UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2013

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 001-35902

Insys Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

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

(602) 910-2617
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title Of Each Class	Name Of Each Exchange On Which Registered
Common Stock, $0.0002145 Par Value Per Share	The NASDAQ Global Market LLC

Securities Registered Pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of Registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment of this Form 10-K. ☐

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. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☑

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☑

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant was approximately $73.4 million as of June 30, 2013 based on the closing sales price of the common stock on the NASDAQ Global Market.

There were 22,273,494 shares of the registrant's common stock issued and outstanding as of February 26, 2014.

Documents Incorporated by Reference

Portions of the registrant's Proxy Statement relating to its 2014 Annual Meeting of Stockholders, to be filed with the Securities and Exchange Commission ("SEC") pursuant to Regulation 14A within 120 days after the registrant's fiscal year ended December 31, 2013, are incorporated by reference in Part III of this Form 10-K.

TABLE OF CONTENTS

PART I

ITEM 1. BUSINESS

Overview

As used in this Form 10-K, "we," "us," and "our" refer to Insys Therapeutics, Inc.

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 an incentive-based sales model.

Insys Therapeutics, Inc. was incorporated in Delaware in June 1990, and we maintain headquarters in Chandler, Arizona. We were in the development stage through December 31, 2011. The year 2012 is the first year during which we were considered an operating company and was no longer in the development stage. We completed our initial public offering of common stock in May 2013. On November 8, 2010, we effected a merger with NeoPharm, Inc., or NeoPharm, in a transaction accounted for as a reverse acquisition, or the NeoPharm merger. All of our outstanding share capital was exchanged for newly-issued shares of common stock and convertible preferred stock of NeoPharm. As a result of the NeoPharm merger, we became a wholly-owned subsidiary of NeoPharm and changed our name to Insys Pharma, Inc., or 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 included in this report 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 Therapeutics, Inc. and Insys Pharma.

Information about our company and communities is provided on our Internet website at www.insys.com. The information contained on our website is not considered part of this Annual Report on Form 10-K. Our periodic and current reports, including any amendments, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended are available, free of charge, on our website as soon as reasonably practicable after they are electronically filed with or furnished to SEC. These filings are also available on the SEC's website at www.sec.gov. Information contained on our website it not considered part of this annual report.

We are leveraging our capabilities in dronabinol formulation and manufacturing, as well as our sublingual spray drug delivery technology, to develop a robust portfolio of differentiated, wholly-owned product candidates. Our lead product candidate is Dronabinol Oral Solution, a proprietary, orally administered liquid formulation of dronabinol, which will be our second branded supportive care product, if it successfully obtains all required regulatory approvals. We believe this product candidate may provide increased flexibility in dosing for doctors and more convenient delivery and an improved absorption profile for 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.

Our Products and Product Candidates

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 as a commercial product 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 December 2013, Subsys was the most prescribed branded TIRF product with 28.3% 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 Subsys. According to Source Healthcare Analytics, in 2013, TIRF products generated $421.2 million in annual 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 in 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.

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 Dronabinol SG Capsule 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.

Our lead product candidate is Dronabinol Oral Solution, a proprietary, orally administered liquid formulation of dronabinol, which has yet to be approved for commercialization. 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 2013, according to IMS Health, and potentially expanding the usage of dronabinol-based products.

The Potential Market for BTCP Management

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, an estimated 50% to 90% of whom 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.

Strategy

Grow Subsys market share and revenues. We launched Subsys as a commercial product in March 2012. By December 2013, we had a 28.3% 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 educating the medical community 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.

Achieve FDA approval for Dronabinol Oral Solution and advance our synthetic cannabinoid 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. We also have the capability to manufacture synthetic cannabidiol (CBD) and we intend to pursue clinical studies that could result in future commercial products containing CBD.

Continue to 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 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. 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.

Use our core competencies and expertise to expand our dronabinol and cannabidiol 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. We are currently constructing a second manufacturing 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 synthetic cannabinoid product candidates, if approved.

Research and 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. 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, including buprenorphine, buprenorphine with naloxone, ondansetron, sildenafil, diclofenac and ketorolac, 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 2014.

Additionally, we are focused on the development of other earlier stage product candidates. Specifically, we are currently completing preclinical work on three products that utilize our proprietary spray technology platform and will expand our supportive care franchise:

- Buprenorphine (semi-synthetic opioid to treat moderate and acute chronic pain)
- Buprenorphine/Naloxone (opioid antagonist to treat addiction)
- Ondansetron (serotonin 5-HT3 receptor antagonist used mainly as an antiemetic to treat nausea and vomiting following chemotherapy)

We have also initiated preclinical development of three additional sublingual spray candidates:

- Sildenafil (the active ingredient in Viagra)
- Diclofenac (a non-steroidal anti-inflammatory drug (NSAID) taken or applied to reduce inflammation and as an analgesic reducing pain)
- Ketorolac (for short-term management of moderate to moderately severe pain requiring analgesia at the opioid level)

Further, we have the ability to manufacture pure, synthetic cannabidiol and are evaluating the potential utility of this in a variety of indications.

We intend to file one NDA and at least three IND's with the FDA in 2014.

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 $421.2 million in U.S. sales in 2013.

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.

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, an estimated 50% to 90% of whom 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 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, Galena Pharmaceutical's Abstral, an immediate-release transmucosal sublingual tablet, and Depomed's Lazanda, a nasal spray. According to Source Healthcare Analytics, TIRF products generated $421.2 million in 2013 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.

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.

- *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 2014 shows that approximately 39,000 prescriptions of Subsys have been dispensed since launch in March 2012. Subsys' total prescription share of the TIRF market has increased each quarter since launch. In December 2013, Subsys was the most prescribed branded TIRF product with 28.3% market share.

Physician Prescriber Base: Approximately 1,850 physicians were responsible for 90% of all TIRF prescriptions dispensed in 2013, according to Source Healthcare Analytics. We have targeted our initial commercialization efforts towards the majority of these high prescribers. As of December 2013, there were approximately 1,140 unique physician prescribers of Subsys, according to the TIRF risk evaluation mitigation strategy, or REMS, database. As of December 2013, approximately 81% of the top 118 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 7,100 unique patients as of December 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 80% of prescriptions as of December 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.

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.

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.

- *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 expect to submit an NDA for Dronabinol Oral Solutionby the second half of 2014.

Other Product Candidates

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

Future Cannabinoid 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. We also have the capability to manufacture synthetic cannabidiol and intend to work with medical researchers to determine its viability.

Sublingual Spray Product Candidates. As described above, 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 our commercial organization. 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. 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.

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 December 31, 2013, there were approximately 8,500 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 in 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 December 2013, 81% of the top 118 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.

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 and 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. 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. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

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 and initial launch quantities of Dronabinol Oral Solution, if approved, as well as to support the continued development of our other dronabinol product candidates in the near-term. We believe this facility 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 have commenced construction of 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. We expect to initiate manufacturing activities in the new facility in the fourth quarter of 2014.

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 Pharma Solutions, LLC, or 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. The initial term of the agreement is five years, unless earlier terminated, and annually renews for additional periods of two years, unless we or Catalent give the other party at least 12 months' prior written notice of our, or their, desire to terminate the agreement.

Subsys is manufactured by contract manufacturers and sub-component fabricators. AptarGroup, Inc., or Aptar, 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 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. The agreement has a term of five years from the effective date, subject to early termination clauses.

We entered into a manufacturing agreement effective as of May 24, 2011 with DPT Lakewood, LLC, or DPT, pursuant to which we engaged DPT on an exclusive basis to provide processing and packaging services with respect to Subsys. The contract requires us to provide rolling quarterly forecasts, a portion of which constitute firm purchase commitments. Unless terminated earlier, the initial term of the agreement will continue until December 31, 2017, subject to automatic extension and early termination clauses.

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 Pharmaceutical Industries Ltd's Fentora and Actiq, Galena Biopharma Inc.'s Abstral, Depomed Inc.'s 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.

Additionally, we are aware of companies in late stage development for CINV product candidates, including A.P. Pharma, Inc.'s APF530 (Phase 3) Aphios Corp.'s Zindo (Phase 2/3), Tesaro, Inc.'s Rolapitant (Phase 3) and Roche Holding/Helsinn Group's netupitant (Phase 3). 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 December 31, 2013, we owned or licensed from third parties a total of nine issued U.S. utility patents and ten pending U.S. utility patent applications. These U.S. patents and patent applications will expire between 2015 and 2034. 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 Orange Book listed (with the F.D.A.) U.S. Patent Nos. 8,486,972 ('972 patent) and 8,486,973 ('973 patent) and two pending U.S. patent applications. Both of these patents cover SUBSYS brand fentanyl and will expire no sooner than 2030. The '972 patent covers the SUBSYS sublingual fentanyl spray formulation, while the '973 patent covers the use of the SUBSYS sublingual fentanyl spray for the treatment of pain. The SUBSYS sublingual fentanyl spray is useful for delivering fentanyl directly to the sublingual mucosa to achieve appreciable plasma concentration levels within five minutes and differs from other fentanyl formulations in that it is readily absorbed bringing quick and effective pain relief to the patient without the need for injections or IVs. We also currently have seven issued foreign patents and 11 pending foreign patent applications covering at least formulations and methods of use relating to SUBSYS. Any patents that issue from our pending foreign patents and applications are expected to expire no earlier than 2027.

Dronabinol

Our dronabinol patent portfolio currently consists of two issued U.S. patents, two pending U.S. patent applications and one P.C.T. patent application. The claims of the patents and applications are directed to formulations of dronabinol and methods of manufacturing and packaging dronabinol. The issued dronabinol patents will expire in 2028. Any patents that issue from our pending patent applications will likely expire between 2028 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 "Legal Proceedings," a former officer of Insys Pharma has 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 but we 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 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.

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 the issuance of 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. 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.

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, dosage, 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 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 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 December 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 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, however, must 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 our Subsys product, 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. Accordingly, our 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 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 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 violations 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.

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.

Employees

As of December 31, 2013, we employed 202 full-time employees, including 12 manufacturing employees, 145 sales and marketing employees, 29 employees in research and development, and 16 employees in administration. As of the same date, nine 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.

ITEM 1A. RISK FACTORS

Risks Related to Our Business and Industry

We are largely dependent on the commercial success of our two approved products, Subsys and Dronabinol SG Capsule, and although we have generated revenue and profit from sales of Subsys and Dronabinol SG Capsule, we may not be able to continue to be profitable.

We anticipate that in the near term our ability to maintain profitability will depend upon the continued commercial success of our two approved products, Subsys and Dronabinol SG Capsule, which were only recently launched. To date, we have limited history concerning the 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 and the ultimate resolution of our ongoing dispute with Mylan;
- 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;
- our ability to comply with regulatory requirements; and
- our ability to find an effective distribution model or platform in the event that our relationship with Mylan ends.

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 and profits from Subsys and Dronabinol SG Capsule. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

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;
- the U.S. Drug Enforcement Administration, or DEA, scheduling classification for controlled substances, such as our dronabinol-based and fentanyl-based products;
- availability and perceived advantages of alternative treatments;
- any negative publicity related to our or our competitors' products;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies;
- pricing and cost effectiveness;
- our ability to obtain sufficient third-party payor coverage and reimbursement;
- the willingness of patients to pay out of pocket in the absence of third-party payor coverage; and
- our ability to maintain compliance with regulatory requirements.

For example, while we believe our sublingual spray delivery method for Subsys appeals to patients, some patients may not view our sublingual spray device as easy to administer, safe and effective, and otherwise may not react favorably to sublingual delivery. In accordance with the risk evaluation mitigation strategy, or REMS, protocol for all TIRF products, physicians are advised to begin patients at the lowest dose available for the applicable TIRF product, which for Subsys is 100 mcg. If patients do not experience pain relief at initial low-dose prescriptions of Subsys, they or their physicians may conclude that Subsys is ineffective in general and may discontinue use of Subsys before titrating to an effective dose. In addition, many third-party

payors require usage and failure on cheaper generic versions of Actiq prior to providing reimbursement for Subsys and other branded TIRF products, which limits Subsys' use as a first-line treatment option.

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

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

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

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

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

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

Prior to our launch of Subsys in March 2012, we built a commercial organization including sales, marketing, managed markets, trade and distribution functions, which is now focused exclusively on marketing and selling Subsys. We utilize in the United States, with respect to Subsys, and plan to utilize in the United States, with respect to any of our product candidates for which we obtain regulatory approval and maintain sales and marketing responsibility, an incentive-based sales model similar to that employed at Sciele Pharma and other companies previously led by members of our board, including our founder, Executive Chairman and principal stockholder. Under this model, we maintain a low-cost commercial organization that is smaller than many of our competitors, which could hinder our efforts to broadly market Subsys and any other products that we are able to commercialize as compared to our competitors. Our commercial organization has only recently been established, and may not perform over time as we currently anticipate. To the extent our commercial organization does not perform over time as we currently anticipate, we will need to consider alternatives, such as entering into arrangements with third parties to market and sell our products. Any arrangement would likely result in significantly greater sales and marketing expenses or lower revenues than our current estimates.

Our field sales force promotes 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 currently distribute Dronabinol SG Capsule exclusively through Mylan pursuant to our May 2011 supply and distribution agreement. We have an ongoing dispute with Mylan that may result in the termination of this relationship or otherwise be resolved in a manner that materially and adversely affects our financial condition and results of operations. 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 is not adequately fulfilling its obligations, our business, financial condition, results of operations and prospects would be harmed. See Note 8 under the heading "Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan. Ultimately, 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 has in the past disagreed with us and may in the future disagree with us regarding whether any Dronabinol SG Capsule that we supply to Mylan conforms to specifications and has in the past and may in the future reject batches of Dronabinol SG Capsule for reasons we may not agree with, in which case we would likely 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;

- We and Mylan have an ongoing dispute and may in the future have additional disputes related to obligations and liabilities, including payments, under the applicable agreement which may not be resolved in our favor, if at all;

- 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; and

- The resolution of our ongoing dispute with Mylan may result in the termination of the agreement with Mylan which would require us to either perform this function ourselves or obtain an alternative distributor(s).

