Insys Therapeutics, Inc.
Form 10-K
April 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2016

OR

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

Commission File Number: 001-35902

Insys Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	51-0327886
(State or Other Jurisdiction of Incorporation)	(I.R.S. Employer Identification No.)

1333 S. Spectrum Blvd, Suite 100, Chandler, Arizona	85286
(Address of Principal Executive Offices)	(Zip Code)

(480) 500-3127

(Registrant's Telephone Number, Including Area Code)

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

Title Of Each Class	Name Of Each Exchange On Which Registered
Common Stock, $0.01 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 $300 million as of June 30, 2016 based on the closing sales price of the common stock on the NASDAQ Global Market.

There were 71,957,343 shares of the registrant’s common stock issued and outstanding as of March 28, 2017.

Documents Incorporated by Reference

Portions of the registrant's Proxy Statement relating to its 2017 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, 2016, are incorporated by reference in Part III of this Form 10-K.

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GLOSSARY OF TERMS

The following glossary provides definitions for certain acronyms and terms used in this Annual Report on Form 10-K. These acronyms and terms are specific to our company, commonly used in our industry, or are otherwise frequently used throughout our document.

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

MMA	Medicare Prescription Drug, Improvement, and Modernization Act of 2003
Mylan	Mylan Pharmaceuticals, Inc.
NDA	New Drug Application
NeoPharm	NeoPharm, Inc.
NOL	Net operating loss carryforward
NRV	Net Realizable Value
NSAID	Non-steroidal anti-inflammatory drug
Orange Book	FDA's Approved Drug Products with Therapeutic Equivalence Evaluations

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

PART I

ITEM 1. BUSINESS

Overview

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

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

Insys Therapeutics, Inc. was incorporated in Delaware in June 1990, and maintains headquarters in Chandler, Arizona.

For further detail concerning our company and communities, see the “Available Information” section included in this Item 1.

We are leveraging our capabilities in cannabinoid formulation and manufacturing, as well as our sublingual spray drug delivery technology, to develop a portfolio of differentiated, wholly-owned product candidates. Our lead product candidate is SYNDROS™, 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 an improved absorption profile for patients, which may contribute to increased patient compliance because of less dose-to-dose variability and allow us to further penetrate and potentially expand the market for the use of dronabinol. We received FDA approval for SYNDROS™ in July 2016. In March 2017, the DEA issued an interim final ruling that would result in SYNDROS™ being placed in Schedule II of the CSA. We are currently awaiting the finalization of labeling by the FDA as the final approval prior to commercial launch.

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 NDA in March 2011 and received marketing approval for SUBSYS® ® from the FDA in January 2012 for the treatment of BTCP. BTCP is characterized by sudden, often unpredictable, episodes of pain that can peak in severity at less than one minute to 10 minutes despite background pain controlled by around-the-clock medication. We believe SUBSYS® is an important, differentiated treatment option for patients and physicians relative to other TIRF products due to its rapid onset of action, improved bioavailability, most complete range of dosage strengths and ease of administration. Our product label includes data from our pivotal clinical trial demonstrating that SUBSYS® may provide pain relief in as little as 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. 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. Upon launch, SUBSYS® was the fourth new branded product in the TIRF market over the prior five 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 according to Source Healthcare Analytics. In December 2016, SUBSYS® was the most prescribed TIRF product, with 42% market share on a prescription basis according to IMS. According to Source Healthcare Analytics, in 2016, TIRF products generated $710 million in annual U.S. product sales. Traditionally, the physician prescriber base for TIRF products is concentrated, with approximately 1,600 physicians writing 90% of all

TIRF product prescriptions in 2016, according to IMS. As a result, our commercial organization has been able to promote SUBSYS® using a highly targeted approach designed to maximize impact with physicians who are TIRF REMS enrolled. In addition, our commercial organization continues to specifically target oncology health care providers and practices.

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

Dronabinol, the active ingredient in Marinol, is a synthetic cannabinoid whose chemical name is THC, an approved second-line treatment for CINV and anorexia associated with weight loss in patients with AIDS. 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.

Our lead product candidate is SYNDROS™, a proprietary, orally administered liquid formulation of dronabinol, which has yet to be approved for commercialization. SYNDROS™ 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 PK of SYNDROS™ versus Marinol. This PK study demonstrated that 100% of subjects receiving SYNDROS™ achieved detectable plasma levels at 15 minutes compared to less than 25% of subjects receiving Marinol. In this study, SYNDROS™ 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 SYNDROS™ capturing a significant share of the existing U.S. market for dronabinol products and potentially expanding the usage of dronabinol-based products. We received FDA approval for SYNDROS™ in July 2016. In March 2017, the DEA issued an interim final ruling that would result in SYNDROS™ being placed in Schedule II of the CSA. We are currently awaiting the finalization of labeling by the FDA as the final approval prior to commercial launch.

Our discontinued Dronabinol SG Capsule product was commercially launched in December 2011, and we sold Dronabinol SG Capsule exclusively to Mylan in the United States under a supply and distribution agreement. We do not have any current plans to manufacture or market this product in the future.

Strategy

Achieve finalization of labeling by the FDA for SYNDROS™ 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 SYNDROS™ product candidate has demonstrated rapid and less variable 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 CBD and we are pursuing clinical studies that could result in future commercial products containing CBD. We received FDA approval for SYNDROS™ in July 2016. In March 2017, the DEA issued an interim final ruling that would result in SYNDROS™ being placed in Schedule II of the CSA. We are currently awaiting the finalization of labeling by the FDA as the final approval prior to commercial launch.

SUBSYS® market share and revenues. We launched SUBSYS® as a commercial product in March 2012. As of December 31, 2016, there were approximately 8,100 physicians enrolled in the TIRF REMS program. Enrollment in this class-wide REMS program is required by the FDA in order to prescribe TIRF products. Approximately 1,600 physicians comprise 90% of TIRF prescriptions dispensed in 2016, according to IMS. Our sales and marketing efforts have primarily targeted approximately 100% of these top 1,600 prescribing physicians with a focus on the highest prescribers.

Continue to leverage our commercial organization to market SUBSYS® and, if finalization of labeling by the FDA is obtained, SYNDROS™, and other complementary products. We commercialize SUBSYS® through our commercial sales organization. We intend to market SYNDROS™ when finalization of labeling by the FDA is obtained, and other proprietary supportive care products, if approved, using this same commercial sales

organization. We may also pursue opportunities to acquire commercial products or product candidates that could further leverage our supportive care commercial sales organization.

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, naloxone, ondansetron, sildenafil, diclofenac, epinephrine and ketorolac, where we believe our proprietary sublingual spray technology has the potential to provide a clinically meaningful therapeutic advantage over existing delivery methods.

Use our core competencies and expertise to expand our dronabinol and cannabidiol manufacturing capabilities. Because 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 API for initial launch quantities of SYNDROS™. In 2014, we completed construction of a second manufacturing facility that will enable us to supply sufficient commercial quantities of dronabinol API for the anticipated commercialization of our proprietary synthetic cannabinoid product candidates, once scheduled by the DEA, which is required prior to commercialization of this product.

Our Products and Product Candidates

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

Product	Indication	Pathway	Status
SUBSYS® (fentanyl sublingual spray)	1. Breakthrough Cancer Pain	505(b)(2)[1]	Marketed
SYNDROS™ (dronabinol oral solution)	1. CINV	505(b)(2)	NDA Filed;
	2. Appetite Stimulation in AIDS Patients		Approved: April 1, 2016; Scheduled March 2017
			Pending finalization of labeling by the FDA
Cannabidiol Oral Solution	1.Pediatric Epilepsy	505(b)(1)[2]	• Pediatric study in refractory epilepsy ongoing
	2.Prader Willi		• Prader Willi Phase 2 planned for 2nd Half 2017
Buprenorphine Sublingual Spray	Acute Pain	505(b)(2)	Phase 3 completed;
			NDA submission 2nd Half 2017
Buprenorphine/Naloxone Sublingual Spray	Opioid Dependence	505(b)(2)	Formulation under development
Naloxone Sublingual Spray	Opioid Antagonist	505(b)(2)	Formulation under development

Fentanyl/Naloxone	Abuse Deterrent for Intravenous	505(b)(2)	Formulation under development

[1] Anticipated regulatory pathway. A 505(b)(2) 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.

[2] Application is a complete NDA that contains all the studies conducted by the applicant necessary to demonstrate a drug's safe and effective use.

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Additionally, we intend to develop SUBSYS® for additional indications that may include management of pain for procedures conducted in a monitored setting such as bone marrow biopsy, burn dressing changes, radiation oncology, post-operative procedures. We anticipate initiating some of these studies to support a new indication in 2017 based on the guidance we anticipate receiving from the FDA.

Further in 2017, we intend to develop SYNDROS ™ for additional indications which may include the treatment of agitation in Alzheimer's Disease and the treatment of anorexia associated with weight loss in cancer patients.

We are also actively engaged in the development of other earlier stage product candidates. Specifically, we are currently completing preclinical work on six products that utilize our proprietary spray technology platform with the goal of expanding our supportive care franchise:

- Epinephrine (Type I allergic reactions including anaphylaxis)
- Ondansetron (nausea and vomiting in cancer chemotherapy)
- Sildenafil (the active ingredient in Viagra)
- Diclofenac (a 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)
- Hydromorphone (opioid used to treat moderate to severe pain)

Further, we have the ability to manufacture pure, synthetic cannabidiol in our DEA-approved and FDA-inspected Round Rock, TX manufacturing facility and have received orphan drug designations from the FDA for the following:

Indication		Drug	Approval Date
Gastric Cancer		Liposomal Encapsulated Paclitaxel	12/3/2014
Ovarian Cancer		Liposomal Encapsulated Paclitaxel	1/21/2015
Malignant Glioma		IL-13	11/2/2001
Interstitial Pulmonary Fibrosis (IPF)		IL-13	4/30/2010
Lennox-Gastaut Syndrome	(rare pediatric epilepsy)	Cannabidiol	6/23/2014
Dravet Syndrome		Cannabidiol	7/1/2014
(rare pediatric epilepsy)			
West Syndrome		Cannabidiol	7/23/2015
(Rare pediatric epilepsy)			
Glioblastoma multiforme		Cannabidiol	8/20/2014
Pontine glioma		Cannabidiol	9/24/2014
Pediatric Schizophrenia		Cannabidiol	11/17/2014

SUBSYS® -Sublingual Fentanyl Spray

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, NSAIDs, 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 at less than one minute to 10 minutes, BTCP episodes can last several minutes to an hour, and usually occur several times per day. Pain is a widely prevalent condition of cancer patients, approximately 60% of cancer patients with persistent pain may experience 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 second 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, Sentynl Therapeutics’ Abstral®, an immediate-release transmucosal sublingual tablet, and Depomed’s Lazanda®, a nasal spray. According to Source Healthcare Analytics, TIRF products generated $821.6 million in 2015 U.S. sales. Although these existing therapies provide improvements over oral opioids, we believe that the market adoption of SUBSYS® 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 often underserved due to the limitations of other TIRF therapies, which include:

- Time until significant pain relief: Patients suffering from BTCP require rapid pain relief as peak intensity of episodic breakthrough pain can occur at less than one minute to 10 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 51% 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 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.

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:

- Pain relief in five minutes: SUBSYS® is the only product to show pain relief when measuring the sum of pain intensity difference 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.
- 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 December 2016 shows that approximately 162,000 prescriptions of SUBSYS® have been dispensed since launch in March 2012. In December 2016, SUBSYS® was the most prescribed branded TIRF product with 42% market share according to IMS.

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The continuing and heightened publicity surrounding the national opioid epidemic continues to result in sensitivity by some healthcare professionals to prescribe, and pharmacies to dispense, opioids. In part, this sensitivity by healthcare professionals and pharmacies is the result of third-party payers, such as insurance companies, and regulatory and government agencies increasingly scrutinizing the indications and uses for which healthcare professionals are prescribing, and pharmacies are dispensing, opioids. Moreover, ongoing state and federal investigations into our sales, marketing and other commercial practices and developments and media reports that may arise in connection with such investigations may negatively affect our relationships with healthcare professionals and pharmacies and their prescribing or dispensing habits. Consequently, these current and potential future events have and will likely continue to affect the manner in which, and the situations when, SUBSYS® is being prescribed, dispensed and approved for coverage.

Physician Prescriber Base: Approximately 1,600 physicians were responsible for 90% of all TIRF prescriptions dispensed in 2016, according to IMS. We have targeted our commercialization efforts towards approximately 100% of these top 1,600 prescribing physicians with a focus on the highest prescribers. As of December 2016, there were approximately 3,900 unique physician prescribers of SUBSYS®.

Patient Use: Existing patient data generated by available databases demonstrates that the number of SUBSYS® -experienced patients has increased steadily since launch with over 22,100 unique patients as of December 2016. Importantly, the proportion of SUBSYS® prescriptions written for repeat SUBSYS® patients has continued to increase since July 2012 from 50% of prescriptions to over 92% of prescriptions as of December 2016. 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 most major commercial health insurance plans. Some third-party payers require usage and failure on cheaper generic versions of Actiq prior to providing reimbursement for SUBSYS® and other branded TIRF products. We concentrate on assisting physicians and payers with developing 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 payer reimbursement is in place, we may offer patients coupons to reduce out of pocket costs.

Cannabinoid Product Family

SYNDROS™ (dronabinol oral solution)

Our lead proprietary dronabinol product candidate is SYNDROS™. The DEA has issued an interim final ruling that would result in SYNDROS™ being placed in Schedule II of the CSA and we now must interact with the FDA to finalize the labeling prior to commercial launch. 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.

We believe a significant unmet medical need exists for formulations of dronabinol that act more rapidly and are subject to less variable patient absorption. We completed a pivotal bioequivalence study that was a 52-patient crossover bioavailability and PK clinical trial comparing SYNDROS™ with Marinol. In the study, 100% of subjects receiving SYNDROS™ achieved detectable plasma levels at 15 minutes compared to less than 25% of the subjects receiving Marinol. Additionally, SYNDROS™ demonstrated lower intra-subject variability relative to Marinol. We

believe these attributes may be a consideration for the providers in selecting the appropriate formulation of dronabinol for patients, which we also believe will allow us to further penetrate and potentially expand the market for the medical use of dronabinol.

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 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 $1.3 billion in 2013, 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.
- 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 SYNDROS™ product candidate has the potential to address many of the limitations that exist in synthetic cannabinoid products by providing a number of key advantages, including:

- Faster absorption: SYNDROS™ 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 be an important consideration in the selection of a dronabinol product by physicians. Separately, we believe that our proprietary inhalation dronabinol formulation may further accelerate dronabinol's onset of action due to their route of delivery bypassing first-pass metabolism in the liver.
- Reduced dose-to-dose variability: Based on our PK study, we believe SYNDROS™ has lower variability of absorption between patients.

Cannabidiol Oral Solution

Cannabidiol has been shown pre-clinically to protect from seizures in various rodent models of seizures, to alleviate neuropathic pain caused by chemotherapy-induced peripheral neuropathy mouse models treated with paclitaxel, and reduce tumor burden in xenograft mouse model of human glioblastoma tumors. We are developing a Cannabidiol Oral Solution, a synthetic cannabidiol, for childhood catastrophic epilepsy syndromes examples of which include infantile spasms, Dravet Syndrome and Lennox-Gastaut syndrome for which we have received Orphan Drug Designations for CBD.

In addition to the above epilepsy indications, we have also received Orphan Drug Designations for the treatment of CBD in glioblastoma multiforme, pontine glioma, and pediatric schizophrenia.

Early studies in animal models demonstrate that while CBD has anticonvulsant properties and the effectiveness of CBD-enriched cannabinoids in the treatment of epilepsy has been reported. A survey of children using a CBD-enriched plant product reported a reduction in their child's seizures in 84% and 11% reported complete seizure freedom. In an open access program using a CBD-enriched plant deprived product, which included 214 patients who received drug, the median reduction in monthly motor seizures was 36.5% and the drug was generally well-tolerated. However, parental report can be subject to significant bias, especially where expectations are high.

Currently, we have one ongoing and one completed study in epilepsy. The first study, a Phase 1b pharmacokinetic study that is evaluating three different doses of CBD in pediatric patients with refractory epilepsy: 10mg/kg/day, 20mg/kg/day and 40mg/kg/day in pediatric patients with refractory seizures, is ongoing.

A second study, a Phase 2 study to assess the efficacy and safety of Cannabidiol Oral Solution for the treatment of refractory Infantile Spasms, studied the effect of Cannabidiol Oral Solution in patients who have failed all approved treatments. This study has been completed and we are evaluating the development in Infantile Spasms in a less refractory population. Should CBD demonstrate benefit in this population, it will provide a treatment option where currently only poorly tolerated options exist, fulfilling a large unmet need.

Further, we are exploring Cannabidiol Oral Solution for pediatric epilepsies and non-epilepsy indications. The initiation of these studies are planned for the second half of 2017.

Prader-Willi Syndrome, first described in 1956, is a multifaceted developmental disorder and the most common genetic syndrome associated with obesity. It is caused by the absent expression of paternally-inherited genes in the Prader-Willi Syndrome region on 15q11-q13. While it presents with generalized hypotonia and developmental delay in infancy, Prader-Willi Syndrome then manifests with uncontrollable appetite, hyperphagia, and excessive weight gain leading to severe obesity, and it is the appetite behavior classified as hyperphagia in Prader-Willi Syndrome that is the most life threatening. Until recently, no patient lived over the age of 50 due to morbid obesity and its related complications. The mortality rate in patients with Prader-Willi Syndrome is six times higher than patients with other

intellectual disabilities.

Hyperphagic behaviors can also be dangerous in persons who are not obese, with increased risks of death due to choking while sneaking food, and gastric perforations after consuming more food than usual. Approximately 8%

of deaths in individuals with Prader-Willi Syndrome are reported due to the choking, especially on hot dogs. Prader-Willi Syndrome patients also are known to eat discarded (contaminated) food and items that are not for human consumption such as pet food, or even non-food items such as paint or paper.

Currently, there are no FDA-approved therapies for the treatment of hyperphagia or obesity in patients with Prader-Willi Syndrome. In addition, drugs that have demonstrated efficacy in the past have been withdrawn or have significant safety concerns (e.g., rimonabant, beloranib). Recent studies investigating modulation of the endocannabinoid system have shown promise.

The endocannabinoid system appears to be critically involved in the regulation of appetite, body weight, metabolism, hypothalamic-pituitary-adrenal axis, and reward brain circuitry. In clinical studies, compounds with endocannabinoid effects (fenfluramine, rimonabant) have shown significant effects on weight and appetite suppression. These effects on appetite also occurred in 19% of epilepsy patients treated with Epidiolex© (i.e., cannabidiol extracted from the cannabis plant) during an open-access program for patients with pediatric seizure disorder.

We also provide Cannabidiol Oral Solution and some financial support for Investigator Initiated Trials of Cannabidiol Oral Solution in various clinical settings such as cocaine dependence, analgesia, and early psychosis. These trials are currently ongoing.

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 a proprietary inhalation dronabinol formulation. All of these product candidates are in preclinical development. 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 clinical and 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

We currently market SUBSYS® and intend to commercialize SYNDROS™, if finalization of labeling by the FDA is obtained, and future supportive care products, if approved, through our U.S.-based commercial sales organization focused on supportive care. Specifically, we currently market SUBSYS® in the United States through our commercial sales organization. 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 other competing 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 of December 31, 2016, there were approximately 8,100 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 1,600 physicians comprise 90% of TIRF prescriptions dispensed in 2016, according to IMS. Our sales and marketing efforts have primarily targeted approximately 100% of these top 1,600 prescribing physicians with a focus on the highest prescribers. 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 TIRF REMS enrolled physicians and oncologists who prescribe SUBSYS®, and allowing sufficient time for physicians and patients to identify their effective SUBSYS® dose among our broad spectrum of dosage strengths.

Manufacturing and Supply

We produce dronabinol, the API in our dronabinol product family, including 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 the initial launch quantities of SYNDROS™, if finalization of labeling by the FDA is obtained, as well as to support the continued development of our other cannabinoid 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 additional information, see “Risk Factors—Risks Related to Our Business and History—We produce our dronabinol API internally and may encounter manufacturing failures that could impede or delay commercial production of SYNDROS™, if finalization of labeling by the FDA is obtained, or our other dronabinol product candidates, if approved, or the preclinical and clinical development or regulatory approval of our dronabinol product candidates” in Part I, Item 1A of this report.

For our long-term needs, in 2014 we completed construction of a second domestic dronabinol manufacturing facility, which we believe will enable us to supply sufficient commercial quantities of dronabinol API for our continued commercialization of our proprietary dronabinol product candidates, if approved. For additional information, see “Risk Factors—Risks Related to Our Business and History—We have expanded our dronabinol API production capacity by constructing a second facility. We may encounter a number of challenges relating to the management and operation of such a facility, and we may never realize a return on our investment” in Part I, Item 1A of this report.

