presented, 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 2,091,195 and 1,775,157 outstanding stock options as of December 31, 2012 and 2011, respectively.

14. 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.

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INSYS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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 Years Ended December 31,	
	2012	2011
Subsys	$ 8,550	$
Dronabinol SG Capsule	6,926	
Total net revenue	$ 15,476	$

	% of Revenue by Route to Market Years Ended December 31,	
	2012	2011
Pharmaceutical wholesalers	55%	
Generic pharmaceutical distributor	45%	
	100%	

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

One customer accounted for 45% of net revenue for the year ended December 31, 2012. Three wholesalers accounts receivable balances accounted for 34%, 22% and 21% of accounts receivable as of December 31, 2012.

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and trade accounts receivable. The Company places its cash with high credit quality financial institutions and generally limits the amount of credit exposure to the amount of FDIC coverage. However, periodically during the year, the Company maintains cash in financial institutions in excess of the current FDIC insurance coverage limit of $250,000. The Company performs ongoing credit evaluations of its customers financial condition but does not typically require collateral to support customer receivables. The Company establishes an allowance for doubtful accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information.

15. Subsequent Events

The Company evaluated subsequent events through February 26, 2013, which was the date immediately prior to the date the consolidated financial statements were initially filed with the SEC, and re-evaluated subsequent events through May 1, 2013.

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4,000,000 Shares

Common Stock

PROSPECTUS

, 2013

Wells Fargo Securities

JMP Securities

Oppenheimer & Co.

Through and including , 2013 (25 days after the commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery is in addition to a dealer s obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the FINRA filing fee and the NASDAQ Global Market filing fee.

	Amount paid or to be paid
SEC registration fee	$ 6,275
FINRA filing fee	12,920
NASDAQ Global Market filing fee	125,000
Blue sky qualification fees and expenses	25,000
Printing and engraving expenses	750,000
Legal fees and expenses	2,000,000
Accounting fees and expenses	200,000
Transfer agent and registrar fees and expenses	15,000
Miscellaneous expenses	130,019
Total	$ 3,264,214

Item 14. Indemnification of Directors and Officers.

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who were, are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such corporation as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation s best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who were, are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation s best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses (including attorneys fees) actually and reasonably incurred.

Our amended and restated certificate of incorporation and amended and restated bylaws, each of which will become effective upon the closing of this offering, provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

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Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director s duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation includes such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption, may be held liable for such actions. A director who was either absent when the unlawful actions were approved or dissented at the time may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

As permitted by the Delaware General Corporation Law, we have entered into indemnity agreements with each of our directors and executive officers, that require us to indemnify such persons against any and all costs and expenses (including attorneys , witness or other professional fees) actually and reasonably incurred by such persons in connection with any action, suit or proceeding (including derivative actions), whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director or officer or is or was acting or serving as an officer, director, employee or agent of ours or of any of our affiliated enterprises. Under these agreements, we are not required to provided indemnification for certain matters, including:

- indemnification beyond that permitted by the Delaware General Corporation Law;
- indemnification for any proceeding with respect to the unlawful payment of remuneration to the director or officer;
- indemnification for certain proceedings involving a final judgment that the director or officer is required to disgorge profits from the purchase or sale of our stock
- indemnification for proceedings involving a final judgment that the director s or officer s conduct was in bad faith, knowingly fraudulent or deliberately dishonest or constituted willful misconduct or a breach of his or her duty of loyalty, but only to the extent of such specific determination;
- indemnification for proceedings or claims brought by an officer or director against us or any of our directors, officers, employees or agents, except for claims to establish a right of indemnification or proceedings or claims approved by our board of directors or required by law;

indemnification for settlements the director or officer enters into without our consent; or

indemnification in violation of any undertaking required by the Securities Act or in any registration statement that we file.

The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

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Except as otherwise disclosed in the section entitled Business Legal Proceedings in the Business section of this registration statement, there is at present no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and we are not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

We have an insurance policy in place that covers our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

We plan to enter into an underwriting agreement which provides that the underwriters are obligated, under some circumstances, to indemnify our directors, officers and controlling persons against specified liabilities, including liabilities under the Securities Act.