Generally speaking, 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. 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 are at an early stage of commercialization and have a history of net losses and negative cash flow from operations.

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. At December 31, 2013, our accumulated deficit was $89.0 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.

Our ability to generate sufficient revenues from any of our product candidates, if approved, will depend on numerous factors described in the following risk factors, and although we are currently profitable, we may incur losses and negative cash flow in the future. 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 maintain profitability and continue to 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 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 202 as of December 31, 2013, primarily because we established a commercial organization 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 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. 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.

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 improve our business, results of operations and financial condition 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 2014. 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. While we have estimated the approximate cost of approval of this particular product, we cannot be certain that our current estimate of the cost to obtain FDA approval for Dronabinol Oral Solution is currently accurate or that such costs might increase over time. For instance, 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. Ultimately, the FDA has substantial discretion in the drug approval process, including the ability to delay, limit or deny approval of a product candidate for various reasons.

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

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

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

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

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

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

We have no internal manufacturing capabilities other than for our dronabinol API, we are dependent on numerous third parties in our supply chain for the commercial supply of Subsys and Dronabinol SG Capsule, and if we fail to maintain our supply and manufacturing relationships with these third parties or develop new relationships with other third parties, we 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 our successful completion of preclinical studies and clinical trials for our product candidates. There is no assurance that these suppliers will continue to produce the materials in the quantities and quality and at the times they are needed, if at all, especially in light of the fact that we intend to significantly increase our orders for these materials in the near future. Moreover, the replacement of any of these suppliers, particularly the supplier of the starting material for our dronabinol API that is difficult to produce, could lead to significant delays and increase in our costs.

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

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

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

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

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

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

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

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

Subsys competes against numerous branded and generic products already being marketed and potentially those which are or will be in development. Many of these competitive products are offered in the United States by large, well-capitalized companies. Subsys is the fourth new branded TIRF product in the last four years. In the BTCP market, physicians often treat BTCP with a variety of short-acting opioid medications, including morphine, morphine and codeine derivatives and fentanyl. Some currently marketed products against which we directly compete include Teva Pharmaceutical Industries Ltd.'s Fentora and Actiq, Galena's Abstral, Depomed'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 in late stage development for CINV product candidates, including A.P. Pharma, Inc.'s APF530 (Phase 3) Aphios Corp.'s Zindo (Phase 2/3), Tesaro, Inc.'s Rolapitant (Phase 3) and Roche Holding/Helsinn Group's netupitant (Phase 3). If these products are successfully developed and approved over the next few years, they could represent significant competition for Dronabinol SG Capsule and, if approved, our dronabinol product candidates

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

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

If we are unable to achieve and maintain adequate levels of coverage and reimbursement from third-party payors 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 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; if we or Mylan lose any of our significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our sales of Subsys, and the majority of Mylan's sales of Dronabinol SG Capsule, are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2013, four wholesale pharmaceutical distributors, Rochester Drug Corporation, AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc., individually comprised approximately 30%, 21%, 20% and 19%, respectively, of our total gross sales of Subsys, and McKesson Corporation comprised approximately 91% 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.

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 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 (i.e., Phase IV 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.

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 that are the subject of ANDAs are under review by the FDA. If this ruling is allowed, it may increase the number of generics approved as we believe there are active ANDAs which utilize naturally-derived dronabinol and hard gelatin capsule technology. Dronabinol SG Capsule is also subject to regulation by state-controlled substance authorities.

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

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

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

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

In light of widely publicized events concerning the safety risk of certain drug products, particularly drug products that contain controlled substances, regulatory authorities, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products after approval. In addition, the Federal Food, Drug, and Cosmetic Act, or FDCA, authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require a REMS for certain drugs, including certain currently approved drugs. Under the FDCA, companies that violate these and other provisions of the law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties.

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

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

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

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

- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- uncertainty regarding proper dosing;
- unfavorable results from ongoing clinical trials and preclinical studies;
- failure of our contract research organizations, or CROs, or other third-party contractors to comply with all contractual and regulatory requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, our CROs or their employees to comply with all applicable FDA, DEA or other regulatory requirements relating to the conduct of clinical trials or the handling, storage, security and recordkeeping for controlled substances;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- insufficient data to support regulatory approval;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- regulatory concerns with cannabinoid or opioid products generally and the potential for abuse of the drugs.

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

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

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

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

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

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

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

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.

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 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 2014 is 491 kilograms, compared to 393 kilograms for 2013. For 2014, we were allocated what we believe is a sufficient quantity of dronabinol to meet our currently anticipated production and testing needs through 2014. 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 2014 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 2014 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 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 develop, acquire 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 license or sell 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.

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

Our ability to compete in the highly competitive biotechnology and pharmaceuticals industries depends upon our ability to attract and retain highly qualified managerial, scientific, medical and other personnel. We are highly dependent on our management, scientific and medical personnel, as well as our board members, including our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, our President and Chief Executive Officer, Michael L. Babich, and our Chief Medical Officer, Dr. Larry Dillaha. The loss of the services of any of these individuals could impede, delay or prevent the continuing commercialization of Subsys and Dronabinol SG Capsule and the development of our product candidates and could negatively impact our ability to successfully implement our business plan. If we lose the services of any of these individuals, we may not be able to find suitable replacements on a timely basis or at all, and our business would likely be harmed as a result. We do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees. We employ all of our executive officers and key personnel on an at-will basis and their employment can be terminated by us or them at any time, for any reason and without notice; provided, however, that under certain circumstances we may owe them additional compensation in connection with such termination.

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 as well as certain other market based benefits and compensation. 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. 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 or loyalty 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 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, 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 an aggregate of $2.1 million as of December 31, 2013. For state income tax purposes, we have $281.0 million of state NOLs including approximately $271.0 million of Illinois state NOLs which are available to offset future Illinois taxable income. We have placed a valuation allowance on a significant portion of our Illinois state NOLs because it is not more likely than not that such amounts will be realized due to current levels of activity in Illinois.

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 or unanticipated liabilities;
- disruption of our business and diversion of our management’s time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;

- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

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

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

The commercial use of our products and clinical use of our product candidates expose us to the risk of product liability claims. This risk exists even if a product is approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA, such as the case with Subsys and Dronabinol SG Capsule, or an applicable foreign regulatory authority. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with Subsys or Dronabinol SG Capsule or our product candidates could result in injury to a patient or even death. For example, because our sublingual spray technology is designed to be self-administered by patients, it is possible that a patient could fail to follow instructions and as a result apply a dose in a manner that results in injury or death. 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 effect our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

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 accumulated deficit as of December 31, 2013 was $89.0 million. We expect our operating and general and administrative expenses to continue to be significant and increase substantially in connection with our planned research, development and commercialization activities. We believe that the net proceeds from our May 2013 initial public offering, cash generated from operations and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations through at least the next 24 months. We have based these estimates, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Further, we may need to raise additional capital to fund our operations and continue to support our planned research and development and commercialization activities.

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

- the timing and amount of revenue from sales of our approved products, Subsys and Dronabinol SG Capsule, and any subsequently approved product candidates that are commercialized;
- the size and cost of our commercial infrastructure;
- the timing and cost associated with establishing a second dronabinol manufacturing facility;
- the timing of FDA approval and DEA classification of our product candidates, if at all;
- the timing, rate of progress and cost of any future clinical trials and other product development activities for our dronabinol product candidates and any other product candidates that we may develop, in-license or acquire;
- costs associated with marketing and distributing Subsys and any subsequently approved product candidates;
- costs and timing of completion of any additional outsourced commercial manufacturing supply arrangements that we may establish;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with Subsys, Dronabinol SG Capsule and our product candidates;
- costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation;
- costs of operating as a public company;
- the effect of competing technological and market developments;
- our ability to acquire or in-license products and product candidates, technologies or businesses;
- personnel, facilities and equipment requirements; and
- the terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

We may also need to raise additional funds to finance future cash needs through public or private equity offerings, debt financings, 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. 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.

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

We maintain a $15.0 million revolving credit facility with JPMorgan Chase Bank, and although as of December 31, 2013, there are no borrowings outstanding against this facility, we may make borrowings under this facility in the future and such borrowings will need to be repaid. 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 JPMorgan Chase Bank. These restrictions could significantly limit our ability to respond to changes in our business or competitive activities or take advantage of business opportunities that may create value for our stockholders. In addition, in the event of a default under our credit facility, our repayment obligations may be accelerated in full. In the event that we do not have sufficient capital to repay the amounts then owed under the facility, we may be required to renegotiate our credit facility on terms less favorable to us or to cease operations. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

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

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

Risks Related to Regulation of our Products and Product Candidates

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

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

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

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

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

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

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

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

The FDA provides guidelines with respect to appropriate drug and product promotion, product labeling, 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. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion of an ongoing investigation by the Department of Health and Human Services of potential violations involving our Subsys marketing activities.

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.

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 are also subject to ongoing FDA obligations and continued regulatory review with respect to the manufacturing, processing, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for our product. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and with GCPs and good laboratory practices, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

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

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

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

In addition, our product labeling, advertising and promotion are subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription drug products. In particular, a drug product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling, although the FDA does not regulate the prescribing practices of physicians. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability, including substantial monetary penalties and criminal prosecution. For example, we received a subpoena dated December 9, 2013 from the U.S. Department of Health and Human Services, Office of Inspector General. The subpoena primarily requests documents relating to the marketing of Subsys. We are cooperating in responding to the subpoena. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion regarding this ongoing investigation.

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;
- 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.

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 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.

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 vary from country to country. For those countries where we do not have granted patents, we may not have any ability to prevent the unauthorized use of our sublingual spray technology.

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

Further, in countries where we do not have granted patents directed to our formulations or manufacturing or packaging, third parties may be able to make, use, or sell products identical to, or substantially similar to, Subsys, our dronabinol products or product candidates.

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

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

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

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

The laws of some foreign jurisdictions do not provide intellectual property rights to the same extent as in the United States and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties in protecting or are otherwise precluded from effectively protecting our intellectual property in foreign jurisdictions, our business prospects could be substantially harmed. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain evolving or 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 some or none of our or our licensors' pending patent applications will result in issued patents;
- any patents we obtain or our licensors' issued patents may not encompass commercially viable products, may not provide us with any competitive advantages, or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; or
- we may not develop additional proprietary technologies that are patentable.

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

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

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

Although we expect all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidential information and invention agreements, we cannot provide any assurances that all such agreements have been duly executed, will be honored by the employee, consultant, advisor, or third party, or will be held enforceable.

For example, in September 2009, Insys Pharma, our wholly owned subsidiary, 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. In 2014, Insys Therapeutics, Inc., our parent and publicly-held entity, was also named as defendant in this lawsuit. 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. We and the other defendants have 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 materially 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. Regardless of our assessment of the merits of this legal proceeding, it has and continues to be a distraction for management and the board of directors and has caused and may continue to cause us to spend material resources in our defense. Please see the section entitled "Legal Proceedings" for more information on this and other of our pending 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.

If we are sued for alleged infringement of 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 collaborators to pay the other party damages for having violated the other party's patents.

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

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

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

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

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

As is common in the biotechnology and pharmaceutical industry, certain of our employees were formerly employed by other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Moreover, we engage the services of consultants to assist us in the development of our products and product candidates, many of whom were previously employed at or may have previously been or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may be subject to claims that these employees and consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. For example, we have in the past received letters from third parties asserting that one of our employees may have used proprietary information of his former employers in connection with our prior regulatory filings. Litigation may be necessary to defend against these types of claims. Even if we are successful in defending against any such claims, any such litigation would likely be protracted, expensive, a distraction to our management team, not viewed favorably by investors and other third parties, and may potentially result in an unfavorable outcome.

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

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

Risks Relating to 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 December 31, 2013, our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor, beneficially owned approximately 72% of our outstanding, publicly-traded 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;
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us; or
- otherwise effectively limiting the rights of other stockholders because Dr. Kapoor has the ability to approve matters submitted to stockholders, including the election of directors, approval of significant transactions and the amendment of our certificate of incorporation.

In addition, sales of shares of our common stock 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.

Our common stock price has been volatile, which could result in substantial losses for stockholders.

Our common stock is currently traded on The NASDAQ Global Market. We have in the past experienced, and may in the future experience, limited daily trading volume. The trading price of our common stock has been and may continue to be volatile. The market for pharmaceutical companies, in particular, has at various times experienced extreme volatility that often has been unrelated to the operating performance of particular companies. These broad market and industry fluctuations may significantly affect the trading price of our common stock, regardless of our actual operating performance. The trading price of our common stock could be affected by a number of factors, including, but not limited to, changes in expectations of our future performance, changes in estimates by securities analysts (or failure to meet such estimates), quarterly fluctuations in our sales and financial results and a variety of risk factors, including the ones described elsewhere in this report. Periods of volatility in the market price of a company's securities sometimes result in securities class action litigation, which regardless of the merit of the claims, can be time-consuming, costly and divert management's attention. In addition, if we needed to raise equity funds under adverse conditions, it would be difficult to sell a significant amount of our stock without causing a significant decline in the trading price of our stock.

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. 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.

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

Sales of a substantial number of shares of our common stock or securities convertible into our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of December 31, 2013, we had (i) 22,123,248 outstanding shares of common stock; (ii) 2,998,326 shares of common stock issuable upon the exercise of stock options under our 2013 Equity Incentive Plan and other outstanding awards; and (iii) 104,243 shares were available for future issuance under our 2013 Equity Incentive Plan. The exercise of outstanding stock options could result in increased sales of our common stock in the market, which could exert significant downward pressure on our stock price. These sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price we deem appropriate.