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 commercialization of SYNDROS™, if finalization of labeling by the FDA is obtained, and the development and commercialization of our dronabinol-based product candidates. For additional information, see “Risk Factors—Risks Related to Our Business and History—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 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® or to develop our product candidates.” in Part I, Item 1A of this report.

We purchase the fentanyl API utilized in connection with SUBSYS® from one vendor as our sole supplier of the API in this product. SUBSYS® is manufactured by contract manufacturers and sub-component fabricators. 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. On October 30, 2015, we entered into an amended and restated supply, development & exclusive licensing agreement with Aptargroup, Inc. which, among other things, extended our exclusive supply rights to the current sublingual device, currently utilized by SUBSYS®, as well any new device(s) jointly developed by the two companies for a period of seven years. In addition

to extending the term, this amendment added certain minimum purchase commitments and requires certain tiered royalties as a percentage of net revenue to be paid by us ranging from less than one percent to the low single digits, commencing in March 2016 through the term of the agreement, from our sales of SUBSYS® and future products that use the Aptar spray device technology. In January 2016, we assigned our rights, title, duties and

obligations of our manufacturing and supply agreement with DPT and our supply, development & exclusive licensing agreement with Aptar from our parent to our manufacturing subsidiary as part of a corporate restructuring.

We entered into a manufacturing agreement effective as of May 24, 2011 with 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. In April 2015, we entered into an amendment to our manufacturing and supply agreement with DPT, which extends our existing manufacturing and supply agreement to produce SUBSYS® until the end of 2020. In addition to extending the term, this amendment added certain minimum purchase commitments. In July 2016, we, through our manufacturing subsidiary, entered into a further amendment to our DPT manufacturing and supply agreement dated May 24, 2011. This amendment effectively eliminates any prior minimum purchase (and batch) obligations that had been set forth in the amendment dated April 30, 2015 and replaces it with a new annual purchase commitment of $4 million per calendar year commencing January 1, 2017 through December 31, 2020. As a result, the cumulative effect related to this amendment reduces our aggregated minimum purchase commitments with DPT from $50 million to $16 million through December 31, 2020.

Aptar and DPT have been selected for their specific competencies in manufacturing, product design and materials. FDA regulations require that materials be produced under 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, tolerability profile and intellectual property rights. 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 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 five 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.

Cannabinoid Product Family

With respect to our dronabinol product candidates, the market in which we intend to compete is challenging in part because of the presence of generic products. 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 SYNDROS™ and our other dronabinol product candidates are intended to treat. Specifically, SYNDROS™, if finalization of labeling by the FDA is obtained, and our other 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 cannabinoid products may compete with non-synthetic cannabinoid drugs, including therapies such as GW Pharmaceuticals plc's Sativex and Epidiolex, 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' 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 SYNDROS™ and our other dronabinol product candidates, if approved, 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 SYNDROS™.

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 February 13, 2017, we owned or licensed from third parties a total of twenty-nine worldwide patents and fifty-four patent applications including seventeen issued U.S. utility patents and twenty-eight pending U.S. utility patent applications. These U.S. patents and patent applications will expire between 2017 and 2036. 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 five Orange Book listed (with the FDA) U.S. Patent Nos. 8,486,972, 8,486,973, 8,835,459, 8,835,460 and 9,241,935, one granted U.S. patent no. 9,289,387 and two pending U.S. patent applications. These patents are directed to SUBSYS® brand fentanyl and/or the use of the SUBSYS®

sublingual fentanyl spray for the treatment of pain and will expire in 2027 and 2030. We also currently have eleven issued foreign patents and six pending foreign patent applications covering 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 four issued U.S. patents and one pending U.S. patent application. Two of the U.S. patents are directed to formulations of dronabinol and methods of manufacturing and packaging dronabinol in capsules. Two of the U.S. patents and the pending applications are directed to SYNDROS™ brand oral solution formulations of dronabinol. Three of the issued dronabinol patents will expire in 2028, while the forth will expire in 2033. Any patents that issue from our pending patent application will likely expire in 2028.

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. In addition, 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. For example, as described in Note 7 in the Notes to our Consolidated Financial Statements, a former officer of Insys Pharma sought unsuccessfully 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 a 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 fully 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 issued 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 should be 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 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. regulations may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending 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 GLPs. 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 proposed clinical trial 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, 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 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 provide substantial evidence of clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to establish the efficacy and safety 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 PDUFA 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 comprised of 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 data in the NDA and the manufacturing facilities, clinical sites, and the proposed product label, it may issue either 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 that 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 associated with its use. 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

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 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 RLD and has been shown to be bioequivalent to the RLD. 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 RLD 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 that any patents listed for the approved product in the FDA's Orange Book have expired or are not applicable. 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 can take the same actions in reviewing NDA supplements as it does in reviewing original 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 commitments or requirements, 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 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

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 breakthrough 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 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,

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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.

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 United 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 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 payer. Moreover, qui tam suits filed under the False Claims Act can be brought by any individual on behalf of the government and such individuals, commonly known as "relators" or "whistleblowers," may share in any amounts paid by the entity to the government in fines or settlement. The frequency of filing qui tam actions has increased significantly in recent years, causing greater numbers of health care companies to have to defend such qui tam actions and pay substantial sums to settle such actions.

Also, the HIPAA 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.

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 payers 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 payers 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 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 payers 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 payers.

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 payers, 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 payers 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, the PPACA, which 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 HIPAA, as amended by HITECH, and their respective implementing regulations, including the related final published omnibus rule. 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.

Research and Development

Our operating results will also depend significantly on our research and development activities and related regulatory developments. Our research and development expenses were $73.9 million, $56.7 million and $33.1 for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had 59 full-time research and development personnel. We expect research and development expenses to increase as we increase related headcount and continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary cannabinoid product candidates, including SYNDROS™, and sublingual spray product candidates. We do not expect to realize net revenues from all of these research and development initiatives in the near term and may never realize net revenues from these investments. For additional information, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Factors Affecting Our Performance—Product Development and Related Regulatory Processes.

Employees

As of December 31, 2016, we employed 423 full-time employees, including 44 manufacturing employees, 274 sales and marketing employees, 59 employees in research and development, and 46 employees in administration. As of the

same date, 30 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.

Available Information

We make our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports available, free of charge, in the “Investors” section of our Internet website as soon as reasonably practicable after we electronically file these materials with, or furnish these materials to, the SEC. Our website is www.insysrx.com.

You may also read or copy any materials that we file with the SEC at its Public Reference Room at 100 F. Street, N.E., Washington, DC 20549. You may obtain additional information about the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally, you will find these materials on the SEC Internet site at http://www.sec.gov that contains reports, proxy statements and other information regarding issuers that file electronically with the SEC.

ITEM 1A. RISK FACTORS

Risks Related to Our Business and Industry

We are largely dependent on the commercial success of our product, SUBSYS®, and although we have generated revenue and profit from sales of SUBSYS®, 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 main approved product, SUBSYS®. In addition to the risks discussed elsewhere in this section, our ability to continue to generate revenues from this product will depend on a number of factors, including, but not limited to:

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

The continuing and heightened publicity surrounding the national opioid epidemic continues to result in sensitivity by some healthcare professionals to prescribe, and pharmacies to dispense, opioids. In part, this sensitivity by healthcare professionals and pharmacies is the result of third-party payers, such as insurance companies, and regulatory and government agencies increasingly scrutinizing the indications and uses for which healthcare professionals are prescribing, and pharmacies are dispensing, opioids. Moreover, ongoing state and federal investigations into our sales, marketing and other commercial practices and developments and media reports that may

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arise in connection with such investigations may negatively affect our relationships with healthcare professionals and pharmacies and their prescribing or dispensing habits. Consequently, these current and potential future events have and will likely continue to affect the manner in which, and the situations when, SUBSYS® is being prescribed, dispensed and approved for coverage.

If SUBSYS®, SYNDROS™, or any of our product candidates for which we receive regulatory approval, do not maintain broad market acceptance or coverage by third-party payers, the revenues that we generate from this product will be limited.

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

- patients' ability to obtain sufficient third-party payer coverage and reimbursement;
- 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 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;
- the willingness of patients to pay out of pocket in the absence of third-party payer 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 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 payers 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 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® and, if approved, our product candidates that contain controlled substances, may generate public controversy that may adversely affect market acceptance of SUBSYS® and, if approved, such product candidates.

Our efforts to educate the medical community and third-party payers 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 requires significant resources and may not continue to be successful. If our products do not continue to receive an adequate level of acceptance by physicians, third-party payers and patients, we may not generate sufficient revenue from these products to remain profitable.

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

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 our dronabinol product candidates are approved and 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.

The unpredictability and regulation surrounding reimbursement on SUBSYS® and SYNDROS™ may affect our financial condition and results of operations.

Our sales of, and revenue from, SUBSYS® (and our anticipated future revenue from SYNDROS™) depend in significant part on the coverage and reimbursement policies of third-party payers, including government payers such as Medicare and Medicaid, and private health insurers. All third-party payers are sensitive to the cost of drugs and consistently implement efforts to control these costs, which efforts include, but are not limited to, establishing excluded or preferred drug lists. SUBSYS® has been, and will likely continue to be, subject to these restrictions and impediments from third-party payers, particularly PBMs and private health insurers. Our product, SUBSYS®, has been included on an exclusion list for at least one significant PBM and may in the future be included on other PBM exclusion lists. These PBMs, which administer prescription drug benefits for employers and health plans and runs large mail-order pharmacies, have significant influence in the insurance industry. While most PBMs have an exception process that physicians may pursue to have an off-formulary, medically necessary drug covered for patients, being placed on an exclusion list makes it difficult for many patients covered through a PBM administered plan to have SUBSYS® covered by insurance. In the future, we may not be able to work with other PBMs to evaluate price increases and to communicate with managed care and health-system decision-makers to ensure a balanced approach which takes into account the clinical performance and efficacy of our products. Moreover, in the United States, there have been, and we expect there will continue to be, a number of state and federal proposals that limit the amount that third-party payers may pay to reimburse the cost of drugs, particularly for state and federal government programs such as Medicare and Medicaid, as well as managed care providers and private insurance plans. We believe the increasing emphasis on managed care in the United States has and will continue to put pressure on the price and usage of SUBSYS®. Our ability to generate revenue is affected by the availability of third-party reimbursement for SUBSYS® and our results of operations will be negatively affected if we fail to manage adequate reimbursement levels for SUBSYS® from such third-party payers.

In addition, our business operations include administrative reimbursement support assistance for patients, in large part through our patient services hub, to help patients work with their insurance companies. The patient support assistance provided by us, including our patient services hub, is subject to extensive and complex federal and state laws and varied third-party payers standards, procedures, processes and conditions. Our compliance with applicable laws, regulations and standards is expensive and time consuming and substantial governmental resources exist to

enforce and prosecute these applicable laws, regulations and standards and companies that violate such laws, regulations and standards may face substantial penalties. The potential sanctions include significant civil, criminal and administrative penalties, damages and fines and exclusion from participation in federal health care programs. Because of the breadth of these laws and the lack of extensive legal guidance in the form of regulations or court decisions, it is possible that some of our business activities could be subject to challenge or penalty under one or more of these laws. Such a challenge, irrespective of the underlying merits of the challenge or the ultimate outcome of the matter, could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We or our collaborators may not be successful in executing sales and marketing strategies for SUBSYS®, SYNDROS™, 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 SYNDROS™ or any of our product candidates for which we obtain regulatory approval and maintain sales and marketing responsibility, our commercial organization. Our commercial organization 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 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 SUBSYS® in March 2012 and our anticipated launch of SYNDROS™ in 2017, we have increased our number of full-time employees from 32 on December 31, 2010 to 423 as of December 31, 2016, 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 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 and expand our facilities.

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 all necessary approvals for SYNDROS™, which would limit our near-term future revenue growth prospects.

In addition to growing sales of our main approved product, SUBSYS®, the ability to improve our business, results of operations and financial condition in the near-term will depend heavily on our ability to obtain all necessary approvals for the commercial launch of SYNDROS™. We received FDA approval for SYNDROS™ in July 2016. In March 2017, the DEA issued an interim final ruling that would result in SYNDROS™ being placed in Schedule II of the CSA. We are currently awaiting the finalization of labeling by the FDA as the final approval prior to commercial launch.

If we are unable to obtain all necessary approvals for the commercial launch of SYNDROS™, our ability to generate additional near-term revenues beyond those derived from the commercial sale of SUBSYS® will be significantly, if not completely, limited or 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 SYNDROS™, if all necessary approvals are obtained, or our other 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 could cause us to be unable to meet demand for SYNDROS™, if all necessary approvals are obtained, or our other dronabinol product candidates, if approved, 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 support 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 a delay in the commercial launch of SYNDROS™, if all necessary approvals are obtained, or our other dronabinol product candidates, if approved, delays in our preclinical studies, clinical trials and regulatory submissions.

We are aware of only two other manufacturers that are able to produce pharmaceutical grade 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 have expanded our dronabinol API production capacity by constructing a second facility. We may encounter a number of challenges relating to the management and operation of such a facility, and we may never realize a return on our investment.

We have expanded 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 has required significant capital expenditures and has resulted 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 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 obtain regulatory approval for and successfully commercialize our dronabinol product candidates, including SYNDROS™, 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 and maintain a number of regulatory approvals in connection with the production of dronabinol API at our second manufacturing facility. Our ability to obtain and maintain 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. 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 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® or to develop our product candidates.

We rely on a number of third parties for the commercial supply of SUBSYS® and the clinical supply of our product candidates. Our ability to commercially supply SUBSYS® 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 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® or develop our SYNDROS™ or any other product candidates.

We purchase the fentanyl API utilized in connection with SUBSYS® from one vendor as our sole supplier of the API in this product. We purchase 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 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.

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 Aptar, with the final fill, assembly and packaging of SUBSYS® performed by 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 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® will result in the loss of potential revenues and could adversely affect the market’s acceptance of these products. 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® 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® and the 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 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 QSR, our ability to both have the finished sublingual spray device manufactured and to 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 six 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 product candidates, the market in which we intend to compete is challenging in part because generic products generally face greater price competition than branded products and the competition from generic products may have an effect on our product prices, market share, revenues and profitability. We 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 that our dronabinol product candidates are intended to treat. Specifically, 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 SYNDROS™ 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 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 payers for SUBSYS®, 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 payers. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payers 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 payers 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 payers' drug formularies, or lists of medications for which third-party payers provide coverage and reimbursement. The competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers 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 payers 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 payers, 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 payers. Therefore, coverage and reimbursement for drug products can differ significantly from payer to payer. 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 payer 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 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 depend on wholesale pharmaceutical distributors for retail distribution of SUBSYS®; if we lose any of our significant wholesale pharmaceutical distributors, our business could be harmed.

The majority of our sales of SUBSYS® are to wholesale pharmaceutical distributors who, in turn, sell the products to pharmacies, hospitals and other customers. For the year ended December 31, 2016, four wholesale pharmaceutical distributors, Rochester Drug Cooperative, Inc., AmerisourceBergen Corporation, McKesson Corporation, and Cardinal Health, Inc., individually comprised approximately 15%, 17%, 16% and 14%, respectively, of our total gross sales of SUBSYS®. The loss by us 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 can manage these

pricing pressures or that wholesaler purchases will not fluctuate unexpectedly from period to period.

Our sales of SUBSYS® 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, and insufficient product available at the retail level. 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.

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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.

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 GAO, 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 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, SYNDROS™, 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 IRB, 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 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 SYNDROS™.

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 SYNDROS™ and Dronabinol Inhalation Device, 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 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. For 2017, we were allocated what we believe is a sufficient quantity of dronabinol to meet our currently anticipated production and testing needs through 2017. 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 2018 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 2017 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 SYNDROS™, if finalization of labeling by the FDA is obtained, 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 SYNDROS™, 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. The loss of the

services of any of these individuals could impede, delay or prevent the continuing commercialization of SUBSYS® or SYNDROS™ 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.

We are exposed to the risk of fraud or other misconduct of our employees, contractors or agents. Misconduct by employees, contractors or agents could include intentional failures to comply with FDA regulations, provide accurate information by our employees, contractors and agents to the FDA, comply with applicable manufacturing standards, comply with federal and state healthcare privacy, 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, false claims, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These laws also dictate the proper use of patient information and data which is subject to privacy laws such as HIPAA. 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 $1.1 million as of December 31, 2016. For state income tax purposes, we have $268.1 million of state NOLs, all of which relate to 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®, SYNDROS™ and our discontinued 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® SYNDROS™, 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

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SYNDROS™ and our discontinued Dronabinol SG Capsule are synthetic cannabinoids, which are regulated "controlled substances" under the 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 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 associated with SUBSYS®, our discontinued 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

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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.

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 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 facilities are 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 facilities, 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. 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 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 12 months from the issuance of this Annual Report. 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 main approved product, SUBSYS®, and any subsequently approved product candidates that are commercialized;
- the size and cost of our commercial infrastructure;
- 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® 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.

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 payers, 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 presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent;
- 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 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 the Anti-Kickback Statute and false claims laws which may apply to items or services reimbursed by any third-party payer, 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 7 under the heading "Legal Matters" in the Notes to our Consolidated Financial Statements for a discussion of ongoing investigations by HHS, Office of Inspector General, the U.S. District Attorney's Office for the District of Massachusetts and other attorney generals from several states, 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 product, SUBSYS®, 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,

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a product's approval may contain requirements for potentially costly post-approval studies and surveillance, including Phase IV 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 GLPs, which are regulations and guidelines enforced by the FDA for all of our products in clinical and pre-clinical development, and for any clinical trials that we conduct post-approval. To the extent that a product is approved for sale in other countries, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

In the case of SUBSYS® and any of our product candidates containing controlled substances, we and our contract manufacturers 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 have received subpoenas from the HHS, Office of Inspector General, the U.S. District Attorney's Office for the District of Massachusetts and other attorney

generals from several states. The subpoenas primarily request documents relating to the marketing of SUBSYS®. We are cooperating in responding to the subpoenas. See Note 7 under the heading “Legal Matters” in the Notes to our Consolidated Financial Statements for a discussion regarding these ongoing investigations.

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 MMA 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® 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. For example, PPACA 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;
- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the Federal Poverty Level, 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;
- 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 and reporting to the CMS by the 90th day of each subsequent calendar year;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- 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 has 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.

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 ATRA which 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 payers 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 European Union 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® and our product candidates, if and when commercialized, will depend, in part, upon the availability of coverage and reimbursement from third-party payers at the federal, state and private levels. Third-party payers include governmental programs such as Medicare or Medicaid, private insurance plans and managed care plans. These third-party payers 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 payers 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 or could result in lower margins. 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.

Heightened attention on the use of opioids, including government litigation changes in policies, legislation and leadership at the federal and state level could hinder or prevent the commercial success of SUBSYS® and any potential future opioid product candidates.

Many federal and governmental agencies are focused on the abuse of opioids in the United States and agencies such as the HHS have expressed their belief that the United States is in the midst of a prescription opioid abuse epidemic. Common prescription drugs that contain opioids are drugs such as oxycodone, hydrocodone, and fentanyl. Our product, SUBSYS®, is fentanyl based product in the TIRF class. To the extent that the healthcare community, regulatory bodies and governmental agencies associate us with, or determine that we are a part of, this perceived opioid abuse epidemic then this may negatively affect our stock price and our business in various ways including from a marketing, sales and public relations standpoint and these perceptions may also negatively affect our ongoing governmental investigations.

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®, SYNDROS™ and Dronabinol Inhalation Device, 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®, SYNDROS™ and Dronabinol Inhalation Device 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.

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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 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 18 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 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, 2016, our founder and principal stockholder, Dr. John N. Kapoor, beneficially owned approximately 67% 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 we are unable to successfully remediate any material weakness in our internal control over financial reporting, or identify any additional 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, 2016, our management and independent registered public accounting firm concluded that there were material weaknesses in our internal control over financial reporting. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weaknesses we and our independent registered public accounting firm identified related specifically to the lack of effective policies and procedures, or timely and effective reviews by personnel at an appropriate level, for accounting for the rebate component of our product sales allowances and the allowance for excess and obsolete inventory in accordance with U. S. GAAP. We did not have controls designed to validate the completeness and accuracy of underlying data used in the determination of these significant estimates. Overall the management in the finance and accounting group did not display adequate tone at the top with respect to judgment and rigor required to resolve the accounting for the rebates component of our product sales allowances and the allowance for excess and obsolete inventory matters.

While we expect to take the measures necessary to address the underlying causes of these material weaknesses, we cannot at this time estimate how long it will take and our efforts may not prove to be successful in remediating these material weaknesses. While we have not incurred and do not expect to incur material expenses specifically related to the remediation of these material weaknesses, 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, material weaknesses. If we are unable to successfully remediate any material weakness in our internal control over financial reporting, or identify any additional 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.

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, 2016, we had (i) 71,923,550 outstanding shares of common stock; (ii) 7,300,873 shares of common stock issuable upon the exercise of stock options under our 2013 Equity Incentive Plan and other existing stock option plans; and (iii) 4,259,755 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 stockholder rights plan, charter documents and Delaware law might deter acquisition bids for us that you might consider favorable.