Reference is made to the following documents filed as exhibits to this registration statement regarding relevant indemnification provisions described above and elsewhere herein:

Exhibit number	Description of document
1.1	Form of Underwriting Agreement.
3.3	Form of the Registrant s Amended and Restated Certificate of Incorporation to become effective upon closing of this offering.
3.5	Form of the Registrant s Amended and Restated Bylaws to become effective upon closing of this offering.
10.1	Form of Indemnity Agreement by and between the Registrant and its directors and officers.

Item 15. Recent sales of unregistered securities.

The following sets forth information regarding all unregistered securities sold by us since January 1, 2010:

(1) Between January 1, 2010 and November 8, 2010, we granted stock options to purchase up to an aggregate of 9,357 shares of our common stock to employees, consultants and directors under the 2006 plan at exercise prices ranging from $17.69 to $18.61 per share. All of these options have since vested. Of these options, as of March 31, 2013, no options to purchase shares of common stock have been exercised and options to purchase 7,107 shares of common stock remain exercisable.

(2) In November 2010, we acquired Insys Pharma, Inc. in the NeoPharm merger. In connection with the NeoPharm merger, we issued 319,667 shares of our common stock and 14,864,607 shares of our convertible preferred stock to the stockholders of Insys Pharma, and also assumed stock options of Insys Pharma, which were converted into stock options to purchase up to an aggregate of 1,129,872 shares of our common stock.

(3) On November 17, 2010, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.75 million.

(4) On December 10, 2010, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate amount of $1.5 million.

(5) On January 24, 2011, we issued secured demand notes to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.5 million.

(6) On February 11, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $2.0 million.

(7) On March 21, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.5 million.

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(8) On March 28, 2011, we granted stock options to purchase up to an aggregate of 508,491 shares of our common stock to employees, consultants and directors under the 2006 plan at an exercise price of $4.88 per share.

(9) On April 27, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.0 million.

(10) On May 27, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.0 million.

(11) On June 28, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.0 million.

(12) On July 27, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.0 million.

(13) On August 31, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $750,000.

(14) On October 11, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $1.0 million.

(15) On November 14, 2011, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $5.0 million.

(16) On December 28, 2011, we granted stock options to purchase up to an aggregate of 157,000 shares of our common stock to employees, consultants and directors under the 2006 plan at an exercise price of $2.72 per share.

(17) On January 10, 2012, we issued a secured demand note to The John N. Kapoor Trust dated September 20, 1989 in an aggregate principal amount of $3.0 million.

(18) On December 27, 2012, we granted stock options to purchase up to an aggregate of 571,500 shares of our common stock to employees, consultants and directors under the 2006 plan at an exercise price of $3.54.

All of the offers, sales and issuances of the securities described in paragraph (1), and the offers and issuances of options to purchase an aggregate of 1,236,991 shares of our common stock described in paragraphs (8), (16) and (18), were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2006 Equity Incentive Plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

The offers, sales, and issuances of the securities described in paragraph (2) were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof.

The offers, sales, and issuances of the securities described in paragraphs (3), (4), (5), (6), (7), (9), (10), (11), (12), (13), (14), (15) and (17), were deemed to be exempt from registration under the Securities Act in reliance on Section 4(2) of the Securities Act and Rule 506 promulgated under Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor within the meaning of Rule 501 of Regulation D under the Securities Act and had adequate access, through employment, business or other relationships, to information about us.

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Item 16. Exhibits and financial statement schedules.
(a) Exhibits.

Exhibit Number	Description of Document
1.1#	Form of Underwriting Agreement.
2.1#	Agreement and Plan of Merger Among the Registrant, Insys Therapeutics, Inc. and ITNI Merger Sub Inc. dated October 29, 2010.
3.1#	Registrant s Amended and Restated Certificate of Incorporation, as amended and as currently in effect.
3.2#	Form of the Registrant s Amended and Restated Certificate of Incorporation to become effective upon closing of this offering.
3.3#	Registrant s Bylaws, as currently in effect.
3.4#	Form of the Registrant s Amended and Restated Bylaws to become effective upon closing of this offering.
3.5#	Registrant s Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
3.6#	Registrant s Certificate of Amendment of Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
3.7#	Registrant s Certificate of Amendment of Amended and Restated Certificate of Designations, Preferences and Rights of Convertible Preferred Stock of Insys Therapeutics, Inc.
4.1#	Form of Common Stock Certificate of the Registrant.
5.1#	Opinion of Cooley LLP.
10.1+#	Form of Indemnity Agreement by and between the Registrant and its directors and officers.
10.2+#	Insys Therapeutics, Inc. 2006 Equity Incentive Plan, as amended.
10.3+#	Insys Pharma, Inc. Amended and Restated Equity Incentive Plan.
10.4+#	2013 Equity Incentive Plan and Form of Stock Option Grant Notice and Form of Stock Option Agreement thereunder.
10.5+#	2013 Employee Stock Purchase Plan.
10.6+#	Amended and Restated Employment Agreement by and between the Registrant and Michael Babich dated April 18, 2013.
10.7+#	Amended and Restated Employment Agreement by and between the Registrant and Larry Dillaha dated April 18, 2013.
10.8+#	Employment Agreement by and between the Registrant and Darryl Baker dated April 18, 2013.
10.9#	Frye Road Two LLC Triple Net Lease dated as of January 31, 2012 between Insys Pharma, Inc. and Frye Road Two LLC.
10.10#	First Amendment to Lease dated as of November 7, 2012 between Insys Pharma, Inc. and Frye Road Two LLC.
10.11#	Chandler 101 Business Center Office Lease dated as of January 4, 2013 between Insys Pharma, Inc. and Frye Road Industrial LLC.