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

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

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

- establish a classified board of directors so that not all members of our board are elected at one time;
- 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 as a “controlled company” under Nasdaq’s rules and have availed ourselves of certain reduced disclosure requirements applicable to emerging growth companies and may avail ourselves of exemptions from certain Nasdaq independence rules, 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 have taken 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. Investors may find our common stock less attractive because we 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 intend to 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 our May 2013 IPO (December 31, 2018), (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

Moreover, as a result of Dr. Kapoor’s stock ownership and related voting power, we are a “controlled company” as defined in the Nasdaq Listing Rules and, therefore we may avail ourselves of certain exemptions under applicable Nasdaq rules, including exemptions from the rules that require us to have (i) a majority of independent directors on the Board; (ii) independent director oversight of executive officer compensation; and (iii) independent director oversight of director nominations.

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.

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, 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, 2013 in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation was required. Had we and our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional significant deficiencies or material weaknesses may have been identified. If we are unable to successfully remediate any significant deficiency or material weakness in our internal control over financial reporting, or identify any additional significant deficiencies or material weaknesses that may exist, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, and our stock price may decline materially as a result.

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

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

The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Ensuring that we have adequate internal financial and accounting controls and procedures in place is a costly and time-consuming effort that needs to be re-evaluated frequently. We are in the process of documenting, reviewing and, where appropriate, improving our internal controls and procedures in preparation for compliance with the SEC regulations adopted pursuant to Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting beginning with the second annual report that we would expect to file with the SEC and, if we are an accelerated filer, a report by our independent auditors addressing these assessments. In addition, beginning with our annual report on Form 10-K following the date we are no longer an "emerging growth company" as defined in the JOBS Act, we will be required to obtain from our independent registered public accounting firm an attestation report on the effectiveness of our internal control over financial reporting. We will remain an "emerging growth company" until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenues of $1 billion or more, (ii) the last day of our fiscal year following the fifth anniversary of the date of the completion of our May 2013 IPO (December 31, 2018), (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the SEC.

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

In accordance with Nasdaq rules, we are required to maintain a majority independent board of directors, unless we avail ourselves to an exemption for controlled companies. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We lease a total of approximately 63,000 square feet of office and lab space in Chandler, Arizona under lease agreements that expire between December 2014 and May 2021. We believe that the Chandler, Arizona facilities are 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 a total of approximately 64,000 square feet for our U.S.-based, state-of-the-art dronabinol manufacturing facilities, which are both located in Round Rock, Texas under lease agreements that expire between January 2017 and March 2024. We have the option to extend our primary manufacturing facility lease for two 10-year periods following March 2024. We believe that the Round Rock, Texas manufacturing facilities are adequate to meet our current and future needs.

ITEM 3. LEGAL PROCEEDINGS

The information included in Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements in Item 8. *Financial Statements and Supplementary Data* is incorporated herein by reference.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Beginning with our initial public offering on May 7, 2013, our common stock is traded on the NASDAQ Global Market under the symbol INSY. The following table sets forth the high and low sales prices for our common stock for the fiscal periods indicated as reported by the NASDAQ Global Market.

Price Range of Common Stock

	Fourth Quarter		Third Quarter		May 7, 2013 – June 30, 2013		First Quarter	
2013 price range per share	$ 53.64	$ 33.07	$ 37.94	$ 13.90	$ 14.50	$ 8.00	NA	NA

Holders

As of February 26, 2014, there were approximately 43 holders of record of our common stock and 22,273,494 shares of our common stock outstanding.

Dividends

Since our initial public offering, we have not declared nor paid dividends on our common stock and we do not expect to pay cash dividends on our common stock in the foreseeable future. Moreover, we are restricted from making cash dividends pursuant to our existing line of credit (see Note 6 to our Consolidated Financial Statements in Part II, Item 8 of this Form 10-K).

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Company Stock Performance

Not applicable.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Forward-Looking Statements

The information in this Annual Report on Form 10-K, or this Form 10-K, including this discussion in Management's Discussion and Analysis of Financial Condition and Results of Operations, or MD&A, contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. All statements, other than statements of historical facts, included or incorporated in this Form 10-K could be deemed forward-looking statements, particularly statements about our plans, strategies and prospects under this MD&A and under the heading "Business." In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue," "intend" or the negative of these terms or other comparable terminology. All forward-looking statements in this Form 10-K are made based on our current expectations, forecasts, estimates and assumptions, and involve risks, uncertainties and other factors that could cause results or events to differ materially from those expressed in the forward-looking statements. In evaluating these statements, you should specifically consider various factors, uncertainties and risks that could affect our future results or operations as described from time to time in our SEC reports., including those risks outlined under "Risk Factors" in Item 1A of this Form 10-K. These factors, uncertainties and risks may cause our actual results to differ materially from any forward-looking statement set forth in this Form 10-K. You should carefully consider the trends, risks and uncertainties described below and other information in this Form 10-K and subsequent reports filed with or furnished to the SEC before making any investment decision with respect to our securities. All forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by this cautionary statement.

These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management; the amount and timing of estimated costs and the benefits of our planned second dronabinol manufacturing facility and the timing of our initiation of manufacturing activities at the facility; estimated costs to complete development and obtain approvals for our Dronabinol Oral Solution product candidate and the timing related to actions in connection therewith; that net revenue from sales of Dronabinol SG Capsule will fluctuate on a quarterly basis; the sufficiency of our manufacturing capacity; the beneficial attributes of our Dronabinol product candidates; our expectation that gross margins will fluctuate; that sales and marketing and research and development costs will be our largest categories of expenses; that sales and marketing expenses will fluctuate based on changes in Subsys net revenue; that our Subsys revenue will increase in 2014; our development of different dronabinol delivery systems; that we can grow market share and net revenue for Subsys and our strategies relating thereto; that we may pursue strategies relating to synthetic cannabidiol; our sales and marketing strategy for future products; that we may pursue strategic transactions such acquisitions or other companies, asset purchase and out- or in-licensing of products, strategic partnerships, joint ventures, divestitures, business combinations and investments; our ability to obtain foundation materials and manufacture dronabinol in light of govemment quotas; our strategy of using Marinol as a reference drug in future drug approval applications; the number, and expected pathway, of drug applications we expect to file in2014; that physicians and payors will gain familiarity about the features of Sybsys; our plans and strategies for obtaining future international approvals; our plans and strategies to protect our intellectual property; our intention of not paying dividends; the source and sufficiency of our liquidity our capital resources to fund our opèrations; possible capital raising transactions we may pursue; that we may avail ourselves of certain SEC reporting and Nasdaq governance requirements because of our status as an emerging growth company and controlled company, respectively; that we will hire additional sales and marketing, research and development and administrative personnel and that costs relating thereto will increase; accounting estimates and the impact of new or recently issued accounting pronouncements; that cash flows from operations will increase as a result of increased sales of Subsys and Dronabinol; the sufficiency and sources of our capital resources; the impact of pending litigation and our strategy relating thereto; that we will not recognize revenue in the near term from current research and development initiatives; the probability of making payments relating to the NeoPharm contingent payment rights; the impact of changing interest rates; the exposure of our cash to default and illiquidity risks; the potential impact of Section 382 limitations on our NOLs; and the magnitude and impact of ownership changes, including pre-merger changes relating to NeoPharm, under Section 382 of the Internal Revenue Code. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

The following discussion and analysis of the results of operations and financial condition of Insys Therapeutics, Inc. for the years ended December 31, 2013 and 2012 should be read in conjunction with the consolidated financial statements and the notes thereto, and other financial information contained elsewhere in this Form 10-K.

Overview

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

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

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

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

We produce the Active Pharmaceutical Ingredient ("API") for Dronabinol SG Capsule at our U.S.-based, state-of-the-art dronabinol manufacturing facility. While we believe that this facility has the capacity to supply sufficient commercial quantities of dronabinol API for our Dronabinol SG Capsule, initial launch quantities of Dronabinol Oral Solution, if approved, and support the continued development of our other dronabinol product candidates in the near-term, we have commenced construction of a second dronabinol manufacturing facility, which we anticipate will enable us to supply sufficient commercial quantities of dronabinol API for our continued commercialization of Dronabinol SG Capsule and for the commercialization of our proprietary dronabinol product candidates, if approved. In May 2011, we entered into a supply and distribution agreement with Mylan, pursuant to which we engaged Mylan to exclusively distribute Dronabinol SG Capsule within the United States. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

In addition, we are developing other product candidates, such as cannabinoid line extensions and sublingual spray product candidates. Our most advanced potential cannabinoid line extension is Dronabinol Oral Solution. This product candidate has demonstrated more rapidly detectable blood levels and a more reliable absorption profile than Marinol in our clinical studies. We believe these attributes may ultimately increase patient compliance because of more rapid onset of action and less dose-to-dose variability, which we believe will allow us to further penetrate and potentially expand the market for the medical use of dronabinol. We completed a pre-NDA meeting with the FDA and a pivotal bioequivalence study for Dronabinol Oral Solution in 2012 and we completed the clinical dossier for this product candidate during the third quarter of 2013. We are currently engaged in an ongoing dialogue with the U.S. FDA and U.S. Drug Enforcement Agency ("DEA") regarding the potential scheduling classification for this product candidate. As a result, we expect to file the NDA by the second half of 2014.

Factors Affecting Our Performance

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

Approved Product Sales. Our operating results will depend significantly upon our, and any of our third-party distributors', sales of approved products. During the years ended December 31, 2013 and 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 selling efforts with respect to our products. In addition, our results will also depend on our mix of sales between Subsys and Dronabinol SG Capsule as well as the amounts of dosage strengths sold. Subsys gross margins are substantially higher than those of Dronabinol SG Capsule. For example, though we expect gross margins to fluctuate from period to period, Subsys gross margin was approximately 90% and Dronabinol SG Capsule gross margin was approximately 25% for the year ended December 31, 2013. Moreover, our gross margins improve on a unit-by-unit basis as we sell higher dosage strengths of our products. Importantly, the proportion of prescriptions written for repeat Subsys patients has continued to increase since July 2012 from 50% of prescriptions to over 80% of prescriptions as of December 2013. Generally, repeat Subsys patients receive significantly higher doses of Subsys on average than first-time patients as patients are titrated from a starter dose of Subsys to their effective dose in accordance with the TIRF REMS protocol. As Subsys was first launched in March, 2012, prior to the fourth quarter of 2013, we deferred 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 estimated patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. In the fourth quarter of 2013, we changed the timing of our revenue recognition for Subsys and began recognizing revenue upon shipment to our customers, which resulted in a one-time increase of $1.5 million in product sales and $0.9 in gross profit during the fourth quarter of 2013.

Investments in Our Infrastructure and Growth . Our ability to increase our sales and to further penetrate our target market segments is dependent in part on our ability to invest in our infrastructure and in our sales and marketing efforts. In order to drive further growth, we may hire additional sales and marketing personnel and invest in marketing our products to our target physician prescriber base. For example, as of December 31, 2013, we had 145 full-time sales and marketing personnel. This will lead to corresponding increases in our operating expenses, although we anticipate that these investments will result in increased product sales and net revenue. In addition, we have commenced construction on 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 million to $13 million, of which approximately $4 million had been spent by December 31, 2013. This second facility will also increase our operating expenses. We have incurred and will continue to incur substantial operating costs in connection with our transition to operating as a public company, including increasing headcount and salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors' and officers' insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

Product Development and Related Regulatory Processes. Our operating results will also depend significantly on our research and development activities and related regulatory approvals and compliance. Our research and development expenses were $8.5 million and $6.3 million for the years ended December 31, 2013 and 2012, respectively. As of December 31, 2013, we had 29 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary cannabinoid product candidates, including Dronabinol Oral Solution, and sublingual spray product candidates. 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 $4.0 million. We do not expect to realize net revenues from all of these research and development initiatives in the near term and may never realize net revenues from these investments. Due to the risks inherent in conducting preclinical studies and clinical trials, the regulatory approval process and the costs of preparing, filing and prosecuting patent applications, our development completion dates and costs will vary significantly for each product candidate and are very difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable regulations require the expenditure of substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals or acceptable U.S. Drug Enforcement Administration, or DEA, classifications for our product candidates, in particular those related to Dronabinol Oral Solution, could cause our research and development expenditures to increase significantly and, in turn, have a material adverse effect on our results of operations.

Basis of Presentation

Net Revenue

During the year ended December 31, 2012, we began recognizing net revenue from sales of Subsys made by us, and from Dronabinol SG Capsule under our supply and distribution agreement with Mylan. We sell Subsys in packages of various sized single-dose units in dosage strengths of 100, 200, 400, 600, 800, 1,200 and 1,600 mcg, to wholesale pharmaceutical distributors and retail pharmacies, collectively, our customers, on a wholesale basis. Sales to our customers are subject to specified rights of return. From product launch in March 2012 to September 30, 2013, because we did not have sufficient historical information to estimate returns, we deferred 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 estimated patient prescriptions dispensed using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. In the fourth quarter of 2014, in response to our ability to estimate returns, we changed the timing of our revenue recognition for Subsys and began recognizing revenue upon shipment to our customers, which resulted in a one-time increase of $1.5 million in product sales and $0.9 million in gross profit during the fourth quarter of 2014. The deferred revenue balance was $3.8 million at December 31, 2012, which was net of estimated pharmacy discounts, stocking allowances, prompt pay discounts, chargebacks, rebates and patient discount programs.