On August 15, 2014, after approval by our stockholders, we entered into a rights agreement traditionally referred to as a poison pill. This rights agreement will have certain anti-takeover effects which will cause substantial dilution to a person or group that attempts to acquire the Company on terms not approved by our Board. In addition, 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 a “controlled company” under Nasdaq’s rules and may avail ourselves of exemptions from certain Nasdaq independence rules, which could make our common stock less attractive to investors.

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;

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(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 may 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS
Not applicable.

ITEM 2. PROPERTIES
We lease a total of approximately 100,000 square feet of office and lab space in Chandler, Arizona under lease agreements that expire between August 2020 and June 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 for our foreseeable future needs. Additionally, we lease a total of approximately 90,000 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 2018 and March 2024. We have the option to extend our primary manufacturing facility lease for two 5-year periods following March 2024. We believe that the Round Rock, Texas manufacturing facilities are adequate to meet our current needs and that suitable additional or alternative space will be available for our foreseeable future needs.

ITEM 3. LEGAL PROCEEDINGS
The information included in Note 7 under the heading “Legal Matters” in the Notes to our Consolidated Financial Statements in Part II, 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		Second Quarter		First Quarter	
2016 price range per share	$15.06	$8.70	$19.96	$11.55	$18.65	$11.45	28.91	14.18

	Fourth Quarter		Third Quarter		Second Quarter		First Quarter	
2015 price range per share	$33.88	$20.15	$46.17	$26.07	$42.69 [(1)]	$25.67 [(1)]	31.24 [(1)]	20.79 [(1)]

[(1)] Share price adjusted to reflect a 2-for-1 stock split that occurred on June 8, 2015.

Holders

As of March 28, 2017, there were approximately 37 holders of record of our common stock and 71,957,343 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.

Issuer Purchases of Equity Securities

Share Repurchase Program

On November 5, 2015, we announced a stock repurchase program which authorizes up to $50 million in repurchases of common stock. As of December 31, 2016, we had $17.4 million remaining under this program. There were no repurchases of our common stock during the three months ended December 31, 2016. Also see Note 8 of the Notes to our Consolidated Financial Statements for additional information on this repurchase program.

Company Stock Performance

The following graph compares our total cumulative shareholder return as compared to the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index for the period beginning on May 3, 2013 (our IPO date) and ending on December 31, 2016. Total shareholder return assumes $100.00 invested at the beginning of the period in our common stock, the stocks represented by the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index, respectively. Total return assumes reinvestment of dividends.

This stock performance graph shall not be considered soliciting material and shall not be deemed “filed” for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, whether made on, before or after the date of this filing and irrespective of any general incorporation language in such filing.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth certain financial data with respect to our business. The selected consolidated financial data should be read in conjunction with our Consolidated Financial Statements and related Notes and Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other information contained elsewhere in this Annual Report on Form 10-K. The selected financial data in the table below as of December 31, 2014, 2013 and 2012 and for the years ended December 31, 2013 and 2012, were derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K.

	Years Ended December 31,				
	2016	2015	2014	2013	2012
	(In thousands, except share and per share data)				
		(As Revised)	(As Revised)		
Consolidated Statement of Comprehensive Income Data:					
Net revenue	$242,275	$330,323	$219,092	$99,289	$15,476
Gross profit	216,882	301,469	196,514	86,624	7,849
Operating income (loss)	7,326	90,456	60,990	32,559	(23,440)
Income tax expense (benefit)	834	32,941	25,089	(8,800)	—
Net income (loss)	7,590	58,053	36,054	40,377	(24,378)
Net income (loss) per common share:					
Basic	$0.11	$0.81	$0.52	$0.78	$(0.87)
Diluted	$0.10	$0.77	$0.49	$0.70	$(0.87)
Weighted average common shares outstanding					
Basic	71,618,793	71,592,581	68,759,070	51,839,536	27,948,102
Diluted	74,145,918	75,707,651	73,335,132	57,469,234	27,948,102
Dividends declared per common share	$—	$—	$—	$—	$—

	December 31,				
	2016	2015	2014	2013	2012
	(In thousands)				
		(As Revised)	(As Revised)		
Consolidated Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$182,880	$159,091	$82,863	$45,782	$361
Total current assets	230,972	252,051	146,465	78,350	11,889
Total assets	356,136	351,285	215,635	100,558	18,741
Total current liabilities, including debt	78,614	90,436	48,709	21,081	83,419
Total liabilities	86,547	98,980	52,445	21,081	83,419
Total stockholders' equity (deficit)	269,589	252,305	163,190	79,477	(64,678)

Refer to Note 2 of the Consolidated Financial Statement for a summary of the amounts and financial statement line items impacted by the revision of previously issued financial statements for the correction of immaterial errrors.

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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 heading 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," "believ "estimates," "predicts," "potential," "continue," "intend" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these identifying words. 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 the heading "Risk Factors" in Part I, 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; PBM formulary changes relative to SUBSYS® or established for SYNDROS™ (once commercially launched, if at all) may have a material impact on future net revenue; our intent to file an IND application for the treatment of epilepsy with cannabidiol; the sufficiency of our manufacturing capacity; the beneficial attributes of our dronabinol product candidates and delivery mechanisms; that our suppliers are equipped to supply us with our current and future chemical needs; that pending dronabinol candidates will default to Schedule II classification; that changes in healthcare laws will result in reduced Medicaid and Medicare payments for prescription drugs; 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; our development of different dronabinol delivery systems; our anticipated timing of the commercial launch of SYNDROS™; our ability to obtain finalization of labeling by the FDA as the final approval prior to commercial launch of SYNDROS™; that we can maintain or even 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 and delivery systems; that we may pursue strategic transactions such acquisitions or other companies, asset purchase 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 government quotas; our strategy of using Marinol as a reference drug in future drug approval applications; the expected pathway of drug applications we expect to file in the future; that physicians and payers will continue to gain familiarity about and accept the features of SUBSYS®; our plans and strategies for obtaining future international approvals; our plans and strategies to protect our intellectual property; our intention of not paying dividends; possible capital raising transactions we may pursue; that we may avail ourselves of certain Nasdaq governance provisions because of our status as a controlled company; that research and development and operating costs will increase; that our investments in our sales and research and development infrastructure will result in increased sales; accounting estimates and the impact of new or recently issued accounting pronouncements; that cash flows from operations will increase and/or stabilize as a result of sales of SUBSYS®; the source and sufficiency of our liquidity and capital resources to fund our operations; trends in restrictions and

impediments relating to reimbursement policies imposed by PBMs; 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; our exposure to interest rate changes and market risks related to our investment; and the potential impact of Section 382 limitations on our NOLs. The words “anticipates,” “believes,” “estimates,” “expects,” “intends,” “may,” “plans,” “projects” “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, 2016 and 2015 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 one commercially marketed product and one product awaiting final labeling approval by the FDA, prior to commercial launch, after receiving FDA approval in July 2016 and DEA scheduling in March 2017:

- SUBSYS® — a proprietary, single-use product that delivers fentanyl, an opioid analgesic, for transmucosal absorption underneath the tongue, offered in 100, 200, 400, 600, 800, 1,200 and 1,600 mcg dosages. SUBSYS® is approved for the treatment of BTCP in opioid-tolerant patients. We received FDA approval for SUBSYS® in January 2012 and commercially launched SUBSYS® in March 2012.
- SYNDROS™ — a dronabinol oral solution that is equivalent to Marinol, an approved second-line treatment for CINV and anorexia associated with weight loss in patients with AIDS. We received FDA approval for SYNDROS™ in July 2016. In March 2017, the DEA issued an interim final ruling that would result in SYNDROS™ being placed in Schedule II of the CSA. We are currently awaiting the finalization of labeling by the FDA as the final approval prior to commercial launch.

We also have one discontinued product:

- Dronabinol SG Capsule — a dronabinol soft gelatin capsule that is a generic equivalent to Marinol, an approved second-line treatment for CINV and anorexia associated with weight loss in patients with AIDS, offered in 2.5, 5.0 and 10.0 milligram dosages. We received FDA approval for Dronabinol SG Capsule in August 2011. We commercially launched Dronabinol SG Capsule through our former exclusive distribution partner, Mylan Pharmaceuticals, Inc., in December 2011. We do not have any current plans to manufacture or market this product in the future.

We market SUBSYS® through our U.S.-based field sales force focused on supportive care physicians. Consistent with most pharmaceutical manufacturing companies, we sell and distribute SUBSYS® primarily to pharmaceutical wholesalers and collect sales proceeds from those wholesalers. For the year ended December 31, 2016, sales to our four largest wholesale customers accounted for 67% of gross revenue. We also sell SUBSYS® directly to certain specialty pharmaceutical retailers who distribute our product. For the year ended December 31, 2016 direct sales to specialty pharmaceutical retailers accounted for 33% of gross revenue. We do not own or have any ownership stake in any pharmaceutical wholesaler or specialty pharmacy, nor do we have an option to acquire any wholesaler or specialty pharmacy. All pharmacies that fulfill SUBSYS® prescriptions are fully independent. Our relationships with every pharmacy that fulfills SUBSYS® prescriptions are non-exclusive in that each of these pharmacies may also fulfill prescriptions for other pharmaceutical manufacturers, including our competitors. For the year ended December 31, 2016, over 920 independent pharmacies have fulfilled at least one SUBSYS® prescription.

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

likely continue to be, subject to these restrictions and impediments from third-party payers, particularly PBMs and private health insurers. We provide administrative reimbursement support assistance, in large part through our

insurance reimbursement support hub, which provides administrative support assistance to help patients coordinate with their insurance companies.

We are also developing other product candidates, such as cannabinoid line extensions and sublingual spray product candidates.

We produce the API for SYNDROS™ at our U.S.-based, state-of-the-art dronabinol manufacturing facility. While we believe that this facility has the capacity to supply sufficient commercial quantities of dronabinol API for our initial launch quantities of SYNDROS™, if final approvals are obtained, and support the continued development of our other dronabinol product candidates in the near-term, we have opened and expanded a second dronabinol manufacturing facility, which we anticipate will enable us to supply sufficient commercial quantities of dronabinol API for the anticipated commercialization of our proprietary dronabinol product candidates, if approved.

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

Factors Affecting Our Performance

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

Approved Product Sales. Our operating results will depend significantly upon our, and any of our third-party distributors', sales of approved products. During the year ended December 31, 2016, all of our net revenues were generated from the sale of our approved product, SUBSYS®. We will not generate any revenue from the sale of our discontinued Dronabinol SG Capsule in future periods. Our results will depend on prescription volume generally, which we believe will be driven primarily by achievement of broad market acceptance and coverage by third-party payers and effectiveness of the marketing and selling efforts with respect to SUBSYS®. Moreover, our gross margins improve on a unit-by-unit basis as we sell higher dosage strengths of our products. Importantly, the proportion of prescriptions written for repeat SUBSYS® patients has continued to increase since July 2012 from 50% of prescriptions to approximately 92% of prescriptions as of December 31, 2016. Generally, repeat SUBSYS® patients receive significantly higher doses of SUBSYS® on average than first-time patients as patients are titrated from a starter dose of SUBSYS® to their effective dose in accordance with the TIRF REMS protocol.

According to IMS, the total market for TIRF products for the year ended December 31, 2016 was approximately 72,000 prescriptions and we estimate SUBSYS® prescriptions were approximately 43% of the TIRF market, compared to a total market for TIRF products of approximately 94,000 prescriptions and approximately 46% SUBSYS® market share for the year ended December 31, 2015.

The continuing and heightened publicity surrounding the national opioid epidemic continues to result in sensitivity by some healthcare professionals to prescribe, and pharmacies to dispense, opioids. In part, this sensitivity by healthcare professionals and pharmacies is the result of third-party payers, such as insurance companies, and regulatory and government agencies increasingly scrutinizing the indications and uses for which healthcare professionals are prescribing, and pharmacies are dispensing, opioids. Moreover, ongoing state and federal investigations into our sales, marketing and other commercial practices and developments and media reports that may arise in connection with such

investigations may negatively affect our relationships with healthcare professionals and pharmacies and their prescribing or dispensing habits. Consequently, these current and potential future events have and will likely continue to affect the manner in which, and the situations when, SUBSYS® is being prescribed, dispensed and approved for coverage. While we continue to sell directly into wholesalers and retail pharmacies for

our revenue, the direct pressures discussed above related to the retail demand-side components of our business contributed to the decline in full-year 2016 SUBSYS® revenue when compared to 2015.

Third-Party Payer Interactions and Government Programs Associated with Reimbursement. Our interaction with third-party payers is critical to the success of our business and financial condition. Our relationships with these third-party payers evolves on a regular basis and is often difficult to predict. By way of example, from time to time, third-party payers modify which drugs they choose to reimburse. For instance, on or around August 1, 2014, ESI officially released its exclusion list of drugs, effective January 1, 2015, in connection with its national preferred formulary. Other PBMs may take similar actions and these actions may have a material impact on our net revenue in the future. As we have in the past, we will continue working with PBMs to evaluate price increases and to communicate with managed care and health-system decision-makers to ensure a balanced approach, which takes into account the clinical performance and efficacy of our products.

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

Investments in Our Infrastructure and Growth. Our ability to increase our sales and to further penetrate our target market segments is dependent in part on our ability to invest in our infrastructure and in our sales and marketing efforts. In order to drive further growth, we may hire additional sales and marketing personnel and invest in marketing our products to our target physician prescriber base. For example, as of December 31, 2016, we had 274 full-time sales and marketing personnel. This will lead to corresponding increases in our operating expenses, although we anticipate that these investments will result in increased product sales and net revenue. In addition, we have constructed a second dronabinol manufacturing facility, which we anticipate will supply us with sufficient commercial quantities of dronabinol API for the commercialization of our proprietary dronabinol product candidates, if approved. This second facility will also increase our operating expenses.

Product Development and Related Regulatory Processes. Our operating results will also depend significantly on our research and development activities and related regulatory developments. Our research and development expenses were $75.4 million and $55.3 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had 59 full-time research and development personnel. We expect research and development expenses to increase as we continue our planned preclinical studies and clinical trials for our product candidates, particularly our proprietary cannabinoid product candidates, including SYNDROS™, and sublingual spray product candidates. We do not expect to realize net revenues from all of these research and development initiatives in the near term and may never realize net revenues from these investments. Due to the risks inherent in conducting preclinical studies and clinical trials, the regulatory approval process and the costs of preparing, filing and prosecuting patent applications, our development completion dates and costs will vary significantly for each product candidate and are very difficult to estimate. The lengthy process of seeking regulatory approvals and the subsequent compliance with applicable

regulations require the expenditure of substantial additional resources. Any failure by us to obtain, or any delay in obtaining, regulatory approvals or acceptable DEA classifications for our product candidates, in particular those related to SYNDROS™, could cause our research and development expenditures to increase significantly and, in turn, have a material adverse effect on our results of operations.

Basis of Presentation

Revision of Previously issued Financial Statements for Correction of Immaterial Errors

During September 2016, we identified an error related to the accounting for the rebates component of our product sales allowances since 2014. We determined that we had miscalculated our rebate obligations on government payer and managed care contracts. In addition, we recorded out-of-period adjustments that resulted in an increase in operating expenses of $1,500,000 related to stock option modifications during the three months ended March 31, 2016 and a decrease in income tax expense of $834,000 related to the deductible interest expense portion of accrued litigation award and settlements recorded during 2016. We concluded that the errors were not material to previously issued annual financial statements. However, to correctly present net revenue, operating expenses and income tax expense in the appropriate annual period, management has revised the 2015 and 2014 financial statements. Refer to Note 2 of the Consolidated Financial Statements for a summary of the amounts and financial statement line items impacted by the revision. All amounts set forth in the discussion and analysis of the results of operations and financial condition for the years ended December 31, 2015 and 2014 have been adjusted to reflect these revisions.

Net Revenue

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 specialty retail pharmacies, collectively, our customers, on a wholesale basis. Sales to our customers are subject to specified rights of return. We record revenue for SUBSYS® at the time the customer receives the shipment.

Cost of Revenue, Gross Profit and Gross Margin

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

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

Sales and Marketing Expenses

Our sales and marketing expenses consist primarily of salaries, commissions, benefits, consulting fees, costs of obtaining prescription and market data, and market research studies related to SUBSYS®. As of December 31, 2016, we had 274 full-time sales and marketing personnel. 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. We will also incur expenses directly related to the launch of SYNDROS™, if finalization of labeling by the FDA is obtained.

Research and Development Expenses

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

- external research and development expenses incurred under agreements with third-party CROs and investigative sites, third-party manufacturers and consultants;
-

employee-related expenses, which include salaries, benefits and stock-based compensation for the personnel involved in our preclinical and clinical drug development activities; and

- facilities, depreciation and other allocated expenses, equipment and laboratory supplies.

To date, our research and development efforts have been focused primarily on our fentanyl, dronabinol and cannabidiol programs. As of December 31, 2016, we had 59 full-time research and development personnel. We expect research and development expenses to increase as we continue our planned preclinical studies and clinical trials for our product candidates. We determine which research and development projects to pursue, as well as the level of funding available for each project, based on the scientific and preclinical and clinical results of each product candidate and related regulatory action.

The following table provides a breakdown of our research and development expenses (in millions):

	Years Ended December 31,		
	2016	2015 (As Revised)	2014
Cannabidiol	$15.3	$ 16.3	$5.8
Buprenorphine	9.4	3.4	3.4
Fentanyl	4.5	2.8	2.8
LEP-ETU and IL-13	2.3	2.5	1.1
Naloxone	3.0	2.2	0.2
Dronabinol	3.9	6.3	1.6
Ondansetron	1.2	1.4	0.7
Buprenorphine/Naloxone	1.0	4.6	0.8
Sildenafil	0.6	0.2	0.8
Internal research and development costs	29.5	15.9	15.9
Other	3.2	1.2	-
Total research and development expenses	$73.9	$ 56.8	$33.1

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, 2016, we had 46 full-time general and administrative personnel. We expect general and administrative expense to modestly increase as a result of expanding our operating activities and the costs we incur operating as a public company. We expect these increases to include salaries and related expenses, legal and consultant fees, regulatory fees as new products are commercialized, accounting fees, director fees, increased directors' and officers' insurance premiums, fees for investor relations services, and enhanced business and accounting systems.

Charges Related to Litigation Award and Settlements

Charges related to litigation award and settlements for the year ended December 31, 2016 represent legal expense accruals of $3.4 million related to a settlement reached with the State of New Hampshire and $0.5 million in connection with the investigation by the State of Massachusetts. Charges related to litigation award and settlements for the year ended December 31, 2015 represent a $9.5 million accrual associated with our dispute with Dr. Kottayil and a $1.1 million legal settlement with the ODOJ related to sales of SUBSYS® in Oregon. See Note 7 of the Notes to our Consolidated Financial Statements for a discussion on our ongoing dispute with Dr. Kottayil and other legal matters.

Income Taxes, Net Operating Loss Carryforwards

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 $1.1 million as of December 31, 2016, which begin to expire in 2018.

For state tax purposes, we had approximately $268.1 million of state NOLs at December 31, 2016, all of which relate to Illinois. Based on projections and our limited activity in Illinois, we estimate that approximately $266.1 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 $20.6 million. A portion of the Illinois NOLs not utilized began expiring in 2015.

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 U.S. 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 document, 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®. 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® was commercially launched in March 2012 and is monitored by an FDA mandated REMS program known as the TIRF REMS. We sell SUBSYS® in the United States to wholesale pharmaceutical distributors and directly to retail pharmacies (collectively, our customers) subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. SUBSYS® currently has a shelf life of 36 months from the date of manufacture. We record revenue for SUBSYS® at the time the customer receives the shipment.

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

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

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

allowance for product returns is included in accrued sales allowances.

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

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

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.

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. The allowance for patient discount programs is included in accrued sales allowances.

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

Chargebacks. We provide discounts primarily to authorized users of the FSS of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These 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. The allowance for chargebacks is included as a reduction to accounts receivable.

A roll-forward of our product sales allowances for the years ended December 31, 2016 and 2015 is as follows (in thousands):

	Wholesale Discounts [1]	Patient Discount Programs	Rebates	Returns	Total
Balance at December 31, 2014 (As Revised)	$5,418	$2,227	$10,943	$1,159	$19,747
Revenue allowances:					
Provision related to current period sales	38,036	60,991	62,689	3,158	164,874
Provisions related to sales made in prior years	—	—	(367)	138	(229)
Payment and credits related to sales made in current period	(30,480)	(53,848)	(41,030)	—	(125,358)
Payment and credits related to sales made in	(5,418)	(2,227)	(7,543)	(1,257)	(16,445)

prior periods					
Balance at December 31, 2015 (As Revised)	$7,556	$7,143	$24,692	$3,198	$42,589
Provision related to current period sales	27,968	95,609	41,703	626	165,906
Provisions related to sales made in prior years	—	—	(962)	—	(962)
Payment and credits related to sales made in current period	(23,696)	(85,489)	(27,740)	—	(136,925)
Payment and credits related to sales made in prior periods	(6,369)	(7,143)	(21,410)	(1,272)	(36,194)
Balance at December 31, 2016	$5,459	$10,120	$16,283	$2,552	$34,414

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

Sales Practices

We have, from time to time, late in a fiscal quarter, offered to certain customers extended payment terms primarily in an effort to increase customer orders during that quarter, which may have impacted sales in subsequent quarterly periods. We believe this practice is consistent with industry practice. For all sales under which this incentive was provided during the periods presented in this discussion and analysis, revenue received from such sales was properly accounted for in accordance with ASC 605 — "Revenue Recognition" and was recognized in the proper applicable accounting 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.