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Exhibit Number	Description of Document
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10.13*#	First Amendment to Softgel Commercial Manufacturing and Packaging Agreement dated as of March 5, 2012 by and between the Registrant and Catalent Pharma Solutions, LLC.
10.14*#	Supply and Distribution Agreement dated as of May 20, 2011 by and between the Registrant and Mylan Pharmaceuticals Inc.
10.15*#	Amendment to Supply and Distribution Agreement dated as of March 13, 2012 by and between the Registrant and Mylan Pharmaceuticals Inc.
10.16*#	Manufacturing Agreement dated as of March 7, 2011 by and between the Registrant and DPT Lakewood, LLC.
10.17*#	Letter Agreement dated April 23, 2012, amending the DPT Lakewood, LLC Manufacturing Agreement dated as of March 7, 2011.
10.18*#	Supply Agreement dated as of March 7, 2011 by and between the Registrant and AptarGroup, Inc.
10.19#	Loan Agreement dated as of February 17, 2012 by and between the Registrant and Bank of America, N.A.
10.20#	Amendment No. 1 to Loan Agreement dated as of February 11, 2013 by and between the Registrant and Bank of America, N.A.
10.21#	Amendment No. 2 to Loan Agreement and Waiver dated as of March 27, 2013 by and between the Registrant and Bank of America, N.A.
10.22+#	Non-Employee Director Compensation Policy.
21.1#	Subsidiaries of the Registrant.
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.
23.2#	Consent of Cooley LLP. Reference is made to Exhibit 5.1.
24.1#	Power of Attorney.

\+ Indicates management contract or compensatory plan.
* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.
\# Previously filed.

(b) Financial statement schedules.

No consolidated financial statement schedules are provided because the information called for is not required or is shown either in the consolidated financial statements or the notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the Underwriting Agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or

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otherwise, the Registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The Registrant hereby undertakes that:

(a) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(b) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Chandler, State of Arizona, on the 2nd day of May, 2013.

INSYS THERAPEUTICS, INC.

By: /s/ Michael L. Babich
Michael L. Babich

President and Chief Executive Officer

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael L. Babich Michael L. Babich	President, Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	May 2, 2013
/s/ Darryl S. Baker Darryl S. Baker	Chief Financial Officer (Principal Financial and Accounting Officer)	May 2, 2013
/s/ John N. Kapoor* John N. Kapoor, Ph.D.	Executive Chairman of the Board of Directors	May 2, 2013
/s/ Patrick P. Fourteau* Patrick P. Fourteau	Member of the Board of Directors	May 2, 2013
/s/ Steven Meyer* Steven Meyer	Member of the Board of Directors	May 2, 2013
/s/ Brian Tambi* Brian Tambi	Member of the Board of Directors	May 2, 2013
/s/ Pierre Lapalme* Pierre Lapalme	Member of the Board of Directors	May 2, 2013
Theodore H. Stanley, M.D.	Member of the Board of Directors	May 2, 2013

* Pursuant to Power of Attorney

/s/ Michael L. Babich

By: **Michael L. Babich**

Attorney-in-Fact

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23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.
23.2#	Consent of Cooley LLP. Reference is made to Exhibit 5.1.
24.1#	Power of Attorney.

\+ Indicates management contract or compensatory plan.

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

\# Previously filed.