We sell Dronabinol SG Capsule exclusively to Mylan in dosage strengths of 2.5, 5.0 and 10.0 milligrams under the Mylan label. Mylan distributes Dronabinol SG Capsule and on a monthly basis pays us an amount equal to the value of Dronabinol SG Capsule it sold to wholesale pharmaceutical distributors and retail pharmacies, less contractually defined deductions for chargebacks, rebates, sales discounts, distribution and storage fees, and royalties. We are obligated to pay Mylan a royalty between 10% and 20% on Mylan's net product sales, and a single digit percentage fee on such sales for distribution and storage services. We bear no risk of product return upon acceptance by Mylan. As Mylan has control over the amount it charges to wholesale pharmaceutical distributors for Dronabinol SG Capsule and the discounts offered to the distributors, the sales price is not fixed and determinable at the date we ship such product to Mylan. Accordingly, we recognize revenue on the sale of Dronabinol SG Capsule upon Mylan's sale of product to wholesale distributors, which is the point at which the sales price is fixed and determinable. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

Cost of Revenue, Gross Profit and Gross Margin

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

The cost of revenue associated with the deferred product revenues are recorded as deferred costs, which are included in inventories until such time as the deferred revenue is recognized. Deferred cost of revenue was $0 and $546,000 as of December 31, 2013 and 2012, respectively.

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

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries, commissions, benefits, consulting fees, costs of obtaining prescription and market data, and market research studies related to Subsys. As of December 31, 2013, we had 145 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 2014 to the extent that expected increases in Subsys net revenue are realized.

Research and Development Expenses

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

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

To date, our research and development efforts have been focused primarily on our fentanyl and dronabinol programs. As of December 31, 2013, we had 29 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary dronabinol product candidates, including Dronabinol Oral Solution. We determine which research and development projects to pursue, as well as the level of funding available for each project, based on the scientific and preclinical and clinical results of each product candidate and related regulatory action. We expect our research and development expenses, along with our sales and marketing expenses, to be our largest categories of operating expenses for the foreseeable future.

The following table provides a breakdown of our research and development expenses during the years ended December 31, 2013 and 2012 (in millions):

	Years ended December 31,	
	2013	**2012**
Dronabinol	$ 2.0	$ 1.7
Fentanyl	0.8	1.6
Buprenorphine	0.6	-
Buprenorphine/Naloxone	0.6	-
Sildenafil	0.2	-
LEP-ETU and IL-13	0.2	-
Internal research and development costs	4.1	3.0
Total research and development expenses	$ 8.5	$ 6.3

General and Administrative Expenses

Our general and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, accounting, business development and internal support functions. In addition, general and administrative expenses include facility costs not otherwise included in research and development expenses, and professional fees for legal, consulting and accounting services. As of December 31, 2013, we had 16 full-time general and administrative personnel. We expect general and administrative expense will increase as a result of increasing related headcount, expanding our operating activities and the costs we will incur operating as a public company. We expect these increases to include salaries and related expenses, legal and consultant fees, accounting fees, director fees, increased directors' and officers' insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

Other Income (Expense), Net

In connection with the NeoPharm merger, the NeoPharm board approved the distribution, immediately after the merger, of non-transferable contingent payment rights to its stockholders of record as of November 5, 2010. These rights entitle the pre-merger stockholders of NeoPharm to receive cash payments aggregating $20.0 million (equivalent to $0.70402 per share) if, prior to the five year anniversary of the NeoPharm merger, the FDA approves an NDA for any one or more of the NeoPharm product candidates that were under development at the time of the merger. The distribution is payable within nine months of FDA approval. The initial fair value of this contingent payment was determined to be approximately $1.8 million based on the assumed probability of any payment being made to the prior NeoPharm stockholders in 2015, discounted to present value at a rate of 15%, a Level 3 fair value measurement. In October 2012, 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 $2.1 million was recorded as other income for the year ended December 31, 2012.

Interest Expense, Net

Interest income (expense), net has consisted primarily of the interest accrued on outstanding promissory notes payable to The John N. Kapoor Trust and the Kapoor Children 1992 Trust. These trusts are controlled by or are affiliated with our founder, Executive Chairman and principal stockholder, Dr. John N. Kapoor. These promissory notes carried interest rates equal to the applicable prime rate plus 2.0%, which was 5.25% as of May 7, 2013. We recorded interest expense of $0.9 million and $2.6 million related to accrued interest on these notes during the years ended December 31, 2013 and 2012, respectively. Upon completion of our IPO in May 2013, all outstanding principal and accrued interest on the Kapoor Notes converted into 7,410,341 shares of common stock and all of the Kapoor Notes were cancelled.

During the year ended December 31, 2012, we entered into a $15.0 million revolving credit facility with Bank of America. The outstanding principal balance under this facility was $11.4 million as of May 7, 2013 and we recorded interest expense of $0.1 million during each of the years ended December 31, 2013 and 2012, in connection with borrowings under this credit facility. This balance was paid off on May 10, 2013 with proceeds from the IPO.

During the year ended December 31, 2013, we entered into a $15.0 million revolving credit facility with JPMorgan Chase Bank. As of December 31, 2013, there have been no outstanding borrowings against this facility.

From May 7, 2013 through December 31, 2013, we recorded interest income of approximately $22,400 that was earned from the excess cash held as a result of our IPO.

Income Tax Benefit, Net Operating Loss Carryforwards

In each period prior to December 31, 2013, we have recorded a valuation allowance for the full amount of our net deferred tax assets, as the realization of our deferred tax assets was uncertain. As a result, we have not previously recorded any federal or state income tax benefit in our consolidated statements of comprehensive income (loss).

As of December 31, 2013, we had approximately $13.1 million of federal net operating loss carry forwards ("NOLs"), including $11.0 million related primarily to excess tax deductions relating to stock option exercises which have not been benefitted in the financial statements, and $2.1 million of which is subject to a significant Section 382 limitation as noted below. For federal tax purposes, the Section 382 NOL carryforward is limited on an annual basis and begins expiring in 2034. The remaining $11.0 million NOL carryforward, which is not limited, expires in 2032 to the extent that it is not utilized.

During the fourth quarter of 2013, we determined it was more likely than not that we would be able to utilize all our federal net operating loss carryforwards based on our profitability in 2013 and our expectations of future profitability. Accordingly, we reversed the deferred tax asset valuation allowance associated with the federal NOLs and other deferred tax assets in the amount of $18.6 million and recorded an overall income tax benefit of $8.8 million for the year ended December 31, 2013.

For state tax purposes, we had approximately $292 million of state NOLs at December 31, 2013, including $11.0 million related primarily to excess tax deductions relating to the exercise of stock options. Approximately $271 million of these NOLs relate only to Illinois. Based on projections and our limited activity in Illinois, we estimate that approximately $267 million of these Illinois NOLs will not be utilized. For this reason, we recorded a valuation allowance for the estimated tax benefit relating to this amount, or $20.7 million. Generally, the state NOL carryforwards begin expiring in 2027 if not utilized. The Illinois NOLs begin expiring in 2014 if not utilized.

Under Section 382 of the Code, substantial changes in our ownership may limit the amount of NOLs that can be utilized annually in the future to offset taxable income, if any. Specifically, this limitation may arise in the event of a cumulative change in ownership of our company of more than 50% within a three-year period as determined under the Code, which we refer to as an ownership change. Any such annual limitation may significantly reduce the utilization of these NOLs before they expire. Our ability to utilize federal NOLs created prior to the NeoPharm merger is significantly limited.

Based on the above, we have estimated the amount of pre-NeoPharm merger federal NOLs that are available to offset post-NeoPharm merger income at approximately $2.1 million as of December 31, 2013. Post-NeoPharm merger, federal NOLs of approximately $11.0 million, which resulted primarily from excess tax over book deductions for stock option deductions and are not currently benefited, are available as of December 31, 2013, are not subject to this annual limitation, and begin expiring in 2032.

Significant Accounting Polices 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 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 history of prescriptions of Subsys, we were not able to reliably estimate expected returns of the product at the time of shipment prior to the fourth quarter of 2013. Accordingly, we initially deferred the recognition of revenue and related product costs of Subsys product shipments until the product was dispensed through patient prescriptions. The quantity of prescription units dispensed was estimated using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. Based on the shipment and prescription trends for Subsys and based on an analysis of historical return rates of our own experience with Subsys, we concluded that we had the information needed to reasonably estimate product returns for Subsys during the fourth quarter of 2013. Beginning in the fourth quarter of 2013, in response to our ability to reasonably estimate returns, we began recognizing revenue for Subsys sales at the time of shipment to our customers. Accordingly, in the fourth quarter of 2013, we recognized a one-time increase of $1.5 million in net product sales of Subsys, representing product sales previously deferred, net of estimated product returns, wholesaler discounts, prompt pay discounts, stocking allowances, patient discount programs, rebates, and chargebacks. Including deferred cost of sales, this change resulted in a one-time $0.9 million increase to operating income for the year ended December 31, 2013. Prior to this change, cost of manufacturing Subsys associated with the deferred revenue was recorded as deferred costs, which were included in inventory, until such time as the deferred revenue was 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:

Product Returns. We allow customers to return product for credit on returned product that is within six months before and up to 12 months following its product expiration date. The shelf life of Subsys is currently 36 months from the date of manufacture. We monitored actual product sold through to patient prescriptions since product launch, which provides us with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

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

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 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. The allowance for patient discount programs is included in accrued expenses.

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. The allowance for rebates is included in accrued expenses.

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. The allowance for chargebacks is included in accrued expenses.

A rollforward of our product sales allowances for the years ended December 31, 2013 and 2012 is as follows (in thousands):

	Wholesale Discounts [1]	Patient Discount Programs	Rebates	Returns	Total
Balance at December 31, 2011	$ -	$ -	$ -	$ -	$ -
Revenue allowances:					
Provision related to current period sales	1,309	3,565	235	-	5,109
Provisions related to sales made in prior years	-	-	-	-	-
Recorded to balance sheet [2]	538	1,540	102	-	2,180
Payment and credits related to sales made in current period	(1,013)	(3,565)	(203)	-	(4,781)
Payment and credits related to sales made in prior periods	-	-	-	-	-
Balance at December 31, 2012	834	1,540	134	-	2,508
Revenue allowances:					
Provision related to current period sales	9,038	10,351	6,997	1,294	27,680
Provisions related to sales made in prior years	-	3	371	12	386
Recorded to balance sheet [2]	-	-	-	-	-
Provision related to change in revenue recognition	(526)	(1,490)	(102)	221	(1,897)
Payment and credits related to sales made in current period	(5,764)	(7,905)	(3,110)	(928)	(17,707)
Payment and credits related to sales made in prior periods	(834)	(1,543)	(505)	-	(2,882)
Balance at December 31, 2013	$ 2,748	$ 956	$ 3,785	$ 599	$ 8,088

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

(2) From product launch in March 2012 to September 30, 2013, because we did not have sufficient historical information to estimate returns, we deferred 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. 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. Because we changed the timing of our revenue recognition in the fourth quarter of 2013, no such amounts were deferred at December 31, 2013.

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 we ultimately charge to Mylan is fixed and determinable. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

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.

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, 2013 and 2012.

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 previously estimated the fair value of our common stock. Upon the completion of our May 2013 IPO, our common stock is 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.

- 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.

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.

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. In the fourth quarter of 2013, we determined that it was more likely than not that we will ultimately be able to utilize a portion of deferred tax assets for which a valuation allowance had been provided. Accordingly, during the year ended December 31, 2013, the valuation allowance was reduced by $26.2 million and we recorded a total income tax benefit of $8.8 million.

Recently Issued Accounting Pronouncements

Recent accounting pronouncements which may be applicable to us are discussed in “Note 2. Significant Accounting Policies” in our Consolidated Financial Statements contained herein in Part II, Item 8.

Results of Operations

Comparison of year ended December 31, 2013 to year ended December 31, 2012

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

	Years ended December 31,	
	2013	**2012**
Net revenue	100.0%	100.0%
Cost of revenue	12.8	49.3
Gross profit	87.2	50.7
Operating expenses:		
Sales and marketing	29.4	73.7
Research and development	8.6	40.7
General and administrative	16.5	52.8
Impairment of intangible assets and goodwill	-	34.9
Total operating expenses	54.5	202.2
Operating income (loss)	32.8	(151.5)
Other (expense) income:		
Interest expense, net	(0.9)	(17.3)
Other expense (income)	(0.1)	11.3
Total other (expense) income	(1.0)	(6.1)
Income (loss) before income taxes	31.8	(157.5)
Income tax benefit	8.8	-
Net income (loss)	40.6%	(157.5)%

Net Revenue. Net revenue increased $83.8 million, or 542%, to $99.3 million for the year ended December 31, 2013, compared to $15.5 million for the year ended December 31, 2012. The increase in net revenue was primarily attributable to the $87.1 million, or 1020%, increase in net revenue of Subsys to $95.7 million for the year ended December 31, 2013 compared to $8.6 million for the year ended December 31, 2012, as Subsys was initially marketed in 2012. Included in this increase is $1.5 million from the change in timing of our revenue recognition for Subsys products. Provisions for wholesaler discounts, patient discounts, rebates and returns increased to $9.0 million, $10.4 million, $7.4 million and $1.3 million, respectively, or 22.7% on a combined basis of gross revenue from the sale of Subsys for the year ended December 31, 2013, compared to $1.3 million, $3.6 million and $0.2 million, and zero, respectively, or 37.4% on a combined basis of gross revenue from the sale of Subsys for the year ended December 31, 2012. The decrease in revenue provisions as a percentage of gross revenue was primarily attributable to decreased provisions for patient discounts compared to gross revenue. We expect net revenue from sales of Subsys to continue to increase during 2014 due primarily to anticipated increases in the number of prescriptions fulfilled, combined with changes in prescription strength mix. The increase in sales of Subsys was partially offset by a decrease in sales of Dronabinol SG Capsule of $3.3 million to $3.6 million for the year ended December 31, 2013, compared to $6.9 million for the year ended December 31, 2012. The decrease in sales of Dronabinol SG Capsule was due primarily to a dispute with our exclusive distributor of Dronabinol SG Capsule and the resulting impact of reduced product supply and lower selling prices since 2012. As Dronabinol SG Capsule is marketed by Mylan, we expect net revenue from sales of Dronabinol SG Capsule to continue to fluctuate on a quarterly basis.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $5.1 million to $12.7 million for the year ended December 31, 2013 compared to $7.6 million for the year ended December 31, 2012. The increase in cost of revenue was primarily attributable to the increase in sales of Subsys during the year ended December 31, 2013. Gross profit increased $78.8 million to $86.6 million for the year ended December 31, 2013 compared to $7.8 million for the year ended December 31, 2012. Gross margin for the year ended December 31, 2013 was approximately 87% compared to approximately 51% for the year ended December 31, 2012. The increase in gross margin was due primarily to a higher mix of sales of Subsys, which yields higher gross margins than sales of Dronabinol SG Capsule. Subsys gross margin was approximately 90% and 81% for the years ended December 31, 2013 and 2012, respectively. This increase in 2013 is attributable to a shift in sales mix to higher margin products in 2013 as repeat patients progress to higher dosage prescriptions as well as the effects of higher patient discounts during 2012 in connection with the market launch of Subsys. Dronabinol SG Capsule gross margin was approximately 25% and 13% for the years ended December 31, 2013 and 2012, respectively, based on changes in patient discounts offered by our distributor Mylan.