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, 2016 and 2015.

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 our IPO, we did not have a reliable history of market prices for our common stock. Following our IPO, while we have an active trading market, we do not have sufficient historical data to accurately estimate 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. Industry peers consist of other public companies in the pharmaceutical industry that are 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 term 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 Comprehensive Income 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. As of December 31, 2016, we have recorded a valuation allowance of $23.5 million, related to Arizona research and development credits and Illinois NOLs expiring before being used.

Recently Issued Accounting Pronouncements

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

Results of Operations

The following table presents certain selected consolidated financial data expressed as a percentage of net revenue:

	Years Ended December 31,		
	2016	2015 (As Revised)	2014 (As Revised)
Net revenue	100.0%	100.0 %	100.0 %
Cost of revenue	10.5	8.7	10.3
Gross profit	89.5	91.3	89.7
Operating expenses:			
Sales and marketing	28.8	24.4	26.5
Research and development	30.5	17.2	15.1
General and administrative	25.6	19.1	20.2
Charges related to litigation award and settlements	1.6	3.2	-
Total operating expenses	86.5	63.9	61.8
Operating income	3.0	27.4	27.9
Other income:			
Interest income	0.4	0.2	0.1
Other income	0.1	-	-
Total other income	0.5	0.2	0.1
Income before income taxes	3.5	27.5	28.0
Less: income tax expense	0.3	10.0	11.5
Net income	3.2 %	17.5 %	16.5 %

Comparison of year ended December 31, 2016 to year ended December 31, 2015

Net Revenue. Net revenue decreased $88.0 million, or 26.7%, to $242.3 million for the year ended December 31, 2016 compared to $330.3 million for the year ended December 31, 2015. The decrease in net revenue was attributable to a decrease in net revenue of SUBSYS®, which was the result of a 24.5% decrease in SUBSYS® shipments to pharmaceutical wholesalers and specialty pharmaceutical retailers for the year ended December 31, 2016, as compared to the year ended December 31, 2015, partially offset by a 1.2% increase in net sales price, which was impacted by price increases in January 2015, July 2015, January 2016 and July 2016 combined with changes in mix of prescribed dosages and changes in provisions for wholesaler discounts, patient discounts, rebates and returns. Provisions for patient discounts, wholesaler discounts, rebates and returns were $95.6 million, $28.0 million, $40.7 million and $0.7 million, respectively, or 40.5% on a combined basis of gross revenue from the sale of SUBSYS® for the year ended December 31, 2016, compared to $61.0 million, $38.0 million, $62.3 million and $3.3 million, respectively, or 33.3% on a combined basis of gross revenue from the sale of SUBSYS® for the year ended December 31, 2015. The increase in product sales allowances was primarily attributable to higher volumes of patient assistance. As described in “Factors Affecting Our Performance – Approved Product Sales”, the continuing sensitivity by some healthcare professionals to prescribe, and pharmacies to dispense, opioids, scrutiny by third-party payers and governmental agencies, and ongoing state and federal investigations, and media reports related thereto contributed to the decrease in full-year SUBSYS® revenue when compared to 2015.

There was no net revenue from the sales of Dronabinol SG Capsule during the year ended December 31, 2016, compared to $1.3 million during the year ended December 31, 2015.

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Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue decreased $3.5 million to $25.4 million for the year ended December 31, 2016 compared to $28.9 million for the year ended December 31, 2015. The decrease in cost of revenue was primarily attributable to the decrease in sales of SUBSYS® during the year ended December 31, 2016. Gross profit decreased $84.6 million to $216.9 million for the year ended December 31, 2016 compared to $301.5 million for the year ended December 31, 2015 due primarily to the decrease in sales of SUBSYS®. Gross profit was also impacted by a $6.7 million increase in our reserve for excess and obsolete inventory to $6.8 million for the year ended December 31, 2016 compared to $0.1 million during the year ended December 31, 2015 related to SUBSYS®. Gross margin for the year ended December 31, 2016 was approximately 90% compared to approximately 91% for the year ended December 31, 2015.

Sales and Marketing Expense. Sales and marketing expense decreased $11.0 million to $69.7 million for the year ended December 31, 2016 compared to $80.7 million for the year ended December 31, 2015. The decrease in sales and marketing expense was due primarily to lower sales compensation expense and incremental product selling and marketing expense associated with the decrease in sales of SUBSYS®.

Research and Development Expense. Research and development expense increased $17.1 million to $73.9 million for the year ended December 31, 2016 compared to $56.8 million for the year ended December 31, 2015. The increase in research and development expense was due primarily to an increase in research and development personnel and to clinical and development expenses incurred during 2016 related to our growing product pipeline. Also contributing to the increase in research and development expense was a charge for product not commercially viable of $2.4 million for the year ended December 31, 2016 related to SYNDROS™. There was no similar charge for the year ended December 31, 2015.

General and Administrative Expense. General and administrative expense decreased $0.8 million to $62.1 million for the year ended December 31, 2016 compared to $62.9 million for the year ended December 31, 2015. The decrease in general and administrative expense was due primarily to decreases in legal expense incurred in connection with various ongoing government investigation and subpoena related matters and decreases in stock-based compensation costs of $2.1 million to $17.7 million for the year ended December 31, 2016 compared to $19.8 million for the year ended December 31, 2015. The decrease in legal expense was offset by an increase in general and administrative personnel costs. We expect to continue to incur significant legal expense for the foreseeable future until government investigations and subpoena related matters are resolved. Such costs could materially exceed the amounts we have historically incurred in connection with government investigations and subpoena related matters on an annual basis.

Charges Related to Litigation Award and Settlements. Charges related to litigation award and settlements for the year ended December 31, 2016 represent accruals of $3.4 million related to a settlement reached with the State of New Hampshire and $0.5 million in connection with the investigation by the State of Massachusetts. Charges related to litigation award and settlements for the year ended December 31, 2015 represent a $9.5 million accrual associated with our dispute with Dr. Kottayil and a $1.1 million legal settlement with the ODOJ related to sales of SUBSYS® in Oregon. See Note 7 of the Notes to our Consolidated Financial Statements for a discussion of ongoing legal matters.

Other Income. We reported other income of $1.1 million for the year ended December 31, 2016 and $0.5 million for the year ended December 31, 2015 due primarily to the result of our investing excess cash.

Income Tax Expense. Provision for income taxes was $0.8 million for the year ended December 31, 2016 representing an effective tax rate of 9.9%. Provision for income taxes was $32.9 million for the year ended December 31, 2015 representing an effective tax rate of 36.1%. The decrease in income tax expense and corresponding decrease in the effective tax rate for the year ended December 31, 2016 was due primarily to our utilization of available research and development and orphan drug tax credits in excess of pre-tax income.

Comparison of year ended December 31, 2015 to year ended December 31, 2014

Net Revenue. Net revenue increased $111.2 million, or 50.8%, to $330.3 million for the year ended December 31, 2015 compared to $219.1 million for the year ended December 31, 2014. The increase in net revenue was primarily attributable to the $112.5 million, or 52.0%, increase in net revenue of SUBSYS® to $329.0 million for the year ended December 31, 2015 compared to $216.5 million for the year ended December 1, 2014. The increase in SUBSYS®

revenue is primarily a result of a 30% increase in shipments to pharmaceutical wholesalers and retailers for the year ended December 31, 2015 as compared to the year ended December 31, 2014, as well as a 20% increase in net sales price, which was impacted by price increases in January 2014, April 2014, July 2014, January 2015 and July 2015, combined with changes in mix of prescribed dosages and changes in provisions for wholesaler discounts, patient discounts, rebates and returns. Provisions for wholesaler discounts, patient discounts, rebates and returns increased to $38.0 million, $61.0 million, $62.3 million and $3.3 million, respectively, or 33.8% on a combined basis of gross revenue from the sale of SUBSYS® for the year ended December 31, 2015, compared to $22.4 million, $36.5 million, $24.4 million and $2.8 million, respectively, or 39.2% on a combined basis of gross revenue from the sale of SUBSYS® for the year ended December 31, 2014. The increase in revenue provisions as a percentage of gross revenue was primarily attributable to an increase in the issuance of patient discount credits and rebate claims from managed care organizations and government programs. The increase in sales of SUBSYS® was partially offset by a decrease in sales of Dronabinol SG Capsule of $1.3 million to $1.3 million for the year ended December 31, 2015, compared to $2.6 million for the year ended December 31, 2014. We entered into a settlement agreement with Mylan in October 2015, which resulted in termination of our former distribution agreement with Mylan. Accordingly, we will not generate any meaningful revenue from the sale of Dronabinol SG Capsule in future periods.

Cost of Revenue, Gross Profit and Gross Margin. Cost of revenue increased $6.3 million to $28.9 million for the year ended December 31, 2015 compared to $22.6 million for the year ended December 31, 2014. The increase in cost of revenue was primarily attributable to the increase in sales of SUBSYS® during the year ended December 31, 2015. Gross profit increased $105.0 million to $301.5 million for the year ended December 31, 2015 compared to $196.5 million for the year ended December 31, 2014. Gross margin for the year ended December 31, 2015 was approximately 91% compared to approximately 90% for the year ended December 31, 2014. 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, and the effects of the 2014 inventory expiry issue described below. SUBSYS® gross margin was approximately 92% and 91% for the years ended December 31, 2015 and 2014, respectively. This increase in 2015 is attributable to a shift in sales mix to higher margin products in 2015 as repeat patients progress to higher dosage prescriptions.

During July 2014, we were notified by Mylan that certain Dronabinol SG Capsule inventories were approaching their product expiry date, and therefore, the inventory was not saleable to Mylan customers. As a result of this notice, we recorded $0.7 million in revenue related to the recognition of non-refundable deposits for amounts paid by Mylan for this inventory, and a corresponding $1.4 million charge to cost of revenue for the second quarter of 2014.

Sales and Marketing Expense. Sales and marketing expense increased $22.6 million to $80.7 million for the year ended December 31, 2015 compared to $58.1 million for the year ended December 31, 2014. The increase in sales and marketing expense was due primarily to higher sales compensation expense and incremental product marketing expense associated with the increase in sales of SUBSYS®.

Research and Development Expense. Research and development expense increased $23.7 million to $56.8 million for the year ended December 31, 2015 compared to $33.1 million for the year ended December 31, 2014. The increase in research and development expense was due primarily to an increase in research and development personnel and to clinical and development expenses incurred during 2015 related to our growing product pipeline.

General and Administrative Expense. General and administrative expense increased $18.6 million to $62.9 million for the year ended December 31, 2015 compared to $44.3 million for the year ended December 31, 2014. The increase in general and administrative expense was due primarily to increases in legal expense incurred in connection with various ongoing government investigation and subpoena related matters, which increased $6.8 million to $12.7 million for the year ended December 31, 2015 compared to $5.9 million for the year ended December 31, 2014. Legal expenses associated with litigation and other matters decreased $5.4 million to $5.6 million for the year ended December 31, 2015 compared to $11.0 million for the year ended December 31, 2014. Also contributing to the increase in general and administrative expense was an increase in stock-based compensation costs of $10.0 million to

$19.8 million for the year ended December 31, 2015 compared to $9.8 million for the year ended December 31, 2014. The other increases in general and administrative expense resulted from growth in administrative infrastructure to support the growth of the business.

Charges Related to Litigation Award and Settlements. Charges related to litigation award and settlements for the year ended December 31, 2015 represent a $9.5 million accrual associated with our dispute with Dr. Kottayil and a $1.1 million legal settlement with the ODOJ related to sales of SUBSYS® in Oregon. See Note 7 of the Notes to our Consolidated Financial Statements for a discussion of ongoing legal matters. There was no similar expense for the year ended December 31, 2014.

Other Income. We reported interest income of $0.5 million for the year ended December 31, 2015 and $0.2 million for the year ended December 31, 2014 primarily the result of our investing excess cash.

Income Tax Expense. Provision for income taxes was $32.9 million for the year ended December 31, 2015 representing an effective tax rate of 36.1%. Provision for income taxes was $25.1 million for the year ended December 31, 2014 representing an effective tax rate of 41.1%.

Liquidity and Capital Resources

Sources of Liquidity

We incurred losses from our inception through December 31, 2012. 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 and principal stockholder, Dr. John Kapoor.

On May 7, 2013, we completed our IPO, pursuant to which we sold 13,800,000 shares of our common stock (4,600,000 on a pre-split basis) at a price of $2.66 per share ($8.00 on a pre-split basis), which included the underwriters' exercise of their over-allotment option. As a result of the IPO, we raised a total of $32.5 million in net proceeds after deducting underwriting discounts and commissions of $2.6 million and offering expenses of $1.8 million. 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 25,586,580 shares of common stock (8,528,860 on a pre-split basis).

Since the completion of our IPO, we have financed our operations principally with existing cash on hand and cash flows from operations.

Cash Flows

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

	Years Ended December 31,		
	2016	2015 (As Revised)	2014 (As Revised)
Net cash provided by operating activities	$58.9	$ 102.3	$ 50.6
Net cash used in investing activities	(22.0)	(90.2)	(70.3)
Net cash provided by (used in) financing activities	(11.8)	9.3	32.4
Net increase in cash and cash equivalents	25.1	21.4	12.7
Cash and cash equivalents, beginning of period	79.5	58.1	45.4
Cash and cash equivalents, end of period	$104.6	$ 79.5	$ 58.1

Cash Flows from Operating Activities. Net cash provided by operating activities was $58.9 million and $102.3 million for the years ended December 31, 2016 and 2015, compared to $50.6 million for the year ended December 31, 2014. The decrease in net cash provided from operating activities from 2015 to 2016 primarily reflects the lower net income for the period driven by a reduction in SUBSYS® net sales, adjusted in part by depreciation and amortization, stock-based compensation expense and is also impacted by changes in working capital. The increase in net cash from operating activities from 2014 to 2015 primarily reflects higher net income driven primarily by the growth in SUBSYS® net sales, adjusted in part by depreciation and amortization, stock-based compensation expense, deferred income taxes, excess tax benefits on stock options and awards 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 $22.0 million and $90.2 million for the years ended December 31, 2016 and 2015, compared to $70.3 million for the year ended December 31, 2014. During 2016, we invested $11.4 million of excess cash in short-term and long-term investments, net of proceeds and we also invested $10.7 million for purchases of equipment and leasehold improvements. During 2015, we invested $76.3 million of excess cash in short-term and long-term investments, net of proceeds and we also invested $13.8 million for purchases of equipment and leasehold improvements. During 2014, we invested $48.4 million of excess cash in short-term and long-term investments, net of proceeds and we also invested $22.2 million for purchases of equipment and leasehold improvements, including $18.0 million in connection with the construction of our second dronabinol facility.

Cash Flows from Financing Activities. Net cash used in financing activities was $11.8 million for the year ended December 31, 2016, as compared to net cash provided by financing activities of $9.3 million and $32.4 million for the years ended December 31, 2015 and 2014. During the year ended December 31, 2016, we expended approximately $16.1 million to repurchase shares of our common stock and recognized $1.7 million due to tax deficiencies on stock options and awards, partially offset by proceeds from the exercise of stock options of $3.8 million and proceeds from shares issued under our employee stock purchase plan of $2.3 million. During the year ended December 31, 2015, we recognized $13.6 million of financing cash flows from excess tax benefits on stock options and awards, $9.5 million from the proceeds from exercise of stock options and $2.6 million of proceeds from shares issued under an employee stock purchase plan, partially offset by $16.5 million expended to repurchase shares of our common stock. During the year ended December 31, 2014, we recognized $21.4 million of financing cash flows from excess tax benefits on stock options and awards, $9.0 million from the proceeds from exercise of stock options and $2.0 million of proceeds from shares issued under an employee stock purchase plan.

We invoice pharmaceutical wholesalers and specialty pharmaceutical retailers upon shipment of SUBSYS®. To date, our customers have typically paid us 30 to 60 days from their applicable invoice dates.

Our cash flows for 2017 and beyond will depend on a variety of factors, including sales of SUBSYS® and our anticipated launch of SYNDROS™, regulatory approvals, investments in manufacturing and production, capital equipment, and research and development. We expect our net cash flows from operating activities to fluctuate with the sales of SUBSYS® and, if applicable, SYNDROS™, partially offset by anticipated expansion in research and development, manufacturing, and general and administrative expenses.

Funding Requirements

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

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

- the levels and mix of our product sales;
- the rates of progress, costs and outcomes of our clinical trials and other product development programs, including product candidates that we may develop, in-license or acquire;
- regulatory approvals, DEA classifications and other regulatory related events;
- personnel, facilities, equipment and other similar requirements;
- costs of operating as a public company;
- the effects of competing technological and market developments;
- costs associated with litigation and government investigations;

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

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

Contractual Obligations

Contractual Obligations	Total	Payments Due in Less Than 1 Year	Payments Due in 1-3 Years	Payments Due in 3-5 Years	Payments Due in More Than 5 Years
Operating leases	$30,278	$ 3,113	$ 6,715	$ 6,021	$ 14,429
Purchase obligations	36,290	7,500	15,910	12,880	—
	$66,568	$ 10,613	$ 22,625	$ 18,901	$ 14,429

Off-Balance Sheet Arrangements

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

At December 31, 2016, $54.0 million of our cash equivalent investments was in money market securities that are reflected as cash equivalents because all maturities are within 90 days. Our money market securities may consist of commercial paper, Federal agency discount notes and money market funds. We believe our interest rate risk with respect to these investments is limited due to the short-term duration of these arrangements and the yields earned, which approximate current interest rates.

Our policy for our short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Our investment portfolio, consisting of fixed income securities that we hold on an available-for-sale basis, was approximately $133.1 million as of December 31, 2016 and $122.8 million as of December 31, 2015. These securities, like all fixed income instruments, are subject to interest rate risk and would likely decline in value if market interest rates increase. We have the ability to hold our fixed income investments until maturity and, therefore, we would not expect to recognize any material adverse impact in income or cash flows if market interest rates increase.

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

Interest Rate Sensitivity

Principal Amount by Expected Maturity as of December 31, 2016

	Financial instruments mature during year ended:					
	2017	2018	2019	2020	2021	Thereafter
CD's, commercial paper and available-for-sale securities	$80.0	$32.4	$20.7	$—	$—	—
Weighted-average yield rate	0.61%	0.29%	0.23%	—	—	—

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

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

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Insys Therapeutics, Inc.

Chandler, Arizona

We have audited the accompanying consolidated balance sheets of Insys Therapeutics, Inc. (the “Company”) as of December 31, 2016 and 2015 and the related consolidated statements of comprehensive income, stockholders’ equity, and cash flows for each of the three years in the period ended December 31, 2016. 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. An audit 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. at December 31, 2016 and 2015, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Insys Therapeutics, Inc.’s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 31, 2017 expressed an adverse opinion thereon.