Sales and Marketing Expense. Sales and marketing expense increased $17.8 million to $29.2 million for the year ended December 31, 2013 compared to $11.4 million for the year ended December 31, 2012. The increase in sales and marketing expense was due primarily to variable sales compensation expense and incremental product marketing expense associated with the increase in sales of Subsys, as Subsys was initially marketed in 2012. As Dronabinol SG Capsule is marketed by Mylan, we did not incur any sales and marketing expense related to Dronabinol SG Capsule.

Research and Development Expense. Research and development expense increased $2.2 million to $8.5 million for the year ended December 31, 2013 compared to $6.3 million for the year ended September 30, 2012. The increase in research and development expense was due primarily to an increase in research and development personnel during 2013 in response to our growing product pipeline.

General and Administrative Expense. General and administrative expense increased $8.2 million to $16.4 million for the year ended December 31, 2013 compared to $8.2 million for the year ended December 31, 2012. The increase in general and administrative expense was due primarily to costs incurred in connection with increases in administrative infrastructure to support the growth of Subsys sales combined with increased cost of being a public company during 2013.

Impairment of Intangible Assets and Goodwill. During the year 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.

Interest Expense. Interest expense was $0.9 million for the year ended December 31, 2013, compared to $2.7 million for the year ended December 31, 2012. The decrease in interest expense was primarily a result of the conversion of the Kapoor Notes to common stock and the repayment of the $15.0 million line of credit in May 2013.

Other Income (Expense), Net. Other income (expense), net was $(54,000) for the year ended December 31, 2013, compared to $1.7 million for the year ended December 31, 2012. Other income (expense), net for the year ended December 31, 2012 includes a gain of $2.1 million resulting from the reversal of an accrual for contingent consideration in connection with the NeoPharm merger as we concluded that it was not probable that it would be paid.

Income Tax Benefit. 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. In the fourth quarter of 2013, we determined that we will ultimately be able to utilize a portion of deferred tax assets for which a valuation allowance had previously been provided. Accordingly, during the year ended December 31, 2013, the valuation allowance was reduced by $26.2 million and we recorded a total income tax benefit of $8.8 million.

Liquidity and Capital Resources

Sources of Liquidity

We incurred losses from our inception through December 31, 2012. As of December 31, 2013, we had an accumulated deficit of $89.0 million. Prior to our initial public offering, or IPO, we financed our operations primarily through the issuance of promissory notes to The John N. Kapoor Trust and the Kapoor Children 1992 Trust, which are controlled by or affiliated with our founder, Executive Chairman and principal stockholder.

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

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

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

In October 2013, we entered into a $15.0 million revolving credit facility with JPMorgan Chase Bank, N.A., which includes a $500,000 letter of credit facility. Under the terms of the credit facility, amounts outstanding bear interest at LIBOR plus 1.5% and the credit facility is subject to a 0.35% non-usage fee. Advances are subject to a borrowing base such that the maximum advances that may be outstanding under is limited to 80% of the book value of eligible accounts receivable. The credit facility matures on September 30, 2014. At December 31, 2013, no amounts were outstanding and $12.1 million was available to borrow, taking into account the applicable borrowing base limitations.

Cash Flows

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

	Years ended December 31,	
	2013	**2012**
Net cash provided by (used in) operating activities	$ 24.2	$ (13.6)
Net cash used in investing activities	(5.5)	(1.0)
Net cash provided by financing activities	26.3	15.0
Net increase in cash and cash equivalents	45.0	0.4
Cash and cash equivalents, beginning of year	0.4	-
Cash and cash equivalents, end of year	$ 45.4	$ 0.4

Cash Flows From Operating Activities. Net cash provided by operating activities was $24.2 million for the year ended December 31, 2013 and net cash used in operating activities was $13.6 million for the year ended December 31, 2012. The net cash provided during the year ended December 31, 2013 primarily reflects the net income for the year driven primarily by growth in Subsys net sales, adjusted in part by depreciation and amortization, stock-based compensation expense and non-cash interest expense and is also impacted by changes in working capital.

Cash Flows From Investing Activities. Net cash used in investing activities was $5.5 million and $1.0 million for the years ended December 31, 2013 and 2012, respectively, and consists primarily of the purchase of equipment and leasehold improvements. During 2013, we incurred approximately $4 million in connection with the construction of our second dronabinol facility and we expect to incur an addition $7 million to $9 million in 2014 to complete construction.

Cash Flows From Financing Activities. Net cash provided by financing activities was $26.3 million and $15.0 million for the years ended December 31, 2013 and 2012, respectively. During the year ended December 31, 2013, we received $32.5 million in net proceeds in connection with our IPO. We used $11.9 million of these proceeds to pay in full the credit facility with Bank of America. During the year ended December 31, 2013, we also received proceeds of $2.1 million from the exercise of stock options and $0.9 million of proceeds from shares issued under an employee stock purchase program. Additionally, we recognized excess tax benefits on stock options and awards of $2.7 million. 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 increased borrowings under promissory notes payable to The John N. Kapoor Trust and The Kapoor Children 1992 Trust of $3.0 million.

We invoice wholesalers upon shipment of Subsys. To date, our wholesalers have typically paid us 30 to 60 days from their applicable invoice dates.

Our cash flows for 2014 and beyond will depend on a variety of factors, including sales of Subsys and Dronabinol SG Capsule and any additional approved products, regulatory approvals, investments in manufacturing and production such as our planned second dronabinol manufacturing facility, capital equipment, and research and development. We expect our net cash inflows from operating activities to increase as we expect to increase sales of Subsys and Dronabinol SG Capsule, partially offset by anticipated expansion in sales and marketing, research and development, manufacturing, and general and administrative expenses as a public company.

Funding Requirements

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

As of December 31, 2013, we had $12.1 million of undrawn capacity available under our revolving credit facility with JPMorgan Chase Bank.

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

- the levels and mix of our product sales;
- the rates of progress, costs and outcomes of our clinical trials and other product development programs, including for Dronabinol Oral Solution and any other product candidates that we may develop, in-license or acquire;
- regulatory approvals, DEA classifications and other regulatory related events;
- personnel, facilities, equipment and other similar requirements;
- costs of operating as a public company;
- the effects of competing technological and market developments;
- costs associated with litigation;
- costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates;
- our ability to acquire or in-license products and product candidates, technologies or businesses; and
- terms and timing of any additional collaborative, licensing, co-promotion or other arrangements that we may establish.

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

Off-Balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required for smaller reporting companies.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2013 and 2012 and the related consolidated statements of comprehensive income (loss), stockholders' equity (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, 2013 and 2012, 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
March 4, 2014

INSYS THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	December 31,	
	2013	**2012**
Assets		
Current Assets:		
Cash and cash equivalents	$ 45,382	$ 361
Restricted cash	400	-
Accounts receivable, net of allowances of $2,748 and $834 as of December 31, 2013 and 2012, respectively	16,313	3,089
Inventories	14,528	7,095
Prepaid expenses and other assets	1,727	1,344
Deferred income tax assets	3,800	-
Total current assets	82,150	11,889
Property and equipment, net	10,127	6,791
Deferred income tax assets	8,238	-
Other assets	43	61
Total assets	$ 100,558	$ 18,741
Liabilities and Stockholders' Equity (Deficit)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 16,557	$ 6,479
Accrued compensation	3,568	1,392
Deferred patient discount program	956	1,540
Deferred revenue	-	3,767
Line of credit	-	11,858
Notes payable to related party, including interest	-	58,383
Total current liabilities	21,081	83,419
Total liabilities	21,081	83,419
Commitments and contingencies (see Note 8)	-	-
Stockholders' Equity (Deficit):		
Convertible preferred stock (par value $0.01 per share, 10,000,000 and 15,000,000 shares authorized as of December 31, 2013 and 2012, respectively ; 0 and 14,864,607 shares issued and outstanding as of December 31, 2013 and 2012, respectively)	-	149
Common stock (par value $0.0002145 per share, 50,000,000 and 25,000,000 shares authorized as of December 31, 2013 and 2012, respectively; 22,123,248 and 856,026 shares issued and outstanding as of December 31, 2013 and 2012, respectively	5	-
Additional paid in capital	168,526	64,604
Notes receivable from stockholders	(21)	(21)
Accumulated deficit	(89,033)	(129,410)
Total stockholders' equity (deficit)	79,477	(64,678)
Total liabilities and stockholders' equity (deficit)	$ 100,558	$ 18,741

See accompanying notes to consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands, except share and per share data)

	Years Ended December 31,	
	2013	**2012**
Net revenue	$ 99,289	$ 15,476
Cost of revenue	12,665	7,627
Gross profit	86,624	7,849
Operating expenses:		
Sales and marketing	29,194	11,411
Research and development	8,499	6,305
General and administrative	16,372	8,170
Impairment of intangible assets and goodwill	-	5,403
Total operating expenses	54,065	31,289
Operating income (loss)	32,559	(23,440)
Other (expense) income:		
Interest expense	(928)	(2,684)
Other (expense) income, net	(54)	1,746
Total other (expense) income	(982)	(938)
Income (loss) before income taxes	31,577	(24,378)
Income tax benefit	8,800	-
Net and comprehensive income (loss)	$ 40,377	$ (24,378)
Net income (loss) per common share:		
Basic	$ 2.34	$ (2.62)
Diluted	$ 2.11	$ (2.62)
Weighted average common shares outstanding		
Basic	17,279,845	9,316,034
Diluted	19,156,411	9,316,034

See accompanying notes to consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(in thousands, except share amounts)

	Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Notes Receivable From Shareholders	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount				
Balance at December 31, 2011	14,864,607	$ 149	784,020	$ -	$ 61,691	$ (21)	$ (105,032)	$ (43,213)
Net loss	-	-	-	-	-	-	(24,378)	(24,378)
Exercise of stock options	-	-	72,006		152			152
Stock based compensation - stock options and awards	-		-		2,761	-	-	2,761
Balance at December 31, 2012	14,864,607	149	856,026	-	64,604	(21)	(129,410)	(64,678)
Conversion of preferred to common stock	(14,864,607)	(149)	8,528,860	2	147	-	-	-
Conversion of notes payable to common stock	-	-	7,410,341	2	59,282	-	-	59,284
Issuance of common stock - initial public offering	-	-	4,600,000	1	32,455	-	-	32,456
Issuance of common stock - employee stock purchase plan	-	-	125,370	-	852	-	-	852
Exercise of stock options	-	-	602,651	-	2,102	-	-	2,102
Excess tax benefits on stock options and awards	-	-	-	-	2,745	-	-	2,745
Stock based compensation - stock options and awards	-	-	-	-	6,339	-		6,339
Net income	-	-	-	-	-	-	40,377	40,377
Balance at December 31, 2013	-	$ -	22,123,248	$ 5	$ 168,526	$ (21)	$ (89,033)	$ 79,477

See accompanying notes to consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years ended December 31,	
	2013	**2012**
Cash flows from operating activities:		
Net income (loss)	$ 40,377	$ (24,378)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	1,788	1,662
Stock-based compensation	6,339	2,761
Deferred income tax benefit	(12,038)	-
Excess tax benefits on stock options and awards	(2,745)	-
Impairment of intangible assets	-	5,300
Impairment of goodwill	-	103
Loss on disposal of assets	-	46
Interest expense, accrued on notes payable	900	2,582
Accretion (re-valuation) of contingent payment obligation	-	(2,114)
Changes in operating assets and liabilities:		
Accounts receivable	(13,224)	(3,089)
Inventories	(7,433)	(360)
Prepaid expenses and other current assets	(365)	(73)
Accounts payable, accrued expenses, and other current liabilities	14,417	166
Deferred revenue	(3,767)	3,767
Net cash provided by (used in) operating activities	24,249	(13,627)
Cash flows from investing activities:		
Change in restricted cash	(400)	-
Purchases of property and equipment	(5,125)	(1,020)
Net cash used in investing activities	(5,525)	(1,020)
Cash flows from financing activities		
Net borrowings (repayments) on line of credit	(11,858)	11,858
Proceeds from notes payable to related party	-	2,987
Excess tax benefits on stock options and awards	2,745	-
Proceeds from exercise of stock options	2,102	152
Proceeds from issuance of common stock - initial public offering	32,456	-
Proceeds from issuance of common stock - employee stock purchase plan	852	-
Net cash provided by financing activities	26,297	14,997
Change in cash and cash equivalents	45,021	350
Cash and cash equivalents, beginning of year	361	11
Cash and cash equivalents, end of year	$ 45,382	$ 361
Supplemental cash flow disclosures:		
Cash paid for interest expense	$ 51	$ 98
Cash paid for income taxes	$ 991	$ -

See accompanying notes to consolidated financial statements.

1. Nature of Business

Insys Therapeutics, Inc., which was incorporated in Delaware in June 1990, and our subsidiaries (collectively, "we," "us," and "our") maintain headquarters in Chandler, Arizona. We were in the development stage through December 31, 2011. The year 2012 is the first year during which we were considered an operating company and were no longer in the development stage.

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

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, we effected a merger with NeoPharm, Inc. ("NeoPharm") in a transaction accounted for as a reverse acquisition (the "NeoPharm merger"). All of our outstanding share capital was exchanged for newly-issued shares of common stock and convertible preferred stock of NeoPharm. As a result of the NeoPharm merger, we became a wholly-owned subsidiary of NeoPharm and changed our 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 Therapeutics, Inc. 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.

Fair Value of Financial Instruments

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

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

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

Subsys

Subsys was commercially launched in March 2012, and is available through a U.S. Food and Drug Administration ("FDA") mandated Risk Evaluation and Mitigation program known as the Transmucosal Immediate Release Fentanyl program ("TIRF REMS"). We sell Subsys in the United States to wholesale pharmaceutical distributors, and on a very limited basis directly to retail pharmacies, 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 prescriptions of Subsys, we were not able to reliably estimate expected returns of the product at the time of shipment prior to the fourth quarter of 2013. Accordingly, we initially deferred the recognition of revenue and related product costs of Subsys product shipments until the product was dispensed through patient prescriptions. The quantity of prescription units dispensed was estimated using an analysis of third-party information, including TIRF REMS mandated data and third-party market research data. Beginning in the fourth quarter of 2013, we were able to reasonably estimate product returns of Subsys. Therefore, we began recognizing revenue for Subsys sales at the time of shipment. Accordingly, in the fourth quarter of 2013, we recognized a one-time increase of $1.5 million in net product sales of Subsys, representing product sales previously deferred, net of estimated product returns, wholesaler discounts, prompt pay discounts, stocking allowances, patient discount programs, rebates, and chargebacks. Including deferred cost of sales, this change resulted in a one-time $0.9 million increase to operating income for the year ended December 31, 2013.

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

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

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

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 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. The allowance for patient discount programs is included in accrued expenses.

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

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

Dronabinol SG Capsule

Dronabinol SG Capsule was commercially launched in December 2011, and we sell Dronabinol SG Capsule exclusively to Mylan Pharmaceuticals, Inc. ("Mylan") in the United States under a supply and distribution agreement. Pursuant to the terms of the Mylan agreement, we manufacture Dronabinol SG Capsule under the Mylan label. Mylan distributes Dronabinol SG Capsule and on a monthly basis pays us an amount equal to the value of Dronabinol SG Capsule it sold to wholesale pharmaceutical distributors, less contractually defined deductions for chargebacks, rebates, sales discounts, distribution and storage fees, and royalties. Under the terms of the supply and distribution agreement with Mylan, we are obligated to pay Mylan a royalty of between 10% and 20% on Mylan's net product sales, and a single digit percentage fee on such sales for distribution and storage services. We bear no risk of product return upon acceptance by Mylan. As Mylan has control over the amount it charges to wholesale pharmaceutical distributors for Dronabinol SG Capsule and the discounts offered to the distributors, the sales price is not fixed and determinable at the date we ship such products to Mylan. Accordingly, we recognize revenue upon Mylan's sale of products to wholesale distributors, which is the point at which the sales price is fixed and determinable. See Note 8 under the heading "-Legal Matters" of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Mylan.

Cash and Cash Equivalents

We consider 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 wholesaler discounts, prompt pay discounts and stocking allowances. We evaluate the collectability of our 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, we did not record an allowance for doubtful accounts as of December 31, 2013 and 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 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.

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 and Goodwill

As described in Note 5, our intangible assets and goodwill were fully impaired in 2012. Prior to that impairment, intangible assets consisted of in-process research and development ("IPR&D") and goodwill which represented the excess of the purchase price over the fair value of the net assets 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.

Income Taxes

We account for our 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.

We record 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.

We recognize 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.

Our policy is to classify interest and penalties associated with income tax liabilities as income tax expense in the statement of operations.

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. We use the Black-Scholes option pricing model for estimating the grant date fair value of stock options using the following assumptions:

- Exercise price - Prior to May 7, 2013, we determined the exercise price based on valuations using the best information available to management at the time of the valuations. Subsequent to our IPO on May 7, 2013, the exercise price is equal to the fair market value of the stock on the grant date which is determined based on quoted market prices.

- Volatility - Prior to the NeoPharm merger, we did not have a history of market prices for our common stock. Between the date of the NeoPharm merger and our IPO on May 7, 2013, we did 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. Following our IPO on May 7, 2013, while we have an active trading market, we do not have sufficient historical data to accurately determine volatility for the period equivalent to the expected term of the stock option grants. 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.

- Expected term - 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.

- Risk-free rate - 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.

- Dividends - The dividend yield assumption is based on our history and expectation of paying no dividends.

- Forfeitures - Forfeitures are assumed to be insignificant.

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 our integration and management strategies, we operate in a single reportable segment.

Recent Accounting Pronouncements

In July 2013, the FASB issued guidance that requires a reporting entity to present an unrecognized tax benefit as a liability in the financial statements separate from deferred tax assets if a net operating loss carry forward, a similar tax loss, or a tax credit carryforward is not available as of the reporting date to settle taxes that would result from the disallowance of the tax position or if a reporting entity does not intend to use the deferred tax asset for such purpose. This standard will be effective for us beginning December 31, 2013. We are currently assessing the impact of this new guidance.

In February 2013, the FASB issued guidance that requires a reporting entity to present information about reclassification adjustments from accumulated other comprehensive income in its financial statements or footnotes. This guidance is effective for fiscal years and interim periods within those years beginning after December 15, 2012. We adopted this guidance in the first interim period for the year ended December 31, 2013 and, as we had no accumulated other comprehensive income as of December 31, 2013 or 2012, there was no impact on our financial position, results of operations or cash flows as of and for the year ended December 31, 2013.

3. Inventories

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

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

	As of December 31,	
	2013	**2012**
Finished goods	$ 8,084	$ 2,221
Work-in-process	3,886	1,731
Raw materials and supplies	2,558	2,597
Deferred costs	-	546
Total inventories	$ 14,528	$ 7,095

Deferred costs as of December 31, 2012 represent the costs of products shipped for which recognition of revenue has been deferred. Because we changed the timing of our revenue recognition for sales of Subsys in the fourth quarter of 2013, no such costs were deferred at December 31, 2013.

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

4. Property and Equipment

Property and equipment are comprised of the following (in thousands):

	Estimated Useful Life (in years)	As of December 31, 2013	As of December 31, 2012
Computer equipment	3 - 5	$ 713	$ 514
Scientific equipment	5 - 7	9,502	4,931
Furniture	5 - 7	487	359
Manufacturing equipment	5	1,975	1,975
Leasehold improvements	*	3,869	3,641
Less: accumulated depreciation and amortization		(6,419)	(4,629)
Total fixed assets		$ 10,127	$ 6,791

* 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 us. 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, we began including amortization expense in cost of revenue.

Total depreciation and amortization expense for the years ended December 31, 2013 and 2012 was $1,790,000 and $1,662,000, respectively.

5. Intangible Assets and Goodwill

As of October 1, 2012, as a result of our 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), we determined that there was an indication that our recorded intangible assets and goodwill associated with our acquisition of NeoPharm might be impaired. Accordingly, we 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 and goodwill associated with NeoPharm were fully impaired. As a result, during the year ended December 31, 2012, we recorded an impairment charge of $5,403,000. This impairment charge is included in the consolidated statements of comprehensive income (loss) under the caption “Impairment of intangible assets and goodwill.”

6. Line of Credit

In February 2012, we entered into a $15,000,000 revolving credit facility (the “Prior Facility”) with Bank of America, N.A. (the “Agent”), which included a $2,000,000 letter of credit facility. Under the terms of the Prior Facility, amounts outstanding bore interest at our election at (a) LIBOR plus 1.0% or (b) British Bankers Association Rate (“BBA”) LIBOR Daily Floating Rate plus 1.0%. The Prior Facility was secured by The Kapoor Trust Letter of Credit issued by the Agent, with the John N. Kapoor Trust (“The JNK Trust”) as applicant. Dr. Kapoor is our founder, Executive Chairman and principal stockholder. We had an outstanding balance of $11,858,000 under the Prior Facility as of December 31, 2012. In May 2013 in connection with the closing of our initial public offering, the then outstanding principal balance of $11,858,000 was paid in full.

In October 2013, we terminated the Prior Facility and we entered into a $15,000,000 revolving credit facility (the “New Facility”) with JPMorgan Chase Bank, N.A., which includes a $500,000 letter of credit facility. Under the terms of the New Facility, amounts outstanding bear interest at LIBOR plus 1.5% and the New Facility is subject to a 0.35% non-usage fee. Advances are subject to a borrowing base such that the maximum advances that may be outstanding under the New Facility is 80% of the book value of eligible accounts receivable. The New Facility matures on September 30, 2014. As of December 31, 2013, no amounts were outstanding and $12,200,000 was available to borrow, taking into account the applicable borrowing base limitations. The New Facility is secured by all of our assets.

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

7. Notes Payable to a Related Party

On May 7, 2013, in connection with the closing of our initial public offering of common stock, the outstanding balance of principal and accrued interest related to several promissory and demand notes ("Kapoor Notes") of $59,284,000 was converted into 7,410,341 shares of common stock at the $8.00 per share public offering price and all of the Kapoor Notes were cancelled.

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

Interest expense on the Kapoor Notes was approximately $900,000 and $2,582,000 for the years ended December 31, 2013 and 2012, respectively.

8. Commitments and Contingencies

Lease Commitments

We lease facilities under non-cancelable operating lease agreements. Future minimum commitments for these operating leases in place as of December 31, 2013, with a remaining non-cancelable lease term in excess of one year, are as follows (in thousands):

Years ending December 31,		
2014	$	1,200
2015		1,863
2016		2,046
2017		1,963
2018		1,777
Thereafter		6,788
Total	$	15,637

Dr. John N. Kapoor, our founder, Executive Chairman and principal stockholder, guarantees the lease commitments under one of these operating leases totaling $555,000 as of December 31, 2013.

The terms of certain lease agreements provide for rental payments on a graduated basis. We recognize rent expense on the straight-line basis over the lease period and have accrued for rent expense incurred but not paid. Rent expense under operating leases for the years ended December 31, 2013 and 2012 was approximately $498,000 and $586,000, respectively.

Defined Contribution Retirement Plans (401(k) Plan)

We sponsor 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 we do not make any matching contributions.

Contractual Commitments

Manufacture and Supply Agreements

DPT Lakewood, LLC ("DPT") – DPT is our contractor which manufactures and packages Subsys. In May 2011, we 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, 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.

Catalent Pharma Solutions, LLC ("Catalent") – 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 finished product. Under the terms of the agreement, which was amended on March 5, 2012, we are 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 we or Catalent gives the other party at least 12 months' prior written notice of its desire to terminate the agreement. As of December 31, 2013, our remaining estimated contractual obligation to be paid for product manufacturing through the end of the term of the agreement was approximately $973,000.

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.

In October 2012, in connection with its analysis of impairment of IPR&D (see Note 5), 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 $2,324,000 was recorded in the statement of comprehensive income (loss) as other income for the year ended December 31, 2012.

Legal Matters

General Litigation and Disputes

From time to time, in the normal course of our operations, we are a party to litigation and other dispute matters and claims. Currently such litigation includes proceedings to which Insys Therapeutics, Inc. and our wholly owned subsidiary, Insys Pharma, Inc., is a party. Litigation can be expensive and disruptive to normal business operations. Moreover, the results of complex legal proceedings are difficult to predict and our view of these matters may change in the future as the litigation and events related thereto unfold. An unfavorable outcome to any legal matter, if material, could have an materially adverse effect on our operations or our financial position, liquidity or results of operations. Following is a brief description of such litigation and dispute proceedings.

Kottayil vs. Insys Pharma, Inc. On September 29, 2009, Insys Pharma, Inc., our wholly owned subsidiary, and certain of our officers and the five directors who comprised the Insys Pharma board of directors as of June 2009, as well as their spouses, were named as defendants in a lawsuit in the Superior Court of the State of Arizona, Maricopa County, or the Arizona Superior Court, brought by Santosh Kottayil, Ph.D., certain of his family members and a trust of which Dr. Kottayil is the trustee.

On January 29, 2014, the plaintiffs filed a second amended complaint in the Arizona Superior Court in which Insys Therapeutics, Inc. was also named as defendant in this lawsuit. On February 25, 2014, we filed a Motion to Dismiss the plaintiffs' claims for a statutory and common law appraisal.

Dr. Kottayil formerly served as President, Chief Scientific Officer and a director of Insys Pharma, among other positions. The complaint brought a cause of action for statutory and common law appraisal of Dr. Kottayil's Insys Pharma common stock. The cause of action for appraisal relates to a reverse stock split that Insys Pharma effected in June 2009, which resulted in Dr. Kottayil's ownership position becoming a fractional share of Insys Pharma common stock. Following the reverse stock split, Insys Pharma cancelled all resulting fractional shares, including the fractional share held by Dr. Kottayil, and offered a cash payment in lieu of the fractional shares. The complaint also brought causes of action for breach of fiduciary duty, fraud and negligent misrepresentation in the defendants' dealings with Dr. Kottayil on the subject of his compensation and stock ownership in Insys Pharma. In January 2010, the plaintiffs added claims seeking to rescind Dr. Kottayil's assignment to Insys Pharma of his interest in all of the fentanyl and dronabinol patent applications previously assigned to Insys Pharma and to recover the benefits of those interests. Dr. Kottayil is seeking, among other relief, the fair value of his Insys Pharma common stock as of June 2, 2009, compensatory and punitive damages, and rescission of all assignments to Insys Pharma of his interest in the patent applications, as well as attorneys' fees, costs and interest.