/s/ BDO USA, LLP

Phoenix, Arizona

March 31, 2017

INSYS THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)

	December 31, 2016	2015 (As Revised)
Assets		
Current Assets:		
Cash and cash equivalents	$104,642	$79,515
Short-term investments	78,238	79,576
Accounts receivable, net of allowances of $6,144 and $8,367 at December 31, 2016 and 2015, respectively	20,654	47,272
Inventories	21,743	41,715
Prepaid expenses and other current assets	5,695	3,973
Total current assets	230,972	252,051
Property and equipment, net	43,172	38,382
Long-term investments	53,796	43,219
Deferred income tax assets, net	23,243	17,607
Other assets	4,953	26
Total assets	$356,136	$351,285
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable and accrued expenses	$27,359	$35,611
Accrued compensation	8,833	10,225
Accrued sales allowances	28,955	35,033
Accrued litigation awards and settlements	13,467	9,567
Total current liabilities	78,614	90,436
Uncertain income tax position	7,933	8,544
Total liabilities	86,547	98,980
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock (par value $0.01 per share; 10,000,000 shares authorized; 0 shares issued and outstanding as of December 31, 2016 and 2015, respectively)	—	—
Common stock (par value $0.01 per share; 100,000,000 shares authorized; 71,923,550 and 71,907,858 shares issued and outstanding as of December 31, 2016 and 2015, respectively)	719	719
Additional paid in capital	256,529	246,685
Unrealized loss on available-for-sale securities, net of tax	(302)	(152)
Notes receivable from stockholders	(21)	(21)

Retained earnings	12,664	5,074
Total stockholders' equity	269,589	252,305
Total liabilities and stockholders' equity	$356,136	$351,285

See accompanying notes to consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

(in thousands, except share and per share data)

	Years Ended December 31,		
	2016	2015 (As Revised)	2014 (As Revised)
Net revenue	$242,275	$330,323	$219,092
Cost of revenue	25,393	28,854	22,578
Gross profit	216,882	301,469	196,514
Operating expenses:			
Sales and marketing	69,651	80,668	58,105
Research and development	73,913	56,781	33,136
General and administrative	62,092	62,948	44,283
Charges related to litigation award and settlements	3,900	10,616	—
Total operating expenses	209,556	211,013	135,524
Operating income	7,326	90,456	60,990
Other income:			
Interest income	1,039	502	151
Other income, net	59	36	2
Total other income	1,098	538	153
Income before income taxes	8,424	90,994	61,143
Less: income tax expense	834	32,941	25,089
Net income	$7,590	$58,053	$36,054
Unrealized loss on available-for-sale securities, net of tax	(150)	(128)	(24)
Total comprehensive income	$7,440	$57,925	$36,030
Net income per common share:			
Basic	$0.11	$0.81	$0.52
Diluted	$0.10	$0.77	$0.49
Weighted average common shares outstanding			
Basic	71,618,793	71,592,581	68,759,070
Diluted	74,145,918	75,707,651	73,335,132

See accompanying notes to consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands, except share amounts)

	Common Stock		Additional	Unrealized Loss on	Notes	Retained	
	Shares	Amount	Paid in Capital	Available-For-Sale Securities	Receivable From Stockholders	Earnings (Accumulated Deficit)	Total
Balance at December 31, 2013	66,369,784	$ 664	$ 167,867	$ —	$ (21)	$ (89,033)	$ 79,477
Exercise of stock options	3,616,790	36	8,920	—	—	—	8,956
Issuance of common stock- employee stock purchase plan	716,114	7	1,982	—	—	—	1,989
Excess tax benefits on stock options and awards	—	—	21,449	—	—	—	21,449
Stock based compensation - stock options and awards	—	—	15,289	—	—	—	15,289
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(24)	—	—	(24)
Net income	—	—	—	—	—	36,054	36,054
Balance at December 31, 2014 (As Revised)	70,702,688	707	215,507	(24)	(21)	(52,979)	163,190
Exercise of stock options	1,607,683	16	9,508	—	—	—	9,524
Issuance of common stock- employee stock purchase plan	151,906	2	2,645	—	—	—	2,647
Excess tax benefits on stock options and awards	—	—	13,596	—	—	—	13,596
Stock based compensation - stock options and awards	5,781	—	21,882	—	—	—	21,882
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(128)	—	—	(128)
Repurchase of common stock	(560,200)	(6)	(16,453)	—	—	—	(16,459)
Net income	—	—	—	—	—	58,053	58,053
Balance at December 31, 2015 (As Revised)	71,907,858	719	246,685	(152)	(21)	5,074	252,305
Exercise of stock options	637,721	6	3,797	—	—	—	3,803

Issuance of common stock- employee stock purchase plan	221,046	2	2,278	—	—	—	2,280
Tax deficiency on stock options and awards	—	—	(1,729)	—	—	—	(1,729)
Stock based compensation - stock options and awards	—	—	21,589	—	—	—	21,589
Unrealized loss on available-for-sale securities, net of tax	—	—	—	(150)	—	—	(150)
Repurchase of common stock	(843,075)	(8)	(16,091)	—	—	—	(16,099)
Net income	—	—	—	—	—	7,590	7,590
Balance at December 31, 2016	71,923,550	$ 719	$ 256,529	$ (302)	$ (21)	$ 12,664	$ 269,589

See accompanying notes to consolidated financial statements.

INSYS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)

	Years Ended December 31,		
	2016	2015 (As Revised)	2014 (As Revised)
Cash flows from operating activities:			
Net income	$7,590	$58,053	$36,054
Adjustments to reconcile net income to net cash provided by operating activities:			
Depreciation and amortization	6,249	5,291	2,500
Stock-based compensation	21,589	21,882	15,289
Deferred income tax benefit	(5,636)	(4,914)	(655)
Loss on disposal of assets	-	41	—
Excess tax benefits on stock options and awards	1,729	(13,596)	(21,449)
Amortization of investment discount	2,029	1,431	367
Changes in operating assets and liabilities:			
Accounts receivable	26,618	(23,770)	(7,796)
Inventories	15,044	(3,616)	(23,571)
Prepaid expenses and other current assets	(1,721)	1,345	(2,967)
Accounts payable, accrued expenses and other current liabilities	(18,487)	50,708	52,813
Accrued litigation award and settlements	3,900	9,423	—
Net cash provided by operating activities	58,904	102,278	50,585
Cash flows from investing activities:			
Change in restricted cash	—	—	400
Purchase of investments	(115,375)	(138,470)	(56,605)
Proceeds from sales of investments	7,948	25,492	—
Proceeds from maturities of investments	96,009	36,643	8,195
Purchases of property and equipment	(10,614)	(13,842)	(22,245)
Net cash used in investing activities	(22,032)	(90,177)	(70,255)
Cash flows from financing activities:			
Proceeds from issuance of common stock	2,280	2,647	1,989
Excess tax benefits on stock options and awards	(1,729)	13,596	21,449
Proceeds from exercise of stock options	3,803	9,524	8,956
Repurchase of common stock	(16,099)	(16,459)	—
Net cash provided by (used in) financing activities	(11,745)	9,308	32,394
Change in cash and cash equivalents	25,127	21,409	12,724
Cash and cash equivalents, beginning of period	79,515	58,106	45,382
Cash and cash equivalents, end of period	$104,642	$79,515	$58,106
Supplemental cash flow disclosures:			
Cash paid for income taxes	$10,742	$15,351	$2,975
Non-cash capital expenditures	$425	$—	$—

See accompanying notes to consolidated financial statements.

INSYS THERAPEUTICS, INC.

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 are a commercial-stage specialty pharmaceutical company that develops and commercializes innovative supportive care products. We have one commercially marketed product: SUBSYS®, a proprietary sublingual fentanyl spray for BTCP in opioid-tolerant adult patients; and one product: SYNDROS™, awaiting final labeling approval by the FDA, prior to commercial launch, after receiving FDA approval in July 2016 and DEA scheduling in March 2017.

2. Significant Accounting Policies

Revision of Previously Issued Financial Statements for Correction of Immaterial Errors

During the three months ended September 30, 2016, we identified an error related to the accounting for the rebates component of our product sales allowances since 2014.. We determined that we had incorrectly applied the accounting guidance in Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) No. 605, “Revenue Recognition” by miscalculating our rebate obligations on government payer and managed care contracts. In addition, we recorded out-of-period adjustments that resulted in an increase in operating expenses of $1,500,000 related to stock option modifications during the three months ended March 31, 2016 and a decrease in income tax expense of $834,000 related to the deductible interest expense portion of the accrued litigation award and settlements recorded during 2016. We assessed the materiality of these errors on our prior annual financial statements, assessing materiality both quantitatively and qualitatively, in accordance with the SEC’s Staff Accounting Bulletin (“SAB”) No. 99 and SAB No. 108 and concluded that the errors were not material to our consolidated financial statements for the years ended December 31, 2015 and 2014. However, to correctly present net revenue, operating expenses and income tax expense in the appropriate periods, management revised its previously issued financial statements for the years ended December 31, 2015 and 2014. Certain amounts in prior periods as previously reported have been reclassified to conform to the current period presentation.

The following tables summarize the impact and financial statement line items impacted by the revision adjustments as of and for the years ended December 31, 2015 and 2014 :

	As of December 31, 2015 (in thousands)		
Consolidated Balance Sheet:	As previously reported	Adjustments	As revised
Deferred income tax assets, net	16,331	1,276	17,607
Total assets	350,009	1,276	351,285
Accounts payable and accrued expenses	36,354	(743)	35,611
Accrued sales allowances	31,526	3,507	35,033
Total current liabilities	87,672	2,764	90,436
Uncertain income tax position	8,635	(91)	8,544
Total liabilities	96,307	2,673	98,980
Additional paid in capital	245,736	949	246,685
Retained earnings	7,420	(2,346)	5,074
Total stockholders' equity	253,702	(1,397)	252,305
Total liabilities and stockholders' equity	$350,009	$ 1,276	$351,285

	Year Ended December 31, 2015 (in thousands, except per share data)		
Consolidated Statement of Comprehensive Income:	As previously reported	Adjustments	As revised
Net revenue	$330,797	$ (474)	$330,323
Gross profit	301,943	(474)	301,469
Operating expenses:			
Research and development	55,281	1,500	56,781
Total operating expenses	209,513	1,500	211,013
Operating income	92,430	(1,974)	90,456
Income before income taxes	92,968	(1,974)	90,994
Less: income tax expense	34,492	(1,551)	32,941
Net income	58,476	(423)	58,053
Total comprehensive income	$58,348	$ (423)	$57,925
Net income per common share:			
Basic	$0.82	$ (0.01)	$0.81
Diluted	$0.77	$ (0.00)	$0.77

	Year Ended December 31, 2015 (in thousands)		
Consolidated Statement of Cash Flows:	As previously reported	Adjustments	As revised
Cash flows from operating activities:			
Stock-based compensation	$20,382	$ 1,500	$21,882
Deferred income tax benefit	(4,118)	(796)	(4,914)
Excess tax benefits on stock options and awards	(13,593)	(3)	(13,596)
Prepaid expenses and other current assets	1,311	34	1,345
Accounts payable, accrued expenses and other current liabilities	51,023	(315)	50,708
Net cash provided by operating activities	102,281	(3)	102,278
Cash flows from financing activities:			
Excess tax benefits on stock options and awards	13,593	3	13,596
Net cash provided by financing activities	$9,305	$ 3	$9,308

	As of December 31, 2014 (in thousands)		
Consolidated Statement of Stockholders' Equity:	As previously reported	Adjustments	As revised
Additional paid in capital	216,061	(554)	215,507
Retained earnings	(51,056)	(1,923)	(52,979)
Total stockholders' equity	165,667	(2,477)	163,190
Total liabilities and stockholders' equity	$215,121	$ 514	$215,635

	Year Ended December 31, 2014 (in thousands)		
Consolidated Statement of Comprehensive Income:	As previously reported	Adjustments	As revised
Net revenue	$222,125	$ (3,033)	$219,092
Gross profit	199,547	(3,033)	196,514
Operating income	64,023	(3,033)	60,990
Income before income taxes	64,176	(3,033)	61,143
Less: income tax expense	26,199	(1,110)	25,089
Net income	37,977	(1,923)	36,054
Total comprehensive income	$37,953	$ (1,923)	$36,030
Net income per common share:			
Basic	$0.55	$ (0.03)	$0.52
Diluted	$0.52	$ (0.03)	$0.49

	Year Ended December 31, 2014 (in thousands)		
Consolidated Statement of Cash Flows:	As previously reported	Adjustments	As revised
Cash flows from operating activities:			
Deferred income tax benefit	(175)	(480)	(655)
Excess tax benefits on stock options and awards	(22,003)	554	(21,449)
Prepaid expenses and other current assets	(2,933)	(34)	(2,967)
Accounts payable, accrued expenses and other current liabilities	50,376	2,437	52,813
Net cash provided by operating activities	50,031	554	50,585
Cash flows from financing activities:			
Excess tax benefits on stock options and awards	22,003	(554)	21,449
Net cash provided by financing activities	$32,948	$ (554)	$32,394

Principles of Consolidation

The consolidated financial statements include the accounts of Insys Therapeutics, Inc. and its wholly-owned subsidiaries. All significant intercompany balances and transactions have been eliminated in the accompanying consolidated financial statements.

Reclassification

Certain amounts in prior periods have been reclassified to conform to the current period presentation.

Fair Value of Financial Instruments

The carrying values of our financial instruments, including cash, accounts receivable and accounts payable approximate their fair value due to the short-term nature of these financial instruments.

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

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

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

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

Revenue Recognition

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

SUBSYS®

SUBSYS® was commercially launched in March 2012, and is 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 directly to specialty retail pharmacies (collectively, our customers) subject to rights of return within a period beginning six months prior to, and ending 12 months following, product expiration. SUBSYS® currently has a shelf life of 36 months from the date of manufacture. We record revenue for SUBSYS® at the time the customer receives the shipment.

We recognize estimated product sales allowances as a reduction of product sales in the same period the related revenue is recognized. Product sales allowances are based on amounts owed or to be claimed on the related sales. These estimates take into consideration the terms of our agreements with customers and third-party payers 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 have monitored actual return history since product launch, which provides us with a basis to reasonably estimate future product returns, taking into consideration the shelf life of product at the time of shipment, shipment and prescription trends, estimated distribution channel inventory levels, and consideration of the introduction of competitive products.

Because of the shelf life of our products and our return policy of issuing credits on returned product that is within six months before and up to 12 months after 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 sales allowances.

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

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

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.

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 channels. The allowance for patient discount programs is included in accrued sales allowances.

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

Chargebacks. We provide discounts primarily to authorized users of the FSS of the General Services Administration under an FSS contract negotiated by the Department of Veterans Affairs and various organizations under Medicaid contracts and regulations. These 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. The allowance for chargebacks is included as a reduction to accounts receivable.

Dronabinol SG Capsule

Our Dronabinol SG Capsule product was commercially launched in December 2011, and we sold Dronabinol SG Capsule exclusively to Mylan in the United States under a supply and distribution agreement. We do not have any current plans to manufacture or market this product in the future.

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, which at times may exceed FDIC limits.

Short-Term and Long-Term Investments

Our policy for short-term and long-term investments is to establish a high-quality portfolio that preserves principal, meets liquidity needs, avoids inappropriate concentrations and delivers an appropriate yield in relationship to our investment guidelines and market conditions. Short-term and long-term investments consist of corporate, various government agency and municipal debt securities, as well as certificates of deposit that have maturity dates that are greater than 90 days. Certificates of deposit and commercial paper are carried at cost which approximates fair value. We classify our marketable securities as available-for-sale in accordance with FASB ASC Topic 320, Investments — Debt and Equity Securities. Available-for-sale securities are carried at fair value with unrealized gains and losses reported in stockholders' equity, net of related tax effects. There were no reclassifications on available-for-sale securities during the year ended December 31, 2016. Reclassifications on available-for-sale securities were insignificant during the year ended December 31, 2015. A decline in the market value of any available-for-sale security below cost that is deemed to be other than temporary, results in impairment of the fair value of the investment. We did not have any realized gains or losses or decline in values judged to be other than temporary during the years ended December 31, 2016, 2015 and 2014. If we had realized gains and losses and declines in value judged to be other than temporary, we would have been required to include those changes in other expense in the consolidated statements of comprehensive income. Premiums and discounts are amortized or accreted over the life of the related available-for-sale security. The cost of securities sold is calculated using the specific identification method.

At December 31, 2016, our certificates of deposit and commercial paper as well as our marketable securities have been recorded at an estimated fair value of $1,296,000, $78,238,000 and $53,796,000 in cash and cash equivalents, short-term investments and long-term investments, respectively.

Accounts Receivable, Net

Trade accounts receivable are recorded at the invoice amount net of allowances for wholesaler discounts, prompt pay discounts, stocking allowances, and doubtful accounts. See “Revenue Recognition” above for a description of our wholesaler discounts, prompt pay discounts, stocking allowances and chargebacks. In the ordinary course of business, and consistent with industry practices, we may from time to time offer extended payment terms to our customers as an incentive for new product launches or in other circumstances. These extended payment terms do not represent a significant risk to the collectability of accounts receivable as of the period-end and are evaluated in accordance with ASC 605 —Revenue Recognition as applicable. 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. We write off accounts receivable against the allowance when a balance is determined to be uncollectable.

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

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 property and equipment is 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.

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 losses (“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 operating results.

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 consolidated statements of comprehensive income.

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.

Advertising and Marketing

Advertising and marketing costs are expensed as incurred. Advertising expense totaled $1,572,000, $1,166,000 and $800,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

Legal Fees

Legal fees are expensed as incurred. Accordingly, we do not accrue for estimated future legal fees to be incurred in connection with litigation and other related legal matters. Legal expense totaled $22,840,000, $19,448,000 and $16,926,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

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, which is generally three to four years, on a straight-line basis. 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 initial public offering of common stock ("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 our IPO, we did not have a reliable history of market prices for our common stock. Following our IPO, while we have an active trading market, we do not have sufficient historical data to accurately estimate 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 term 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 have historically been insignificant.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. 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 materially differ from those estimates.

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 October 2016, the FASB issued ASU No. 2016-16, Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory, to improve the accounting for the income tax consequences of intra-entity transfers of assets other than inventory. Current U. S. GAAP prohibits the recognition of current and deferred income taxes for an intra-entity asset transfer until the asset has been sold to an outside party, which is an exception to the principle of comprehensive recognition of current and deferred income taxes in U. S. GAAP. The amendments in this update eliminate the exception for an intra-entity transfer of an asset other than inventory. The amendments should be applied on a modified retrospective transition basis, and are effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. We are currently evaluating the impact of these amendments on our consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The amendments affect entities required to present a statement of cash flows and provides specific guidance on a variety of cash flow issues to reduce current and potential future diversity in practice. The amendments are effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years, and early adoption is permitted. An entity that elects early adoption must adopt all of the amendments in the same period. The amendments should be applied using a retrospective transition method to each period presented. We are currently evaluating the impact of these amendments on our consolidated financial statements.

In June 2016, the FASB issued ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments. The amendments affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income, and are effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. ASU 2016-13 amends the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in the timelier recognition of losses. We are currently evaluating the impact of these amendments on our consolidated financial statements.

In March 2016, the FASB issued ASU No. 2016-09, Compensation-Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting, to reduce complexity in accounting standards involving several aspects of the accounting for employee share-based payment transactions, including (1) the income tax consequences, (2) classification of awards as either equity or liabilities, and (3) classification in the statement of cash flows. The amendments will be effective for financial statements issued for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years.

Amendments related to the timing of when excess tax benefits are recognized, minimum statutory withholding requirements, forfeitures, and intrinsic value should be applied using a modified retrospective transition, amendments related to the presentation of employee taxes paid on the statement of cash flows when an employer withholds shares to meet the minimum statutory withholding requirement should be applied retrospectively, amendments requiring

recognition of excess tax benefits and tax deficiencies in the income statement and the practical expedient for estimating expected term should be applied prospectively, and amendments related to the presentation of excess tax benefits on the statement of cash flows can be applied using either a prospective transition method or a retrospective transition method. We will adopt the new guidance in the first quarter of 2017. Under the new guidance, excess tax benefits related to equity compensation will be recognized in the provision for income taxes in the consolidated statements of comprehensive income rather than in additional paid-in capital in the consolidated balance sheets and will be applied on a prospective basis. We have not yet determined our selected method of transition for changes to the statements of cash flows related to the classification of excess tax benefits and employee taxes paid for share-based payment arrangements. The related financial statement impacts of adopting the above aspects of this ASU are not expected to be material. However, depending on several factors such as the market price of our common stock, employee exercise behavior and corporate income tax rates, the excess tax benefits associated with the exercise of stock options could generate a significant discrete income tax benefit in a particular interim period potentially creating volatility in net income and net income per share period-to-period and period-over-period.