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

Discovery on all of the foregoing claims was completed and a trial was scheduled to commence on January 27, 2014; however, on January 22, 2014, the court vacated the trial and granted plaintiffs leave to file an amended complaint to add Insys Therapeutics, Inc. as a defendant. This amended complaint filed by plaintiffs re-alleges substantially the same claims set forth in the prior complaint, except that plaintiffs now allege that they are entitled to rescissory damages, plaintiffs have also added our majority stockholder, a private trust, as a defendant to the breach of fiduciary duty claim and plaintiffs have revised their fraud claim against the Insys Pharma director defendants.

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.

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

On May 31, 2013, Mylan filed a demand with the American Arbitration Association, Case No. 55 122 00119 13. Mylan's demand alleged that we were in breach of the Distribution Agreement. On July 10, 2013, we filed a response to Mylan's demand, denying we were in breach of the Distribution Agreement, and asserting counterclaims based on Mylan's material breach of the Distribution Agreement and the duty of good faith and fair dealing. On January 13, 2014, the three-member arbitration panel held a preliminary hearing, where it ordered Mylan to submit an amended and detailed demand by February 3, 2014, to which we responded and submitted amended counterclaims on February 4, 2014. We anticipate that the arbitration will resolve: (1) whether Mylan materially breached the Distribution Agreement by failing to accept delivery of a conforming shipment of product in October 2012; (2) whether Mylan has materially breached the parties Distribution Agreement by failing to use commercially reasonable efforts to market and sell the product; and (3) whether the Distribution Agreement has been terminated because of the parties dispute over floor pricing. We anticipate seeking damages and attorneys' fees as part of the arbitration.

On January 21, 2014, Mylan filed a new lawsuit against us with the District Court, as Case No. 2:14-cv-00119-GMS, asserting a claim for declaratory judgment and seeking a temporary restraining order and preliminary injunction relating to our notice of termination of the Distribution Agreement with respect to the parties' failure to agree on floor pricing. On January 24, 2014, we responded in opposition to the application for temporary restraining order and preliminary injunction, or Application. On January 25, 2014, we moved to compel arbitration of the parties' dispute regarding floor pricing, as already agreed to by the parties. The Court has not yet set a hearing on the Application. We do not believe that there is any basis in law or fact for Mylan's complaint and/or the Application. We intend to seek attorneys' fees incurred in responding to Mylan's lawsuit.

Because of the remaining uncertainty as to the claims (if any) made by Mylan against us, as well as the uncertainty relating to the total damages incurred by us because of Mylan's breaches, we are not able to predict the outcome of this dispute or make a reasonable estimate of the possible loss, if any.

Hillier vs. Insys Therapeutics, Inc. On December 16, 2013, a complaint was filed in the United States District Court for the District of Arizona against us and certain of our officers. The complaint was brought as a purported class action, on behalf of purchasers of our common stock between May 1, 2013 and December 12, 2013, and, in general, included allegations that the defendants violated the federal securities laws by making materially false and misleading statements regarding our business and operations, thereby artificially inflating the price of our common stock. The plaintiff sought unspecified monetary damages and other relief. On February 19, 2014, the plaintiff filed a notice of voluntary dismissal and, on February 20, 2014, the Court terminated the case. Accordingly, we believe this proceeding is resolved and will have no material effect on its consolidated financial position, results of operations, or cash flows.

Government Proceedings

Like other companies in the pharmaceutical industry, we are subject to extensive regulation by national, state and local government agencies in the United States. As a result, interaction with government agencies occurs in the normal course of our operations. Following is a brief description of a pending, potentially material, governmental investigation. It is possible that criminal charges and substantial fines and/or civil penalties or damages could result from any government investigation or proceeding.

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

9. Equity

Convertible Preferred Stock

Pursuant to the NeoPharm merger, all of our outstanding common stock 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 was convertible into common stock on a one-to-0.57377 basis and, until converted, was entitled to the voting and dividend rights of the same number of shares of common stock into which it was convertible. Each share of convertible preferred stock automatically converted into shares of our common stock immediately prior to the closing of our initial public offering of common stock at the conversion ratio.

Common Stock

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

In connection with a one-for-1,500,000 reverse stock split in June 2009, we agreed to repurchase common shares from those stockholders which were left with only fractional shares after the reverse stock split. We recorded a liability of $547,000 to these stockholders as of December 31, 2009 relating to this repurchase of 14,911 aggregate shares. The remaining liability is approximately $144,000 and $508,000 as of December 31, 2013 and 2012, and is included in "Accounts payable and accrued expenses" on our consolidated balance sheets.

Initial Public Offering

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

10. Stock-based Compensation

We currently have the following stock-based incentive plans:

2013 Employee Stock Purchase Plan

The 2013 Employee Stock Purchase Plan (the "ESPP") was adopted by our board of directors and approved by our stockholders, and became effective in connection with our initial public offering in May 2013. The ESPP authorizes the issuance of 175,000 shares of common stock pursuant to purchase rights granted to our employees or to employees of any of our designated affiliates. The number of shares of common stock reserved for issuance will automatically increase on January 1 of each calendar year, from January 1, 2014 through January 1, 2023, by the least of (a) 1% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year, (b) 200,000 shares, or (c) a number determined by our board of directors that is less than (a) and (b). The ESPP is intended to qualify as an "employee stock purchase plan" within the meaning of Section 423 of the Internal Revenue Code of 1986, as amended (the "Code"). As of December 31, 2013, 125,370 shares of common stock have been purchased under the ESPP.

2013 Equity Incentive Plan

The 2013 Equity Incentive Plan (the "2013 Plan") is the successor to and continuation of the 2006 Equity Incentive Plan and the Insys Pharma, Inc., Amended and Restated Equity Incentive Plan. The 2013 Plan was adopted by our board of directors and approved by our stockholders, and became effective in connection with our initial public offering in May 2013. The 2013 Plan provides for the grant of stock awards, including stock options, restricted stock, stock appreciation rights, performance units, performance shares and other stock awards, to our employees, directors and consultants. As of December 31, 2013, options to purchase 1,437,565 shares of common stock were outstanding and 104,243 shares remained available for future grant.

2006 Equity Incentive Plan

The 2006 Equity Incentive Plan (the "2006 Plan") provided for the grant of stock awards, including stock options, restricted stock, stock appreciation rights, performance units, performance shares and other stock awards, to our employees, directors and consultants. The 2006 Plan was adopted in April 2006. As of December 31, 2013, options to purchase 879,562 shares of common stock were outstanding. There were no unvested options outstanding under the Plan as of December 31, 2013. The Plan has been terminated and we will not grant additional equity awards under the Plan.

Awards under the 2006 Plan generally consist of stock options that have an exercise price equal to the fair market value of our common stock on the date of grant, a ten-year term, and vest ratably over four years, subject to continuous employment. Stock awards granted to our 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, we have not made grants of these types of awards.

Insys Pharma, Inc. Amended and Restated Equity Incentive Plan

Insys Pharma, Inc.'s Amended and Restated Equity Incentive Plan (the "Plan") provided for the grant of stock options to employees, directors and consultants to acquire Insys Pharma's voting and non-voting common stock. The Plan was originally adopted by Insys Pharma in December 2002 and was amended and restated in June 2006. In connection with the NeoPharm merger in November 2010, all of the outstanding options granted under the Plan were assumed by us and were converted into options to purchase shares of our common stock at the exchange ratio set forth in the merger agreement. As of December 31, 2013, options to purchase an aggregate of 681,199 shares of our common stock under the Plan were outstanding. There were no unvested options outstanding under the Plan as of December 31, 2013. The Plan has been terminated and we will not grant additional equity awards under the Plan.

Option awards under the Plan were generally granted with an exercise price equal to the fair market value of Insys Pharma's common stock on the date of grant. Option awards under the Plan typically 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 income (loss) with respect to our stock-based compensation plans were as follows (in thousands):

	Years ended December 31,	
	2013	**2012**
Research and development	$ 915	$ 1,055
General and administrative	5,424	1,706
Total cost of stock-based compensation	$ 6,339	$ 2,761

The following table summarizes stock option activity during the years ended December 31, 2013 and 2012:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in millions)
Outstanding as of December 31, 2011	1,856,535	$ 4.18	8.57	$ 21.3
Granted	571,500	$ 3.54		
Cancelled	(193,915)	$ 13.94		
Exercised	(61,547)	$ 2.12		
Outstanding as of December 31, 2012	2,172,573	$ 3.18	8.21	$ 10.2
Granted	1,486,700	$ 14.57		
Cancelled	(58,296)	$ 8.57		
Exercised	(602,651)	$ 3.46		
Outstanding as of December 31, 2013	2,998,326	$ 8.69	8.33	$ 90.1
Vested and exercisable as of December 31, 2012	1,263,197	$ 2.79	7.44	$ 3.5
Vested and exercisable as of December 31, 2013	1,207,102	$ 4.20	7.05	$ 41.7

The aggregate intrinsic value for stock options outstanding and exercisable is defined as the positive difference between the fair market value of our common stock and the exercise price of the stock options. As of December 31, 2013, we expect to recognize $19,286,000 of stock-based compensation for our outstanding options over a weighted-average period of 3.0 years.

Cash received from option exercises under all share-based payment arrangements for the years ended December 31 2013 and 2012, was $2,102,000 and $152,000. For the years ended December 31, 2013 and 2012, we recorded net reductions of $2,745,000 and $0, respectively, of our federal and state income tax liability, with an offsetting credit to additional paid-in capital resulting from the excess tax benefits of stock options.

Stock Option Valuation Information

The weighted-average assumptions used to estimate the fair value of employee stock options granted during the periods presented are as follows:

	2013	2012
Expected volatility	73.54%	65.00%
Risk-free interest rate	2.04%	1.15%
Expected term (in years)	7.0	6.5 - 7.0
Expected dividend yield	0.00%	0.00%

For the years ended December 31, 2013 and 2012, the weighted-average estimated fair value per option granted was $10.07 and $12.70, respectively.

11. Income Taxes

Income tax (benefit) expense consists of the following (in thousands):

	Years Ended December 31,	
	2013	2012
Current income taxes:		
Federal	$ 2,281	$ -
State and local	957	-
Total current income tax	3,238	-
Deferred income taxes:		
Federal	(9,123)	-
State and local	(2,915)	-
Total deferred income tax	(12,038)	-
(Benefit) provision for income taxes	$ (8,800)	$ -

As of December 31, 2013, we had approximately $13.1 million of federal net operating loss carry forwards ("NOLs"), including $11.0 million primarily related to excess tax deductions related to stock option exercises which have not been benefitted in the financial statements, and $2.1 million which is subject to a significant Section 382 limitation as noted below. For federal tax purposes, the Section 382 NOL carryforward is limited on an annual basis and begins expiring in 2034. The remaining $11.0 million NOL carryforward, which is not limited, expires in 2032 to the extent that it is not utilized.

For state tax purposes, we had approximately $292 million of state NOLs at December 31, 2013, including the excess tax deductions from the exercise of stock options. Approximately $271 million of these NOLs relate only to Illinois. Based on projections, we estimate that approximately $267 million of these Illinois NOLs will not be utilized. For this reason, we recorded a valuation allowance for the estimated tax benefit relating to this amount, or $20.7 million. Generally, the state NOL carryforwards begin expiring in 2027 if not utilized. The Illinois NOLs begin expiring in 2014 if not utilized.

At December 31, 2012, a full valuation allowance was placed on our net deferred tax assets because we determined that it was more likely than not that we would not benefit from these tax attributes in the future. During the fourth quarter of 2013, we determined it was more likely than not that we would be able to utilize nearly all types of our deferred tax assets, including all federal net operating loss carryforwards. This determination was made based on our profitability in 2013 and our expectations of future profitability. Accordingly, we reversed the deferred tax asset valuation allowance associated with the majority of our deferred tax assets.

Although we determined that it is more likely than not that all federal net operating loss carryforwards and other net deferred tax assets will be utilized in future years, we also determined that it is more likely than not that the future tax benefit associated with certain state NOL carryforwards will not be realized. Specifically, we determined that approximately $267 million of Illinois NOLs will not be utilized in future years based on our limited activity in the state compared to prior years, and the expiration dates of the NOLs. Accordingly, we have sustained a valuation allowance of approximately $21 million to offset the deferred tax asset relating to these Illinois NOLs.

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 (in thousands):

	2013	2012
Deferred tax assets:		
NOLs and credits	$ 23,429	$ 37,865
Start-up expenditures	3,613	3,954
Stock-based compensation	2,411	1,613
Deferred revenue and allowances	2,310	2,823
Expenses currently not deductible for tax purposes	2,116	727
Gross deferred tax assets	33,879	46,982
Deferred tax asset valuation allowance	(20,684)	(46,924)
Deferred tax assets	13,195	58
Deferred tax liabilities:		
Federal impact of state taxes	(1,021)	-
Property and equipment	(136)	(58)
Net deferred tax assets	$ 12,038	$ -

In assessing the realization of deferred tax assets, we consider 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. We also consider the scheduled reversal of deferred tax liabilities, projected future taxable income or losses, and tax planning strategies in making this assessment. Based upon our current net income and projections for future taxable income over the periods in which the deferred tax assets are deductible, we believe that, with the exception of the Illinois NOL discussed above, the realization of these tax assets is more likely than not. As such, with the exception of the valuation allowance that has been placed on the future tax benefit relating to our Illinois NOLs, no other valuation allowance exists on our deferred tax assets at December 31, 2013.