In February 2016, the FASB issued ASU No. 2016-02, Leases: (Topic 842), to provide guidance on recognizing lease assets and lease liabilities on the balance sheet and disclosing key information about leasing arrangements, specifically differentiating between different types of leases. The core principle of Topic 842 is that a lessee should recognize the assets and liabilities that arise from all leases. The recognition, measurement, and presentation of expenses and cash flows arising from a lease by a lessee have not significantly changed from previous U.S. GAAP guidance. There continues to be a differentiation between finance leases and operating leases. However, the principal difference from previous guidance is that the lease assets and lease liabilities arising from operating leases should be recognized in the balance sheet. The accounting applied by a lessor is largely unchanged from that applied under previous U.S. GAAP guidance. The amendments will be effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years, and early adoption is permitted. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. The modified retrospective approach includes a number of optional practical expedients that entities may elect to apply. These practical expedients relate to the identification and classification of leases that commenced before the effective date, initial direct costs for leases that commenced before the effective date, and the ability to use hindsight in evaluating lessee options to extend or terminate a lease or to purchase the underlying asset. An entity that elects to apply the practical expedients will, in effect, continue to account for leases that commence before the effective date in accordance with previous U.S. GAAP guidance unless the lease is modified, except that lessees are required to recognize a right-of-use asset and a lease liability for all operating leases at each reporting date based on the present value of the remaining minimum rental payments that were tracked and disclosed under previous U.S. GAAP guidance. We are currently evaluating the impact of these amendments on our consolidated financial statements and related disclosures; however, based on our current operating leases, we do not expect that the adoption of this guidance will have a material impact on the consolidated financial statements. See Note 7, Commitments and Contingencies, for information about our lease commitments

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

In July 2015, the FASB issued ASU No. 2015-11, Inventory (Topic 330): Simplifying the Measurement of Inventory. The guidance requires entities to measure most inventory at the lower of cost and NRV, thereby simplifying the current guidance under which an entity must measure inventory at the lower of cost or market. Under the new

guidance, inventory is measured at the lower of cost and NRV, which eliminates the need to determine replacement cost and evaluate whether it is above the ceiling (NRV) or below the floor (NRV less a normal profit margin). The guidance defines NRV as the “estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation.” The guidance is effective for annual periods beginning after

December 15, 2016, and interim periods therein. We will adopt the new guidance in the first quarter of 2017. We do not believe that the adoption of this guidance will have a material impact on our consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09, Revenue from Contracts with Customers (Topic 606). The new standard aims to achieve a consistent application of revenue recognition within the United States, resulting in a single revenue model to be applied by reporting companies under U.S. GAAP. Under the new model, recognition of revenue occurs when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the new standard requires that reporting companies disclose the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The new standard is required to be applied either retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying it recognized at the date of initial application. In March 2016 and April 2016, the FASB issued ASU No. 2016-08 and ASU No. 2016-10, respectively, which further clarified the implementation guidance on principal versus agent considerations contained in ASU No. 2014-09 and the identification of performance obligations and licensing, respectively. In May 2016, the FASB issued ASU 2016-12, narrow-scope improvements and practical expedients which provides clarification on assessing the collectability criterion, presentation of sales taxes, measurement date for non-cash consideration and completed contracts at transition. These standards will be effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). Early adoption is permitted, but not before December 15, 2016, the original effective date of the standard. We are currently analyzing ASU 2014-09, and the related ASU's, to evaluate the impact of the new standard on existing contracts with our customers. This includes reviewing current accounting policies and practices to identify potential differences that would result from applying the requirements under the new standard. We initiated a contract review process during 2016 and expect to complete the contract evaluations and validate results by the end of the second quarter of 2017. We have also started evaluating our existing accounting policies and the new disclosure requirements and expect to complete our evaluation of the impacts of the accounting and disclosure requirements on our business processes, controls and systems by the end of the second quarter of 2017. Full implementation will be completed by the end of 2017. We have not yet determined our selected method of transition.

3. Short-Term and Long-Term Investments

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

	December 31, 2016							
	Cost	Unrealized Gains	Unrealized Losses	Other-Than-Temporary Impairment Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
Cash	$49,331	$ —	$ —	$ —	$49,331	$ 49,331	$ —	$ —
Money market securities	54,015	—	—	—	54,015	54,015	—	—
Marketable securities:								
Certificates of deposit	26,114	—	—	—	26,114	—	13,855	12,259

Commercial paper	1,485	—	—	—	1,485	—	1,485	—
Corporate securities	39,562	—	(135)	—	39,427	500	25,681	13,246
Federal agency securities	30,660	4	(92)	—	30,572	—	10,854	19,718
Municipal securities	35,811	2	(81)	—	35,732	796	26,363	8,573
Total marketable securities	133,632	6	(308)	—	133,330	1,296	78,238	53,796
	$236,978	$ 6	$ (308)	$ —	$236,676	$ 104,642	$ 78,238	$ 53,796

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

December 31, 2015							
	Cost	Unrealized Gains	Unrealized Losses	Other-Than-Temporary Impairment Losses	Fair Value	Cash and Cash Equivalents	Short-term Investments	Long-term Investments
Cash	$55,987	$ —	$ —	$ —	$55,987	$ 55,987	$ —	$ —
Money market securities	20,373	—	—	—	20,373	20,373	—	—
Marketable securities:								
Certificates of deposit	26,223	—	—	—	26,223	—	16,637	9,586
Commercial paper								
Corporate securities	27,186	—	(68)	—	27,118	1,621	19,181	6,316
Federal agency securities	18,823	—	(65)	—	18,758	—	10,129	8,629
Municipal securities	53,870	16	(35)	—	53,851	1,534	33,629	18,688
Total marketable securities	126,102	16	(168)	—	125,950	3,155	79,576	43,219
	$202,462	$ 16	$ (168)	$ —	$202,310	$ 79,515	$ 79,576	$ 43,219

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

	December 31, 2016		December 31, 2015	
	Amortized Cost	Fair Value	Amortized Cost	Fair Value
Marketable securities:				
Due in one year or less	$80,092	$80,027	$82,785	$82,731
Due after one year through 5 years	53,540	53,303	43,317	43,219
Due after 5 years through 10 years	—	—	—	—
Due after 10 years	—	—	—	—
	$133,632	$133,330	$126,102	$125,950

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

	December 31, 2016				December 31, 2015			
	Less Than 12 Months		Greater Than 12 Months		Less Than 12 Months		Greater Than 12 Months	
	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss	Fair Value	Unrealized Loss
Marketable securities:								
Corporate securities	$38,027	$ (134)	$401	$ (1)	$25,137	$ (68)	$ —	$ —
Federal agency securities	26,449	(91)	1,217	(1)	18,759	(65)	—	—
Municipal securities	30,373	(81)	100	—	22,981	(35)	—	—
	$94,849	$ (306)	$1,718	$ (2)	$66,877	$ (168)	$ —	$ —

As of December 31, 2016 and 2015, we have concluded that the unrealized losses on our marketable securities are temporary in nature. Marketable securities are reviewed quarterly for possible other-than-temporary impairment. This review includes an analysis of the facts and circumstances of each individual investment such as the severity of loss, the expectation for that security's performance and the creditworthiness of the issuer. Additionally, we do not intend to sell, and it is not probable that we will be required to sell, any of the securities before the recovery of their amortized cost basis.

4. Fair Value Measurement

At December 31, 2016 and 2015, we held short-term and long-term investments, as described in Note 3, that are required to be measured at fair value on a recurring basis. All available-for-sale investments held by us at December 31, 2016 and 2015, have been valued based on Level 2 inputs. Available-for-sale securities classified within Level 2 of the fair value hierarchy are valued utilizing reports from an independent third-party public quotation service based on closing prices on the last business day of the period presented. In addition, we use the public quotation service to perform price testing by comparing quoted prices listed in reports provided by the asset managers that hold our investments to quotes listed through the public quotation service. These asset managers utilize an independent pricing source to obtain quotes for most fixed income securities, and utilize internal procedures to validate the prices obtained. Our Level 3 asset represents our investment in a long-term corporate convertible promissory note and a warrant to purchase shares issued in connection with the convertible promissory note, which converted to convertible preferred stock as of December 31, 2016. This stock is not listed on any security exchange. The fair value of the preferred stock approximates its carrying value at December 31, 2016.

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

	Fair Value Measurement at Reporting Date			
	Total	Quoted Prices in active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Marketable securities:				
Certificates of deposit	$26,114	$ —	$ 26,114	$ —
Commercial paper	1,485	—	1,485	—
Corporate securities	39,427	—	38,927	500
Federal agency securities	30,572	—	30,572	—
Municipal securities	35,732	—	35,732	—
Total assets measured at fair value	$133,330	$ —	$ 132,830	$ 500

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

	Fair Value Measurement at Reporting Date			
	Total	Quoted Prices in	Significant Other Observable	Significant Unobservable Inputs

		active Markets (Level 1)	Inputs (Level 2)	(Level 3)
Marketable securities:				
Certificates of deposit	$26,223	$ —	$ 26,223	$ —
Commercial paper	—	—	—	—
Corporate securities	27,118	—	27,118	—
Federal agency securities	18,758	—	18,758	—
Municipal securities	53,851	—	53,851	—
Total assets measured at fair value	$125,950	$ —	$ 125,950	$ —

The following table presents additional information about assets measured at fair value on a recurring basis and for which we utilize Level 3 inputs to determine fair value for the years ended December 31, 2016 and 2015 (in thousands):

	December 31, 2016	2015
Convertible stock		
Balance, beginning of period	$—	$ —
Change in fair value	—	—
Purchases	500	—
Balance, end of period	$500	$ —

5. Inventories

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

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

	December 31, 2016	December 31, 2015
Finished goods	$ 8,408	$ 28,216
Work-in-process	6,183	7,018
Raw materials and supplies	7,152	6,481
Total inventories	21,743	41,715
Plus: non-current finished goods	4,928	—
	$ 26,671	$ 41,715

As of December 31, 2016 and 2015, raw materials inventories consisted of raw materials used in the manufacture of the API in our U.S.-based, state-of-the-art dronabinol manufacturing facility and component parts and packaging materials used in the manufacture of SUBSYS®. Work-in-process consists of actual production costs, including facility overhead and tolling costs of in-process dronabinol and SUBSYS® products. Finished goods inventories consisted of finished SUBSYS® products. Non-current finished goods represent those inventories not expected to be sold within 12 months of the balance sheet date and are included in other assets in our consolidated balance sheets. As of December 31, 2016, all work-in-process inventory is expected to be used within 12 months of the balance sheet date and, therefore, is classified as current inventory. We maintain an allowance for excess and obsolete inventory, as well as inventory where its cost is in excess of its net realizable value. Inventory at December 31, 2016 and 2015 were reported net of these reserves of $6,793,000 and $100,000, respectively.

6. Property and Equipment

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

	Estimated Useful Life (in years)	As of December 31, 2016	2015
Computer equipment	3 — 7	$3,462	$2,798
Scientific equipment	3 — 10	12,930	9,283
Furniture	3 — 10	3,128	2,022
Manufacturing equipment	7 — 10	20,583	19,536
Leasehold improvements	*	23,243	16,771
Less: accumulated depreciation and amortization		(20,174)	(12,028)
Total fixed assets		$43,172	$38,382

*The estimated useful life of the leasehold improvements is the lesser of the lease term or the estimated useful life.

Total depreciation and amortization expense for the years ended December 31, 2016, 2015 and 2014 was $6,249,000, $5,291,000 and $2,500,000, respectively.

As of December 31, 2016 and 2015, respectively, there was $6,857,000 and $7,391,000 of construction in progress included in total fixed assets that had not been placed into service and was not subject to depreciation.

7. 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, 2016, with a remaining non-cancelable lease term in excess of one year, are as follows (in thousands):

Years ending December 31,	
2017	$3,113
2018	3,310
2019	3,405
2020	3,495
2021	2,526
Thereafter	14,429
Total	$30,278

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. Landlord incentives are recorded as deferred rent and amortized on a straight-line basis over the lease term. Deferred rent was approximately $3,003,000 as of December 31, 2016 and $3,160,000 as of December 31, 2015. Rent expense under operating leases for the years ended December 31, 2016, 2015 and 2014 was approximately $2,757,000, $2,445,000, and $1,698,000, respectively.

Letters of Credit

As of December 31, 2016, we had a $400,000 unused letter of credit related to the requirements of our facility lease agreement.

Material Agreements

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

In October 2015, we entered into an amended and restated supply, development & exclusive licensing agreement with Aptargroup, Inc. (“Aptar”) which, among other things, extended our exclusive supply rights to the current sublingual device, currently utilized by SUBSYS®, as well any new device(s) jointly developed by the two companies for a period of seven years. In addition to extending the term, this amendment added certain minimum purchase commitments and requires certain tiered royalties as a percentage of net revenue to be paid by us ranging from less than one percent to the low single digits, commencing in March 2016 through the term of this agreement, from our sales of SUBSYS® and future products that use the Aptar spray device technology. As of December 31, 2016, our remaining estimated annual contractual obligation under our agreement with Aptar was $20,290,000.

In January 2016, we assigned our rights, title, duties and obligations of our manufacturing and supply agreement with DPT and our supply, development & exclusive licensing agreement with Aptar from our parent to our manufacturing subsidiary as part of a corporate restructuring.

In July 2016, we, through our manufacturing subsidiary, entered into a further amendment to our DPT manufacturing and supply agreement dated May 24, 2011, as amended. This amendment effectively eliminates any prior minimum purchase (and batch) obligations that had been set forth in the amendment dated April 30, 2015 and replaces it with a new annual purchase commitment of $4,000,000 per calendar year commencing January 1, 2017 through December 31, 2020. As a result, the cumulative effect related to this amendment reduces our aggregated minimum purchase commitments with DPT from $49,740,000 to $16,000,000 through December 31, 2020. As of December 31, 2016, our remaining estimated annual contractual obligation under our agreement with DPT was $16,000,000.

All purchase commitments required under our agreements with DPT and Aptar were met during the years ended December 31, 2016 and 2015.

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

Years ending December 31,	
2017	$7,500
2018	7,500
2019	8,410
2020	8,550
2021	4,330
Thereafter	—
Total	$36,290

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, and beginning October 2014, our matching contribution is 50 percent of the first 6 percent of earnings contributed by each participant. During the years ended December 31, 2016 and 2015, matching contribution plan expenses totaled approximately $730,000 and $670,000, respectively. Matching

contributions for the year ended December 31, 2014 were nominal

Legal Matters

Other than the matters that we have disclosed below, we from time to time become involved in various ordinary course legal and administrative proceedings, which include intellectual property, commercial, governmental and

regulatory investigations, employee related issues and private litigation, which we do not currently believe are either individually or collectively material.

We record accruals for contingencies when it is probable that a liability has been incurred and the amount can be reasonably estimated. These accruals are adjusted periodically as assessments change or additional information becomes available. If the reasonable estimate of a probable loss is a range, and no amount within the range is a better estimate, the minimum amount in the range is accrued. If a loss is not probable or a probable loss cannot be reasonably estimated, no liability is recorded. We have established reserves for certain of our legal matters. Our loss estimates are generally developed in consultation with outside counsel and are based on analyses of potential outcomes. As legal and governmental proceedings, disputes and investigations are inherently unpredictable and, in part, beyond our control, unless otherwise indicated, we cannot reasonably predict the outcome of these legal proceedings, nor can we estimate the amount of loss, or range of loss, if any, that may result from these proceedings. While our liability in connection with certain claims cannot be currently estimated, the resolution in any reporting period of one or more of these matters could have a significant impact on our financial condition, results of operations and cash flows for that future period and could ultimately have a material adverse effect on our consolidated financial position and could cause the market value of our common shares to decline. While we believe we have valid defenses in these matters, litigation and governmental and regulatory investigations are inherently uncertain and we may in the future incur material judgments or enter into material settlements of claims.

Government Proceedings

Like other companies in the pharmaceutical industry, we are subject to extensive regulation by national, state and local government agencies in the United States. As a result, interaction with government agencies occurs in the normal course of our operations. The following is a brief description of pending governmental investigations which we believe are potentially or actually material at this time. It is possible that criminal charges and substantial payments, fines and/or civil penalties or damages or exclusion from federal health care programs or other administrative actions, as well as a corporate integrity agreement or similar government mandated compliance document that institutes significant restrictions or obligations, could result for us from any government investigation or proceeding. In addition, even certain investigations that are not discussed below and which we do not deem to be material at this time could be determined to be material and could have a material adverse effect on our financial condition, results of operations and cash flows.

Department of Health and Human Services Investigation. We received a subpoena, dated December 9, 2013, from the Office of Inspector General of the HHS in connection with an investigation of potential violations involving HHS programs. This subpoena was issued in connection with an investigation by the U.S. Attorney's Office for the Central District of California. This 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. We believe a loss is probable with respect to this investigation, but we are not in a position to estimate a range of such loss or other scope and outcome associated with this investigation.

HIPAA Investigation. On September 8, 2014, we received a subpoena issued pursuant to HIPAA from the U.S. Attorney's Office for the District of Massachusetts. The subpoena requests documents regarding SUBSYS®, including our sales and marketing practices related to this product. This investigation also relates to activities in our patient services hub. We are cooperating with this investigation and have produced documents in response to the subpoena and have provided other requested information. We believe a loss is probable with respect to this investigation, but we are not in a position to estimate a range of such loss or other scope and outcome associated with this investigation.

On or about June 23, 2015, a nurse practitioner located in Connecticut, who served on our speaker bureau in connection with our speaker programs designed to educate and promote product awareness and safety for external health care providers, pled guilty to violating the federal Anti-Kickback Statute in connection with payments of approximately $83,000 from us.

Several of our former employees have been charged in criminal proceedings. On or about February 18, 2016, one of our former sales employees located in Alabama pled guilty to a conspiracy to violate the federal Anti-Kickback

Statute in regards to two Alabama health care professionals who prescribed our product SUBSYS®. These two Alabama health care professionals, who served on our speaker bureau in connection with our speaker programs designed to educate and promote product awareness and safety for external health care providers, were charged by the U.S. Attorney's Office for the Southern District of Alabama, and on or about February 23, 2017, were convicted on 19 of 20 counts brought against them which included charges related to distribution of a controlled substance, drug conspiracy, healthcare fraud conspiracy and money laundering. Moreover, on or about June 19, 2016, a former district sales manager in New York and a former sales representative in New Jersey were charged in a federal court in Manhattan, New York with violating the federal Anti-Kickback Statute in connection with interacting with health care professionals who prescribed our product and served on our speaker bureau. Both of these employees have pled not guilty. On or about October 13, 2016, a former prior authorization specialist and manager of our patient services hub was charged by the U.S. Attorney's Office for the District of Massachusetts with conspiracy to commit wire fraud in connection with the Company's provision of prior authorization support related to our patient services hub. On or about December 8, 2016, the U.S. Attorney's Office for the District of Massachusetts issued an indictment against six former employees, including Michael L. Babich, our former President, CEO and director, on charges including racketeering conspiracy, conspiracy to commit mail fraud, conspiracy to commit wire fraud, conspiracy to violate the Anti-Kickback Statute and forfeiture. Other than the former Alabama sales employee, each of these indicted individuals have entered pleas of not guilty to the charges against them. It is possible that additional individual criminal charges and convictions and pleas could result from our ongoing federal and state government investigations and related proceedings. We continue to assess these matters to ensure we have an effective compliance program.

State Related Investigations. We have received Civil Investigative Demands ("CIDs") or subpoenas, as the case may be, from each of the Office of the Attorney General (or similarly named and authorized office) of the State of Arizona, Colorado, Florida, Illinois, Massachusetts, Maryland, Minnesota, New Hampshire, New Jersey, New York, Oregon, Pennsylvania and Washington. Moreover, we have received an administrative subpoena from the California Insurance Commissioner. In addition, we understand that numerous physicians practicing within several of the aforementioned states have received subpoenas from each applicable state Attorney General or Department of Justice office in connection with interactions with us. Generally, these CIDs and subpoenas request documents regarding SUBSYS®, including our sales and marketing practices related to SUBSYS® in the applicable state, as well as our patient services hub. We are cooperating with each of these investigations and have produced documents in response to these CIDs, subpoenas and related requests for information from each office.

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

In connection with the investigation by the State of Illinois, on August 25, 2016, the Illinois Office of the Attorney General filed a complaint on behalf of the State of Illinois against the Company in the Circuit Court of Cook County, Illinois, Chancery Division. The complaint asserts a claim for violation of the Illinois Consumer Fraud and Deceptive Business Practices Act in connection with the sales and marketing of SUBSYS® in Illinois. The complaint seeks injunctive relief, including a permanent injunction preventing us from engaging in commerce in the State of Illinois and civil penalties. The Circuit Court of Cook County extended the time for us to answer or otherwise respond to the complaint and the next status hearing is April 7, 2017. We continue to cooperate with this investigation and to engage in discussion with the Illinois Office of the Attorney General.

In connection with the investigation by the State of New Hampshire, we entered into a settlement agreement with the State of New Hampshire referred to as an assurance of discontinuance, and made monetary payments totaling approximately $2,900,000 to the State of New Hampshire and a charitable contribution of $500,000 to be used by a

New Hampshire charitable foundation in preventing or remediating problems related to abuse, misuse or misprescribing of opioid drugs. The assurance of discontinuance expressly provides that we do not admit any violation of law or regulation and requires us to maintain certain controls and processes around our promotional and sales activity related to SUBSYS® in New Hampshire. This settlement was reached as result of our cooperation with the State of New Hampshire investigation and after producing documents in response to certain requests for information

by the State of New Hampshire. These amounts have been accrued in the consolidated balance sheet as of December 31, 2016 and the payments in connection with this settlement were made after December 31, 2016.

In connection with the investigation by the State of Massachusetts, we have made a reasonable estimate of a probable loss of approximately $500,000. We continue to cooperate with the State of Massachusetts investigation, including producing documents in response to certain requests for information. This estimated amount has been accrued in the consolidated balance sheet as of December 31, 2016.

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

Opioid Litigation. Many federal and governmental agencies are focused on the abuse of opioids in the United States and agencies such as the HHS have expressed their belief that the United States is in the midst of a prescription opioid abuse epidemic. Common prescription drugs that contain opioids are drugs such as oxycodone, hydrocodone and fentanyl. Our product, SUBSYS®, is a fentanyl-based product in the TIRF class. Certain stakeholders in the healthcare community, regulatory bodies and governmental agencies may associate us with, or determine that we are a part of, this perceived opioid abuse epidemic. Like all TIRF products, our product is part of the mandatory TIRF REMS program which is designed “to ensure informed risk-benefit decisions before initiating treatment, and while patients are treated to ensure appropriate use of TIRF medicines” and “to mitigate the risk of misuse, abuse, addiction, overdose and serious complications due to medication errors with the use of TIRF medicines.” Nevertheless, from time to time, we may be included in litigation or investigations that are directed at the abuse of opioids in the United States.