Effective Tax Rate Reconciliation:

Our federal statutory tax rate is 35.0%, while our effective tax rate was a benefit of 27.9% for the year ended December 31, 2013.

	2013	2012
U.S. statutory tax rate	35.0%	(35.0)%
Increase (reduction) of income taxes resulting from:		
State income taxes, net of federal benefit	11.8	-
Non-deductible and includible items and credits	2.3	1.7
Research and other credits	(1.8)	-
Revalue of contingent payment obligation	-	(3.0)
Other	(0.6)	1.9
Change in valuation allowance	(74.6)	34.4
Total (benefit) provision for income taxes	(27.9)%	0.0%

The following is a reconciliation of the beginning and ending amounts of unrecognized tax benefits (in thousands):

	Years Ended December 31,	
	2013	2012
Beginning balance	$ -	$ -
Additions based on current year's tax positions	270	-
Additions based on prior year's tax positions	55	-
Ending balance	$ 325	$ -

No significant penalties or interest are included in income taxes or accounted for on the balance sheet related to unrecognized tax positions as of December 31, 2013.

Tax years subsequent to 2010 remain open to examination by federal and state taxing authorities. In addition, Insys' pre-NeoPharm merger NOLs remain open to examination.

12. Net Income (Loss) per Share

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

The net income (loss) per share for the years ended December 31, 2013 and 2012, including share and per share amounts, includes the effects of the conversion of convertible preferred stock into 8,528,860 shares of common stock as if the conversion had occurred at the beginning of the respective periods.

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

	Years ended December 31,	
	2013	2012
Net income (loss) per share - basic		
Numerator:		
Net income (loss)	$ 40,377	$ (24,378)
Denominator:		
Weighted average number of common shares outstanding	17,279,845	9,316,034
Basic net income (loss) per common share	$ 2.34	$ (2.62)
Net income (loss) per share - diluted		
Numerator:		
Net income (loss)	$ 40,377	$ (24,378)
Denominator:		
Weighted average number of common shares outstanding	17,279,845	9,316,034
Effect of dilutive stock options	1,876,566	-
Weighted average number of common shares outstanding	19,156,411	9,316,034
Diluted net income (loss) per common share	$ 2.11	$ (2.62)

As we have incurred a net loss for the year ended December 31, 2012, basic and diluted per share amounts are the same, since the effect of potential common share equivalents is anti-dilutive. Anti-dilutive share equivalents included 2,091,195 outstanding stock options as of December 31, 2012. There were no anti-dilutive share equivalents for the year ended December 31, 2013.

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

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

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

	Net Revenue by Product Line	
	Years Ended December 31,	
	2013	2012
Subsys	$ 95,740	$ 8,550
Dronabinol SG Capsule	3,549	6,926
Total net revenue	$ 99,289	$ 15,476

	Percent of Revenue by Route to Market	
	Years Ended December 31,	
	2013	2012
Pharmaceutical wholesalers	96%	55%
Generic pharmaceutical distributors	4%	45%
	100%	100%

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

Product shipments to four pharmaceutical wholesalers accounted for 30%, 21%, 20% and 19% of shipments of Subsys for the year ended December 31, 2013. Product shipments to one generic pharmaceutical distributor accounted for 45% and product shipments to three pharmaceutical wholesalers accounted for 20%, 19% and 13% of shipments for the year ended December 31, 2012. Four pharmaceutical wholesalers' accounts receivable balances accounted for 40%, 21%, 17% and 14% of gross accounts receivable as of December 31, 2013. Three pharmaceutical wholesalers' accounts receivable balances accounted for 34%, 22% and 21% of accounts receivable as of December 31, 2012.

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and trade accounts receivable. We place our cash with high credit quality financial institutions and generally limit the amount of credit exposure to the amount of FDIC coverage. However, periodically during the year, we maintain cash in financial institutions in excess of the current FDIC insurance coverage limit of $250,000. We perform ongoing credit evaluations of our customers' financial condition but do not typically require collateral to support customer receivables. We established an allowance for doubtful accounts based upon factors surrounding the credit risk of specific customers, historical trends and other information.

14. Subsequent Events

On February 26, 2014, our board of directors approved a three-for-two stock split of our common stock to be effected through a stock dividend. The record date for the stock split is the close of business on March 17, 2014, with share distribution scheduled for March 28, 2014. As a result of the dividend, shareholders will receive one additional share of Insys Therapeutics, Inc. common stock, par value $0.0002145, for each two shares they hold as of the record date. The share and and per share amounts in these financial statements have not been adjusted to reflect the stock split.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our President and Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of the end of the period covered by this Annual Report on Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective.

Management's Annual Report on Internal Control Over Financial Reporting

This Annual Report on Form 10-K does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by the rules of the SEC for newly public companies. Further, after the initial transition period provided for newly public companies, for as long as we remain an "emerging growth company" as defined in the JOBS Act, we are exempt from the requirement that our registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting.

Changes in Internal Controls Over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarterly period ended December 31, 2013 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this item will be included in our Proxy Statement to be filed pursuant to Regulation 14A within 120 days after our year ended December 31, 2013 in connection with our 2014 Annual Meeting of Stockholders, or the 2014 Proxy Statement, and is incorporated herein by reference.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to employees, officers and directors, including our executive management team, such as our Chief Executive Officer and Chief Financial Officer. This Code of Business Conduct and Ethics is posted on our website at www.insysrx.com. We intend to satisfy the requirements under Item 5.05 of Form 8-K regarding disclosure of amendments to, or waivers from, provisions of the Code of Business Conduct and Ethics by posting such information on our website.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this item will be included in the 2014 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by this Item will be included in the 2014 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by this item will be included in the 2014 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item will be included in the 2014 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of this report.

(1) *Financial Statements*. The consolidated financial statements listed on the index to Item 8 of this Annual Report on Form 10-K are filed as a part of this Annual Report.

(2) *Financial Statement Schedules.* All financial statement schedules have been omitted since the information is either not applicable or required or is included in the financial statements or notes thereof.

(3) *Exhibits.* Those exhibits marked with a (*) refer to exhibits filed or furnished herewith. The other exhibits are incorporated herein by reference, as indicated in the following list. Those exhibits marked with a (+) refer to management contracts or compensatory plans or arrangements. Portions of the exhibits marked with a (Ω) are the subject of a Confidential Treatment Request under 17 C.F.R. §§ 200.80(b)(4), 200.83 and 240.24b-2. Omitted material for which confidential treatment has been requested has been filed separately with the SEC.

EXHIBIT INDEX

Exhibit Number	Description of Document
2.1	Agreement and Plan of Merger Among the Registrant, Insys Therapeutics, Inc. and ITNI Merger Sub Inc. dated October 29, 2010 (6)
3.1	Registrant's Amended and Restated Certificate of Incorporation, as amended and as currently in effect (1)
3.3	Registrant's Bylaws, as currently in effect (2)
4.1	Form of Common Stock Certificate of the Registrant (14)
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers (7)
10.2+	Insys Therapeutics, Inc. 2006 Equity Incentive Plan, as amended (8)
10.3+	Insys Pharma, Inc. Amended and Restated Equity Incentive Plan (9)
10.4+	2013 Equity Incentive Plan and Form of Stock Option Grant Notice and Form of Stock Option Agreement thereunder (20)
10.5+	2013 Employee Stock Purchase Plan (21)
10.6+	Amended and Restated Employment Agreement by and between the Registrant and Michael Babich dated April 18, 2013 (23)
10.7+	Amended and Restated Employment Agreement by and between the Registrant and Larry Dillaha dated April 18, 2013 (24)
10.8+	Employment Agreement by and between the Registrant and Darryl Baker dated April 18, 2013 (25)
10.9	Frye Road Two LLC Triple Net Lease dated as of January 31, 2012 between Insys Pharma, Inc. and Frye Road Two LLC (15)
10.10	First Amendment to Lease dated as of November 7, 2012 between Insys Pharma, Inc. and Frye Road Two LLC (16)
10.11	Chandler 101 Business Center Office Lease dated as of January 4, 2013 between Insys Pharma, Inc. and Frye Road Industrial LLC (17)

10.12Ω	Softgel Commercial Manufacturing and Packaging Agreement dated as of March 21, 2011 by and between the Registrant and Catalent Pharma Solutions, LLC (10)
10.13Ω	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 (18)
10.14Ω	Supply and Distribution Agreement dated as of May 20, 2011 by and between the Registrant and Mylan Pharmaceuticals Inc. (11)
10.15Ω	Amendment to Supply and Distribution Agreement dated as of March 13, 2012 by and between the Registrant and Mylan Pharmaceuticals Inc. (19)
10.16Ω	Manufacturing Agreement dated as of March 7, 2011 by and between the Registrant and DPT Lakewood, LLC (12)
10.17Ω	Letter Agreement dated April 23, 2012, amending the DPT Lakewood, LLC Manufacturing Agreement dated as of March 7, 2011 (26)
10.18	Supply Agreement dated as of March 7, 2011 by and between the Registrant and AptarGroup, Inc. (13)
10.19+	Non-Employee Director Compensation Policy (22)
10.20	Round Rock Office/Warehouse Lease Agreement dated August 28, 2013 by and between Registrant and Fog Break, Ltd. (3)
10.21	Revolving Credit Agreement dated October 17, 2013 by and between Registrant and JP Morgan Chase Bank, N.A. (4)
10.22	Chandler Corporate Headquarters Office Lease Agreement dated December 18, 2013 by and between Registrant and CAZ 1 LLC (5)
21.1	Subsidiaries of the Registrant (27)
23.1*	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm.
24.1	Power of Attorney (incorporated by reference to the signature page of this Annual Report on Form 10-K)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32*	Certification by Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith)
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document (4)
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document (4)
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document (4)
101.LAB	XBRL Taxonomy Extension Label Linkbase Document (4)
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document (4)

(1) Previously filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Commission on May 8, 2013.

(2) Previously filed as Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the Commission on May 8, 2013.

(3) Previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on September 3, 2013.

(4) Previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on October 23, 2013.

(5) Previously filed as Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on December 20, 2013.

(6) Previously filed as Exhibit 2.1 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.

(7) Previously filed as Exhibit 10.1 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.

(8) Previously filed as Exhibit 10.3 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.

(9) Previously filed as Exhibit 10.4 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.

(10) Previously filed as Exhibit 10.12 to the Company's Form S-1 Registration Statement (No. 333-173154) on July 15, 2011.

(11) Previously filed as Exhibit 10.14 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(12) Previously filed as Exhibit 10.16 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(13) Previously filed as Exhibit 10.18 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(14) Previously filed as Exhibit 4.1 to the Company's Form S-1 Registration Statement (No. 333-173154) on June 9, 2011.

(15) Previously filed as Exhibit 10.9 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(16) Previously filed as Exhibit 10.10 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(17) Previously filed as Exhibit 10.11 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(18) Previously filed as Exhibit 10.13 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(19) Previously filed as Exhibit 10.15 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(20) Previously filed as Exhibit 10.4 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 19, 2013.

(21) Previously filed as Exhibit 10.5 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 19, 2013.

(22) Previously filed as Exhibit 10.22 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(23) Previously filed as Exhibit 10.6 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 25, 2013.

(24) Previously filed as Exhibit 10.7 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 25, 2013.

(25) Previously filed as Exhibit 10.8 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 25, 2013.

(26) Previously filed as Exhibit 10.17 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(27) Previously filed as Exhibit 21.1 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 4, 2014.

Insys Therapeutics, Inc.

By /s/ Michael L. Babich
Michael L. Babich
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Darryl S. Baker and Franc Del Fosse, jointly and severally, his attorney-in-fact, with the power of substitution, for him in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact, or his or her substitute or substitutes, may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Michael L. Babich Michael L. Babich	President and Chief Executive Officer	March 4. 2014
/s/ Darryl S. Baker Darryl S. Baker	Chief Financial Officer and Principal Accounting Officer	March 4. 2014
/s/ John N. Kapoor John N. Kapoor	Director	March 4. 2014
/s/ Patrick P. Fourteau Patrick P. Fourteau	Director	March 4. 2014
/s/ Steven Meyer Steven Meyer	Director	March 4. 2014
/s/ Brian Tambi Brian Tambi	Director	March 4. 2014
/s/ Pierre Lapalme Pierre Lapalme	Director	March 4. 2014
/s/ Theodore H. Stanley, M.D. Theodore H. Stanley, M.D.	Director	March 4. 2014

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Insys Therapeutics, Inc.
Chandler, Arizona

We hereby consent to the incorporation by reference in the Registration Statement on Form S- 8 (No. 333-188306) of Insys Therapeutics, Inc. of our report dated March 4, 2014, relating to the consolidated financial statements of Insys Therapeutics, Inc. which appears in this Form 10-K.

/s/ BDO USA, LLP

Phoenix, Arizona
March 4, 2014

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael L. Babich, certify that:

1. I have reviewed this annual report on Form 10-K of Insys Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2014

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Darryl S. Baker, certify that:

1. I have reviewed this annual report on Form 10-K of Insys Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 4, 2014

/s/ Darryl S. Baker

Darryl S. Baker
Chief Financial Officer

Exhibit 32

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,

AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

For purposes of Section 1350 of Chapter 63 of Title 18 of the United States Code, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, each of the undersigned officers of Insys Therapeutics, Inc., a Delaware corporation ("Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K for the fiscal year ended December 31, 2013 ("Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 4, 2014

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

Dated: March 4, 2014

/s/ Darryl S. Baker
Darryl S. Baker
Chief Financial Officer