For example, in May 2014, Santa Clara and Orange Counties in California filed a complaint in state court in Orange County, California against numerous pharmaceutical manufacturers alleging claims related to opioid marketing practices, including false advertising, unfair competition, and public nuisance. Despite the fact that we are not named specifically in the complaint and this lawsuit was recently stayed, we have received a preservation notice letter from the Office of the County Counsel for the County of Santa Clara. From time to time, we may be included in these types of litigations as a result of the fact that we market an opioid product.

In addition, on March 28, 2017, the Ranking Member of the Committee on Homeland Security and Governmental Affairs of the United States Senate distributed a letter to five manufacturers of opioid products, including the Company, requesting documents and information intended to aid such committee in understanding the challenges industry practices pose to efforts to curb opioid addiction and stem rising prescription drug costs for the federal government. This letter requests documents regarding our business, including the commercialization of SUBSYS®. We intend to cooperate with this inquiry.

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

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Federal Securities Litigation and Derivative Complaints

Federal Securities Litigation. On or about February 2, 2016, a complaint (captioned Richard Di Donato v. Insys Therapeutics, Inc., et al., Case 2:16-cv-00302-NVW) was filed in the United States District Court for the District of Arizona, against us and certain of our current and former officers. The complaint was brought as a purported class action on behalf of purchasers of our common stock between March 3, 2015 and January 25, 2016. In general, the plaintiffs allege that the defendants violated the anti-fraud provisions of the federal securities laws by making materially false and misleading statements regarding our business, operations and compliance with law during the class period, thereby artificially inflating the price of our common stock. On June 3, 2016, the court appointed Clark Miller to serve as lead plaintiff. On June 24, 2016, the plaintiff filed a first amended complaint naming a former employee of Insys Therapeutics, Inc. as an additional defendant and extending the class period. On December 22, 2016, the plaintiff filed a second amended complaint, primarily to add allegations relating to an indictment of Michael L. Babich and certain of our former employees announced on December 8, 2016 and to extend the class period from August 12, 2014 through December 8, 2016. On January 12, 2017, the defendants moved to dismiss the second amended complaint. The plaintiff seeks unspecified monetary damages and other relief. We intend to vigorously defend against this claim.

On or about March 17, 2017, a complaint (captioned Kayd Currier v. Insys Therapeutics, Inc., et al., Case 1:17-cv-01954-PAC) was filed in United States District Court for the Southern District of New York, against us and certain of our officers. The complaint was brought as a purported class action on behalf of purchasers of our securities between February 23, 2016 and March 15, 2017. In general, the plaintiffs allege that the defendants violated the anti-fraud provisions of the federal securities laws by making materially false and misleading statements regarding our business and financial results during the class period, thereby artificially inflating the price of our securities. On or about March 28, 2017, a second complaint making similar allegations (captioned Hans E. Erdmann v. Insys Therapeutics, Inc., et al., Case 1:17-cv-02225-PAC) was filed in the same Court. The plaintiffs in both actions seek unspecified monetary damages and other relief. We intend to vigorously defend against these claims.

Derivative Litigation. On or about August 26, 2016, Gary Hirt and Precieux Art Jewelers Inc. filed a derivative complaint in the Court of Chancery of Delaware against members of our Board of Directors and Michael L. Babich. The plaintiffs allege, among other things, that the defendants breached their fiduciary duties by (a) knowingly overseeing the implementation of an illegal sales and marketing program, (b) consciously disregarding their duty of oversight of our compliance with law and (c) trading on the basis of material non-public information. On November 8, 2016, the plaintiffs filed an amended derivative complaint, and on January 26, 2017 the plaintiffs supplemented the amended derivative complaint, primarily to add allegations relating to the indictment of Michael L. Babich and certain of our former employees announced on December 8, 2016. On November 22, 2016, the defendants moved to dismiss the action. On or about February 2, 2017, Michael Bourque filed a derivative complaint in the Court of Chancery against members of our Board of Directors; Michael L. Babich; Franc Del Fosse, our General Counsel; and Sanga Emmanuel, our Vice President and Chief Compliance Officer. The Bourque derivative complaint contains similar claims as the other derivative complaint. All parties stipulated to consolidate the two actions, and the consolidated action is captioned In re Insys Therapeutics, Inc. Derivative Litigation, C.A. No. 12696-VCMR. Following the submission of motions for appointment as lead counsel, the Court held a hearing on March 23, 2017, and appointed counsel for Gary Hirt and Precieux Art Jewelers Inc. as lead counsel. Lead counsel is required to designate an operative complaint or file a consolidated complaint. The plaintiffs seek unspecified monetary damages and other relief derivatively on behalf of the company. We intend to vigorously defend against these claims.

General Litigation and Disputes

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

Dr. Kottayil is the trustee. Dr. Kottayil formerly served as President, Chief Scientific Officer and a director of Insys Pharma, among other positions. The complaint brought a cause of action for statutory and common law appraisal of Dr. Kottayil's Insys Pharma common stock. The cause of action for appraisal relates to a reverse stock split that Insys Pharma effected in June 2009, which resulted in Dr. Kottayil's ownership position becoming a fractional share of Insys Pharma common stock. Following the reverse stock split, Insys Pharma cancelled all resulting

fractional shares, including the fractional share held by Dr. Kottayil, and offered a cash payment in lieu of the fractional shares. The complaint also brought causes of action for breach of fiduciary duty, fraud and negligent misrepresentation in the defendants' dealings with Dr. Kottayil on the subject of his compensation and stock ownership in Insys Pharma. In January 2010, the plaintiffs added claims seeking to rescind Dr. Kottayil's assignment to Insys Pharma of his interest in all of the fentanyl and dronabinol patent applications previously assigned to Insys Pharma and to recover the benefits of those interests. Dr. Kottayil was seeking, among other relief, the fair value of his Insys Pharma common stock as of June 2, 2009, compensatory and punitive damages, and rescission of all assignments to Insys Pharma of his interest in the patent applications, as well as attorneys' fees, costs and interest.

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

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

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

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

On October 2, 2015, the court entered a final judgment, awarding plaintiffs the amount of $7,317,450, along with pre-judgment interest from June 2, 2009, and post-judgment interest, from October 2, 2015, at the rate of 4.25% per annum, compounded quarterly and taxable costs in the amount of $93,163. On the same date, the court denied Kottayil's request to submit an application for attorneys' fees for his defense of the Insys Pharma counterclaims, finding that the request was premature.

As a result of the final ruling, we have accrued $9,567,000 at December 31, 2016, including $2,249,000 of estimated pre-judgement interest, which represents our current best estimate of this contingent liability. The final outcome of the appeal could cause this estimate to vary materially from the final award.

On October 20, 2015, plaintiffs appealed the foregoing judgment and on November 4, 2015, Insys Pharma and the other defendants against whom judgment was entered filed a notice of cross-appeal. The appeal and cross-appeal remain pending before the Court of Appeals for the State of Arizona.

On or around November 1, 2015, we received a notice from the Plaintiff's attorneys demanding indemnification for legal and other defense costs alleged to have been incurred in connection with Dr. Kottayil's defense of the Insys Pharma counterclaims in the amount of $3,630,000. We responded to these demands by, among other things, requesting for supporting documents and information from the Plaintiffs' counsel which we have not received yet. Accordingly, we are still in the process of assessing the merit of such claims as well as evaluating the basis for the costs claimed. Because of the uncertainty surrounding the ultimate outcome we have not accrued for this claim at this

time; however, we believe that that it is reasonably possible that there may be a material loss associated with this claim and we currently estimate the range of the reasonably possible loss to be between $0 and the $3,630,000 claimed.

As of August 1, 2016, Plaintiffs have filed opening and reply and cross response briefs and we have filed our answering and cross-appeal brief and our reply in support of our cross-appeal. The court has granted but not yet scheduled oral argument.

Markland. On July 1, 2016, Robert N. Markland, as the Personal Representative of the Estate of Carolyn S. Markland filed a complaint in the Circuit Court, Fourth Judicial Circuit, in and for Duval County Florida against our parent, Insys Therapeutics, Inc. The complaint states it is a wrongful death products liability action brought pursuant to Section 768.16, et seq. under Florida law in connection with a death occurring in July 2014 and includes a claim of negligent marketing. The lawsuit seeks unspecified damages for past expenses and costs, pain and suffering and loss of consortium and earnings. On August 4, 2016, we removed this case to federal district court in the Middle District of Florida. On September 2, 2016, we filed a motion to dismiss and are awaiting the court's ruling. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

Buchalter. On September 9, 2016, Jeffrey Buchalter filed a complaint in the Circuit Court for Anne Arundel County, Maryland against Dr. William Tham, Physical Medicine & Pain Management Associates, Maryland Neurological Institute, various physician assistants, and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Insys related to negligent misrepresentation, failure to warn and fraud under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We have filed a motion to sismiss and are awaiting the court's ruling We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

Colby. On or about January 25, 2017, Mackenzie Colby filed a complaint in the Superior Court in the State of New Hampshire against Christopher Clough, PA, Dr. O'Connell's Pain Care Centers, Inc., and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Mr. Clough related to medical negligence against O'Connell's Pain Care Centers, Inc. for respondent superior claims and against Insys Therapeutics, Inc. for negligence, all under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

Perusse. On or about February 21, 2017, Mackenzie Colby filed a complaint in the Superior Court in the State of New Hampshire against Christopher Clough, PA, Dr. John J Schermerhorn, Dr. O'Connell's Pain Care Centers, Inc., and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Mr. Clough related to medical negligence against O'Connell's Pain Care Centers, Inc. for respondent superior claims and against Insys Therapeutics, Inc. and Dr. Schermerhorn for negligence, all under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We intend to vigorously defend this matter and based on currently available information, we do not believe any resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

Cassell. On or about March 8, 2017, Jerome Cassell filed a complaint in the Superior Court in the State of New Hampshire against Christopher Clough, PA, Dr. John J Schermerhorn, Dr. O'Connell's Pain Care Centers, Inc., and Insys Therapeutics, Inc. Plaintiff's complaint states it is a personal injury action against Mr. Clough related to medical negligence against O'Connell's Pain Care Centers, Inc. for respondent superior claims and against Insys Therapeutics, Inc. and Dr. Schermerhorn for negligence, all under state laws. The lawsuit seeks unspecified compensatory and punitive damages. We intend to vigorously defend this matter and based on currently available information, we do not

believe any resolution of this matter will have a material adverse effect on the Company's business, financial position, or future results of operations.

Carver. On or about March 20, 2017, a qui tam complaint entitled United States ex rel. Lori L. Carver v. Physicians Pain Specialists of Alabama, P.C., Xiulu Ruan, M.D., John Patrick Couch, M.D., C&R Pharmacy, LLC, Castle Medical, LLC, Insys Therapeutics, Inc., Industrial Pharmacy Management, LLC and Christopher Manfuso; Civil Action No. 13-392, that had been filed under seal with the U.S. District Court For the Southern District of

Alabama Southern Division, was ordered unsealed by the court. The U.S. Department of Justice declined to intervene in this action. The complaint was originally brought by Ms. Carver, a former employee of Physician Pain Specialists of Alabama, PC, as a private party qui tam relator on behalf of the federal government. The action alleges civil violations of the federal False Claims Act committed by the defendants related to fraudulent claims by defendants for payment in connection with federally-funded Medicare programs as well as other federally-funded health care programs as a result of alleged illegal activity under the Stark Law and Federal Anti-Kickback Laws. We intend to vigorously defend this claim.

Except as it pertains to the $9,567,000 accrued for the dispute with Dr. Kottayil and the potential for damages in the federal securities litigation and derivative action that we believe should be sufficiently covered by our director and officers insurance policies (once we have met any applicable retainage requirement under the applicable policy), we believe that the probability of unfavorable outcome or loss related to all of the above litigation matters and an estimate of the amount or range of loss, if any, from an unfavorable outcome are not determinable at this time. We believe we have meritorious legal positions and will continue to represent our interests vigorously in these matters but the range possible outcomes on these matters is very broad and we are not able to provide a reasonable estimate of our potential liability, if any, nor are we able to predict the outcome of each litigation matter.

Responding to each of these litigation matters, defending any claims raised, and any resulting fines, restitution, damages and penalties, or settlement payments as well as any related actions brought by shareholders or other third parties, could have a material impact on our reputation, business and financial condition and divert the attention of our management from operating our business.

8. Equity

Preferred Stock

In August 2014, we entered into a Rights Agreement with respect to a newly-designated Series A Junior Participating Preferred Stock. In connection with the Rights Agreement, our Board of Directors declared a dividend distribution of the right to purchase one one-hundredth of one share of our Series A Junior Participating Preferred Stock, par value $0.001 per share (a “Right”), for each outstanding share of common stock, par value $0.01 per share, held by the stockholders of the Company at the close of business on September 1, 2014 (the “Record Date”).

Each Right entitles the registered holder to purchase from us one one-hundredth of a share of preferred stock (each, a “Preferred Share” and collectively, the “Preferred Shares”) at a price of $160 per one one-hundredth of a Preferred Share (the “Purchase Price”), subject to adjustment. Each one one-hundredth of a Preferred Share has the designations, powers, privileges, preferences, rights, qualifications, limitations and restrictions that are designed to make it the economic equivalent of one share of common stock.

The Rights will not become exercisable until the earlier to occur of the close of business on (i) the tenth calendar day following acquisition by any person, entity or group of affiliated or associated persons of beneficial ownership of 15% or more of our outstanding shares of common stock (an “Acquiring Person”) or (ii) the tenth business day (or such later date as may be determined by action of the Board prior to such time as any person or entity becomes an Acquiring Person) following the date of commencement of, or the first announcement of, an intention to commence, a tender offer or exchange offer, the consummation of which would result in any person or entity or group of persons or entities acting in concert becoming an Acquiring Person (the earlier of such dates being called the “Distribution Date”). Until the Distribution Date, the Rights will be transferable with and only with our Common Shares. The Rights will expire ten years after the execution of the Rights Agreement unless the Rights are earlier redeemed or exchanged by us.

Each Preferred Share is entitled to a minimum preferential quarterly dividend payment equal to the greater of $1.00 per share or 100 times the aggregate per share price of all cash and non-cash dividends declared per share of common stock. In the event of liquidation, the holders of the Preferred Shares would be entitled to a minimum preferential liquidation payment of $100 per share plus an amount equal to accrued and unpaid dividends and distributions thereon, provided that the Preferred Shares would be entitled to receive an aggregate amount per share

equal to 100 times the aggregate amount to be distributed per share to holders of common stock. Each Preferred Share has 100 votes, voting together with the common stock.

Common Stock

On February 26, 2014, our Board of Directors approved a three-for-two stock split of our common stock effected through a stock dividend. The record date for the stock split was the close of business on March 17, 2014, with share distribution occurring on March 28, 2014. As a result of the dividend, shareholders received one additional share of Insys Therapeutics, Inc. common stock, par value $0.0002145, for each two shares they held as of the record date. All share and per share amounts were retroactively restated for the effects of this stock split.

On May 6, 2014, our shareholders approved an amendment to our certificate of incorporation to increase the authorized shares of common stock from 50,000,000 to 100,000,000 and an amendment to increase the par value for our common stock to $0.01 per share. Our consolidated financial statements and notes herein were retroactively restated to reflect the impact of this amendment.

On May 5, 2015, our Board of Directors approved a two-for-one stock split of our common stock effected through a stock dividend. The record date for the stock split was the close of business on May 26, 2015, with share distribution occurring on June 8, 2015. As a result of the dividend, shareholders received one additional share of Insys Therapeutics, Inc. common stock, par value $0.01, for each one share they held as of the record date. All share and per share amounts were retroactively restated for the effects of this stock split.

Stock Repurchase Program

On November 5, 2015, we announced a stock repurchase program. The stock repurchase program authorizes up to $50 million in repurchases of common stock. This program was effective immediately and has no planned expiration date. The following table summarizes our share repurchase activity for our share repurchase program:

	Number of Shares Purchased	Cost of Share Purchases
Shares purchased at December 31, 2014	—	$—
Shares purchased during 2015	560,200	$16,459,000
Shares purchased at December 31, 2015	560,200	$16,459,000
Shares purchased during 2016	843,075	16,099,000
Shares purchased at December 31, 2016	1,403,275	$32,558,000

As of December 31, 2016, we had $17,442,000 remaining under this program.

9. 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. Under the terms of the

ESPP, eligible employees are granted a purchase right to purchase shares of our common stock that cannot exceed 15% of their earnings, nor exceed the Board of Director defined limits on the number of our common shares that can be offered under the ESPP. The purchase right entitles the eligible employee to purchase shares at the lesser of an amount equal to 85% of the fair market value of the shares on the offering date or 85% of the fair market value of the shares on the purchase date. The ESPP authorizes the issuance of 530,400 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) 600,000 shares (200,000 on a pre-split basis), 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, 2016, 1,465,176 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. 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 lesser of (a) 4% of the total number of shares of common stock outstanding on December 31 of the preceding calendar year; or (b) a number of shares of common stock that may be determined each year by our Board of Directors that is less than the preceding clause (a). As of December 31, 2016, options to purchase 7,300,873 shares of common stock were outstanding and 4,259,755 shares remained available for future grant.

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

	Years Ended December 31,		
	2016	2015 (As Revised)	2014
Research and development	$3,931	$2,133	$5,498
General and administrative	17,658	19,749	9,791
Total cost of stock-based compensation	$21,589	$21,882	$15,289

Included in stock-based compensation for the years ended December 31, 2016, 2015 and 2014 was approximately $3,878,000, $4,867,000 and $4,016,000, respectively, of expense associated with the accelerated vesting of option awards related to terminated employees.

The following table summarizes stock option activity during the year ended December 31, 2016:

		Weighted	
	Weighted	Average	Aggregate Intrinsic
	Average	Remaining	Value
Number of	Exercise	Contractual	(in
Shares	Price	Term (in years)	millions)

Outstanding as of December 31, 2013	8,994,978	$ 1.06		
Granted	3,397,198	$ 4.86		
Cancelled	(1,068,224)	$ 2.86		
Exercised	(3,616,790)	$ 1.15		
Outstanding as of December 31, 2014	7,707,162	$ 2.90		
Granted	1,733,671	$ 14.57		
Cancelled	(695,061)	$ 7.71		
Exercised	(1,607,683)	$ 2.48		
Outstanding as of December 31, 2015	7,138,089	$ 7.57		
Granted	2,337,043	$ 14.86		
Cancelled	(1,536,538)	$ 18.67		
Exercised	(637,721)	$ 5.96		$ 7.0
Outstanding as of December 31, 2016	7,300,873	$ 12.36	7.3	$ 18.7
Vested and exercisable as of December 31, 2016	4,474,906	$ 9.05	6.4	$ 18.0

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, 2016, we expect to recognize $31,171,000 of stock-based compensation for our outstanding options over a weighted-average period of 2.6 years.

The total fair value of shares vested for the years ended December 31, 2016, 2015, and 2014 was $19,970,000, $25,392,000 and $14,572,000, respectively.

Cash received from option exercises under all share-based payment arrangements for the years ended December 31, 2016, 2015 and 2014 was $3,803,000, $9,524,000 and $8,956,000, respectively. For the years ended December 31, 2016, 2015 and 2014, we recorded net reductions of $122,000, $13,593,000 and $22,003,000 respectively, of our federal and state income tax liability, with an offsetting credit to additional paid-in capital resulting from the excess tax benefits related to exercised 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:

	2016	2015	2014
Expected volatility	63.3%	69.9%	69.3%
Risk-free interest rate	1.6 %	1.9 %	1.7 %
Expected term (in years)	7.0	7.0	6.0
Expected dividend yield	0.0 %	0.0 %	0.0 %

For the years ended December 31, 2016, 2015, and 2014, the weighted-average estimated fair value per option granted was $9.20, $19.20 and $10.53, respectively.

10. Income Taxes

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

	Years Ended December 31,		
	2016	2015 (As Revised)	2014 (As Revised)
Current income taxes:			
Federal	$5,916	$31,383	$21,949
State and local	554	6,473	3,794
Total current income tax	6,470	37,856	25,743
Deferred income taxes:			
Federal	(7,762)	(3,759)	465
State and local	2,126	(1,156)	(1,119)
Total deferred income tax	(5,636)	(4,915)	(654)
Income tax expense	$834	$32,941	$25,089

As of December 31, 2016, we had approximately $1.1 million of federal NOLs all of which are subject to a significant Section 382 limitation. 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. For federal tax purposes, the Section 382 NOL carryforward is limited on an annual basis and begins expiring in 2018.

For state tax purposes, we had approximately $268.1 million of state NOLs at December 31, 2016, all of which relate to Illinois. This $268.1 million of state NOLs excludes $0.6 million of NOLs under ASC Topic 718 that have not been benefitted. Based on projections, we estimate that approximately $266.1 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 $20.6 million. The Illinois NOLs began expiring in 2015 if not utilized.

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):

	2016	2015 (As Revised)
Deferred income tax assets:		
NOLs and credits	$27,046	$26,910
Start-up expenditures	2,604	2,896
Stock-based compensation	11,727	8,578
Allowances	1,264	1,581
Expenses currently not deductible for tax purposes	10,652	6,129
Other	1,963	1,142
Gross deferred tax assets	55,256	47,236
Deferred income tax asset valuation allowance	(23,508)	(20,203)
Deferred income tax assets	31,748	27,033
Deferred income tax liabilities:		
Federal impact of state taxes	(1,073)	(1,817)
Property and equipment	(6,246)	(6,189)
Prepaid expenses	(1,186)	(1,420)
Net deferred income tax assets	$23,243	$17,607

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 Arizona research and development credit and 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 a portion of our Arizona research and development credit and our Illinois NOLs of $23.5 million, no other valuation allowance exists on our deferred tax assets at December 31, 2016. We have increased the valuation allowance by $3.3 million from December 31, 2015.

Effective Tax Rate Reconciliation:

Our federal statutory tax rate is 35.0%, while our effective tax rate was 9.9% for the year ended December 31, 2016, as set forth below:

	2016	2015 (As Revised)	2014 (As Revised)
U.S. statutory tax rate	35.0 %	35.0 %	35.0 %
Increase (reduction) of income taxes resulting from:			
State income taxes, net of federal benefit	(0.1)%	2.3 %	4.1 %
Non-deductible litigation expense	3.4 %	3.5 %	3.2 %
Non-deductible and includible items	7.5 %	0.7 %	0.7 %
Non-deductible lobbying expense	8.3 %	—	—
Research and other credits	(63.5)%	(5.4)%	(3.6)%
Uncertain tax positions	4.2 %	2.7 %	1.9 %
Domestic manufacturing deduction	(14.6)%	(3.0)%	(0.3)%
Stock based compensation	5.1 %	0.4 %	0.1 %
Tax exempt interest income	(1.5)%	—	—
Other	0.6 %	—	—
Change in valuation allowance	25.5 %	(0.1)%	—
Total provision for income taxes	9.9 %	36.1 %	41.1 %

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

	Years Ended December 31,	
	2016	2015 (As Revised)
Beginning balance	$8,920	$ 5,323
Additions based on current year's tax positions	758	3,837
Additions based on prior year's tax positions	122	(240)
Ending balance	$9,800	$ 8,920

We establish reserves when it is more likely than not that we will not realize the full tax benefit of a position. We had a reserve of $9,800,000 as of December 31, 2016, mostly related to tax credits of $2,610,000, state and local income tax filing positions of $5,412,000, and $1,778,000 of other permanent differences. If recognized, $9.8 million would affect our effective tax rate.

Although it is reasonably possible that certain unrecognized tax benefits may increase or decrease within the next twelve months due to tax examination changes, settlement activities, expirations of statutes of limitations, or the impact on recognition and measurement considerations related to the results of published tax cases or other similar

activities, we do not anticipate any significant changes to unrecognized tax benefits over the next 12 months. Approximately $706,000 of interest has been included in income taxes and accounted for on the balance sheet related to unrecognized tax positions as of December 31, 2016.

We are currently under examination in the U.S. for tax years 2014 and 2015. Because of NOLs and research credit carryovers, substantially all of our tax years remain open to examination.

11. Net Income per Share

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

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

	Years Ended December 31,		
	2016	2015 (As Revised)	2014 (As Revised)
Historical net income per share - Basic			
Numerator:			
Net income	$7,590	$58,053	$36,054
Denominator:			
Weighted average number of common shares outstanding	71,618,793	71,592,581	68,759,070
Basic net income per common share	$0.11	$0.81	$0.52
Historical net income per share - Diluted			
Numerator:			
Net income	$7,590	$58,053	$36,054
Denominator:			
Weighted average number of common shares outstanding	71,618,793	71,592,581	68,759,070
Effect of dilutive stock options	2,527,125	4,115,070	4,576,062
Weighted average number of common shares outstanding	74,145,918	75,707,651	73,335,132
Diluted net income per common share	$0.10	$0.77	$0.49

The calculation of diluted net income per common share excludes the effects of 2,596,324, 1,460,986 and 1,780,372 outstanding stock options for the year ended December 31, 2016, 2015, 2014, respectively, as the impact of these options was anti-dilutive.

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

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

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

Net Revenue by Product Line
Years Ended December 31,

	2016	2015 (As Revised)	2014 (As Revised)
Subsys	$242,275	$329,040	$216,497
Dronabinol SG Capsule	—	1,283	2,595
Total net revenue	$242,275	$330,323	$219,092

	Percent of Revenue by Route to Market Years Ended December 31,					
	2016		2015		2014	
Pharmaceutical wholesalers	67	%	95	%	99	%
Specialty pharmaceutical retailers	33	%	5	%	0	%
Generic pharmaceutical distributors	0	%	0	%	1	%
	100	%	100	%	100	%

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

Product shipments to our four largest pharmaceutical wholesaler customers accounted for 17%, 16%, 15% and 14% of total shipments and product shipments to one specialty pharmaceutical retailer accounted for 32% of total shipments for the year ended December 31, 2016. Product shipments to our four largest pharmaceutical wholesaler customers accounted for 32%, 20%, 17% and 14% of total shipments for the year ended December 31, 2015. Product shipments to our four largest pharmaceutical wholesaler customers accounted for 38%, 22%, 14% and 14% of shipments of SUBSYS® for the year ended December 31, 2014. Four pharmaceutical wholesalers' accounts receivable balances accounted for 36%, 23%, 21% and 13% of gross accounts receivable as of December 31, 2016. Four pharmaceutical wholesalers' accounts receivable balances accounted for 20%, 19%, 17% and 14% of gross accounts receivable as of December 31, 2015.

Currently, for SUBSYS®, we use one vendor as our sole supplier of the active pharmaceutical ingredient in this product.

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 are exposed to credit risk in the event of a default by the institutions holding our cash to the extent recorded on the consolidated balance sheet. 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.

13. Supplemental Financial Information

A summary of additions and deductions related to the allowances for accounts receivable for the years ended December 31, 2016, 2015 and 2014 are as follows (in thousands):

	Balance at Beginning of Year	Charged to Costs and Expenses	Utilization	Balance at End of Year
Allowance for doubtful accounts:				

Year ended December 31, 2016	$ 811	$ (96)	$ (30)	$ 685
Year ended December 31, 2015	$ 398	$ 413	$ —	$ 811
Year ended December 31, 2014	$ —	$ 398	$ —	$ 398
Allowance for sales wholesaler discounts, prompt pay discounts, stocking allowances, and chargebacks:				
Year ended December 31, 2016	$ 7,556	$ 27,968	$ (30,065)	$ 5,459
Year ended December 31, 2015 (As Revised)	$ 5,418	$ 38,036	$ (35,898)	$ 7,556
Year ended December 31, 2014 (As Revised)	$ 2,748	$ 22,395	$ (19,725)	$ 5,418

14. Quarterly Results of Operations (Unaudited)

The following table sets forth a summary of our unaudited quarterly operating results for each of the last eight quarters in the period ended December 31, 2016. We have derived this data from our unaudited condensed consolidated interim financial statements that, in our opinion, have been prepared on substantially the same basis as the audited consolidated financial statements contained elsewhere in this report and include all normal recurring adjustments necessary for a fair presentation of the financial information for the periods presented. These unaudited quarterly results should be read in conjunction with our consolidated financial statements and notes thereto included elsewhere in this report. The operating results in any quarter are not necessarily indicative of the results that may be expected for any future period.

As discussed in Note 2, our management concluded that the errors related to the miscalculation of rebate obligations on government payer and managed care contracts in addition to the out-of-period adjustments related to stock option modifications during the three months ended March 31, 2016 and the accounting for tax benefits associated with accrued litigation award and settlements recorded during 2016, were not material to our consolidated financial statements for the years ended December 31, 2015 and 2014. However, to correctly present net revenue in the appropriate period during 2016 and 2015, our unaudited condensed consolidated interim financial statements as of and for the quarters ended September 30, June 30, and March 31, 2016 and 2015 will be restated in Quarterly Reports on Form 10-Q/A to make the necessary accounting adjustments in the corresponding quarterly periods. The adjustments shown below represent the impact of the correction of errors to previously issued unaudited condensed consolidated interim financial information as described in Note 2 (in thousands, except per share data).

	Quarter Ended			
	12/31/16	9/30/16	6/30/16	3/31/16
Net revenue - as originally reported	$54,860	$55,180	$67,121	$61,962
Adjustment - prior period underestimation of sales allowances	—	2,593	2,100	(1,541)
Net revenue (As Restated)	$54,860	$57,773	$69,221	$60,421
Gross profit (1) - as originally reported	$45,055	$50,503	$60,848	$57,324
Adjustment - prior period underestimation of sales allowances	—	2,593	2,100	(1,541)
Gross profit (1) (As Restated)	$45,055	$53,096	$62,948	$55,783
Total operating expenses - as originally reported	$48,688	$50,831	$56,504	$55,033
Adjustment - prior period stock option modification	—	—	—	(1,500)
Total operating expenses (As Restated)	$48,688	$50,831	$56,504	$53,533
Income (loss) before income taxes - as originally reported	$(3,341)	$(47)	$4,595	$2,565
Adjustment	—	2,593	2,100	(41)
Income before income taxes (As Restated)	$(3,341)	$2,546	$6,695	$2,524
Income tax expense (benefit) - as originally reported	$311	$(237)	$240	$131
Adjustment	—	(142)	428	103
Income tax expense (benefit) (As Restated)	$311	$(379)	$668	$234
Net income (loss) (2) - as originally reported	$(3,652)	$190	$4,355	$2,434
Adjustment	—	2,735	1,672	(144)
Net income (loss) (2) (As Restated)	$(3,652)	$2,925	$6,027	$2,290
Total comprehensive income (loss) - as originally reported	$(3,880)	$32	$4,425	$2,600
Adjustment	—	2,735	1,672	(144)
Total comprehensive income (loss) (As Restated)	$(3,880)	$2,767	$6,097	$2,456
Net income (loss) per common share:				
Basic - as originally reported	$(0.05)	$—	$0.06	$0.03
Adjustment	—	0.04	0.02	0.00
Basic (As Restated)	$(0.05)	$0.04	$0.08	$0.03
Diluted - as originally reported	$(0.05)	$—	$0.06	$0.03
Adjustment	—	0.04	0.02	0.00
Diluted (As Restated)	$(0.05)	$0.04	$0.08	$0.03

	Quarter Ended			
	12/31/15	9/30/15	6/30/15	3/31/15
Net revenue - as originally reported	$91,135	$91,259	$77,633	$70,770
Adjustment - prior period underestimation of sales allowances	2,779	(2,742)	2,567	(3,078)
Net revenue (As Restated)	$93,914	$88,517	$80,200	$67,692
Gross profit - as originally reported	$84,668	$83,552	$69,328	$64,395
Adjustment - prior period underestimation of sales allowances	2,779	(2,742)	2,567	(3,078)
Gross profit (As Restated)	$87,447	$80,810	$71,895	$61,317
Total operating expenses - as originally reported	$54,948	$44,431	$57,370	$52,764
Adjustment - prior period stock option modification	1,500	—	—	—
Total operating expenses (As Restated)	$56,448	$44,431	$57,370	$52,764
Income before income taxes - as originally reported	$29,907	$39,212	$12,093	$11,756
Adjustment	1,279	(2,742)	2,567	(3,078)
Income before income taxes (As Restated)	$31,186	$36,470	$14,660	$8,678
Income tax expense - as originally reported	$12,896	$13,084	$4,779	$3,733
Adjustment	147	(1,244)	468	(922)
Income tax expense (As Restated)	$13,043	$11,840	$5,247	$2,811
Net income - as originally reported	$17,011	$26,128	$7,314	$8,023
Adjustment	1,132	(1,498)	2,099	(2,156)
Net income (As Restated)	$18,143	$24,630	$9,413	$5,867
Total comprehensive income - as originally reported	$16,826	$26,178	$7,293	$8,051
Adjustment	1,132	(1,498)	2,099	(2,156)
Total comprehensive income (As Restated)	$17,958	$24,680	$9,392	$5,895
Net income per common share:				
Basic - as originally reported	$0.24	$0.36	$0.10	$0.11
Adjustment	0.01	(0.02)	0.03	(0.03)
Basic (As Restated)	$0.25	$0.34	$0.13	$0.08
Diluted - as originally reported	$0.22	$0.34	$0.10	$0.11
Adjustment	0.02	(0.02)	0.02	(0.03)
Diluted (As Restated)	$0.24	$0.32	$0.12	$0.08

(1) The fourth quarter of 2016 includes an allowance of $5,800,000 for excess and obsolete SUBSYS® inventory.
(2) The fourth quarter of 2016 includes charges related to litigation award and settlements of $3,900,000.

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 that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that because of a material weakness in our internal control over financial reporting, as further described below, our disclosure controls and procedures were not effective as of December 31, 2016.

Management’s Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2016. In making this assessment, we used the criteria set forth in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") in Internal Control — Integrated Framework. Based on our assessment using those criteria, our management identified material weaknesses in our internal controls over financial reporting. Specifically, we did not have effective policies and procedures, or timely and effective reviews by personnel at an appropriate level, for accounting for the rebates component of our product sales allowances and the allowance for excess and obsolete inventory in accordance with U.S. GAAP. We did not have controls designed to validate the completeness and accuracy of underlying data used in the determination of these significant estimates. Overall the management in the finance and accounting group did not display adequate tone at the top with respect to judgment and rigor required to resolve the accounting for the rebates component of our product sales allowances and the allowance for excess and obsolete inventory matters. As a result, we concluded that our internal control over financial reporting was not effective as of December 31, 2016.

Our independent registered public accounting firm, BDO USA, LLP, has audited the effectiveness of our internal controls over financial reporting as of December 31, 2016, as stated in its audit report which is included herein.

Previously Reported Material Weakness Relating to Stock Option Awards

As previously reported, we did not have effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock option awards in accordance with U.S. GAAP. Specifically, the design of our control relating to the review of stock option award exercises (the “review control”) was not modified in light of the complex nature of the accounting for modifications resulting in accelerating vesting. The control deficiency did not result in a material misstatement in the consolidated financial statements; however, we previously concluded a material weakness existed in the controls in 2015 over the accounting for stock option awards because such a misstatement could have occurred.

With the oversight of our audit committee, we took corrective steps during 2016 to remediate the underlying causes of the material internal control weakness relating to the review of stock option award exercises. The corrective steps we have taken, which are intended to ensure that we have effective policies and procedures, and effective reviews by personnel at an appropriate level, for accounting for stock option awards in accordance with U.S. GAAP, include:

- We added an experienced director of SEC reporting and compliance during 2016 and will continue to evaluate the structure of the finance organization and add resources as needed.
- We redesigned the "review control" over the accounting for stock option award modifications. The redesigned control includes the timely review and documentation of all modified awards by personnel with U.S. GAAP and public company accounting experience.

As of December 31, 2016, we have completed documentation and implementation of the new and revised internal controls described above. After completing our testing of the design and operating effectiveness of this new procedure, we concluded that the above identified material weakness relating to the review of stock option award exercises in our internal controls over financial reporting has now been fully remediated.

Change in Internal Controls Over Financial Reporting

During the quarterly period ending December 31, 2016, we identified a material weakness in our internal control over financial reporting regarding the accounting for product sales allowances and the allowance for excess and obsolete inventory. Other than remediating the previously disclosed material weakness related to accounting for stock option awards described above, there were no other changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2016, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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

Report of Independent Registered Public Accounting Firm

Board of Directors and Stockholders

Insys Therapeutics, Inc.

Chandler, Arizona

We have audited Insys Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in or Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Insys Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Item 9A, Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit 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 effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses regarding management's failure to design and maintain controls over the accounting for the rebate component of the Company's product sales allowances and the allowance for excess and obsolete inventory have been identified and described in management's assessment. Overall the management in the finance and accounting group did not display adequate tone at the top with respect to judgment and rigor required to resolve the accounting for the rebates component of the Company's product sales allowances and the allowance for excess and obsolete inventory matters. These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2016 financial statements, and this report does not affect our report dated March 31, 2017 on those financial statements.

In our opinion, Insys Therapeutics, Inc. did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Insys Therapeutics, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of comprehensive income, stockholders' equity, and cash flows for each of the

three years in the period ended December 31, 2016 and our report dated March 31, 2017 expressed an unqualified opinion thereon.

/s/ BDO USA, LLP

Phoenix, Arizona

March 31, 2017

Item 5.02Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain officers.

ITEM 9B. OTHER INFORMATION

On February 20, 2017, the Compensation Committee of our Board of Directors approved a 2017 Corporate Annual Cash Bonus Plan (the "Bonus Plan") for the Company with parameters related to the payment of bonuses established for corporate employees including our named executive officers, Dr. Santosh Vetticaden, Darryl S. Baker and Franc Del Fosse. While the Compensation Committee determined that it would approve specific goals and objectives at a later date, the Bonus Plan sets forth a bonus component distribution providing that each of the above mentioned named executive officers' bonus will be distributed 70% on Company performance and 30% on individual performance, at target level. The bonus of the Company's President and Chief Executive Officer (the "CEO"), who will commence employment in mid-April, will be distributed 90% on the Company's performance and 10% on the individual performance, at target level; provided that separate from this Bonus Plan the CEO's offer included a guarantee of a cash bonus for the fiscal year ended December 31, 2017 of a minimum of 80% ($540,000) of his annual base salary. The Bonus Plan also sets forth a bonus pay-out matrix which establishes that once goals are set, named executive officers may earn a threshold (80% of their bonus potential), target (100% of their bonus potential) and maximum (150% of their bonus potential) based upon the achievement of the combination of Company and individual goals.

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, 2016 in connection with our 2017 Annual Meeting of Stockholders, or the 2017 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 2017 Proxy Statement and is incorporated herein by reference.

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

The information required by this Item will be included in the 2017 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 2017 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 2017 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 Part II 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 consolidated 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 ( ) 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 (1)
3.1	Registrant's Amended and Restated Certificate of Incorporation (2)
3.2	Registrant's Amended and Restated Bylaws (3)
3.3	Certificate of Designation of Series A Junior Participating Preferred Stock (4)
4.1	Form of Common Stock Certificate of the Registrant (19)
4.2	Rights Agreement, dated August 15, 2014 between the Insys Therapeutics, Inc. and Computershare Trust Company, N.A. (5)
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers (6)
10.2+	Insys Therapeutics, Inc. 2006 Equity Incentive Plan, as amended (7)
10.3+	Insys Pharma, Inc. Amended and Restated Equity Incentive Plan (8)
10.4+	2013 Equity Incentive Plan and Form of Stock Option Grant Notice and Form of Stock Option Agreement thereunder (9)
10.5+	2013 Employee Stock Purchase Plan (10)
10.6+	Amended and Restated Employment Agreement by and between the Registrant and Michael Babich dated April 18, 2013 (11)
10.7+	Employment Agreement by and between the Registrant and Darryl Baker dated April 18, 2013 (12)
10.8	Softgel Commercial Manufacturing and Packaging Agreement dated as of March 21, 2011 by and between the Registrant and Catalent Pharma Solutions, LLC (13)
10.9	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 (14)
10.10	Manufacturing Agreement dated as of March 7, 2011 by and between the Registrant and DPT Lakewood, LLC (15)
10.11	Letter Agreement dated April 23, 2012, amending the DPT Lakewood, LLC Manufacturing Agreement dated as of March 7, 2011 (16)
10.12	

	Amended and Restated Supply, Development & Exclusive Licensing Agreement dated as of October 30, 2015 by and between the Registrant and AptarGroup, Inc.
10.13	Amendment to Manufacturing and Supply Agreement, dated as of July 14, 2016 by and between the Registrant and DPT Lakewood, LLC (22)
10.14+	Non-Employee Director Compensation Policy (17)
10.15+	Employment Offer Statement effective January 31, 2014 by and between Registrant and Franc Del Fosse. (18)
10.17+*	Form of Restricted Stock Unit Grant Notice and Form of Restricted Stock Grant Agreement thereunder
21.1*	Subsidiaries of the Registrant
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)

Exhibit Number	Description of Document
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
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

(1) Previously filed as Exhibit 2.1 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.
(2) Previously filed as Exhibit 3.1 to the Company's Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2014.
(3) Previously filed as Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on May 9, 2016.
(4) Previously filed as 3.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 18, 2014.
(5) Previously filed as 4.1 to the Registrant's Current Report on Form 8-K filed with the SEC on August 18, 2014.
(6) Previously filed as Exhibit 10.1 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.
(7) Previously filed as Exhibit 10.3 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.
(8) Previously filed as Exhibit 10.4 to the Company's Form S-1 Registration Statement (No. 333-173154) on March 30, 2011.
(9) Previously filed as Exhibit 99.3 to the Company's Form S-8 Registration Statement (No. 333-188306) on May 2, 2013.
(10) Previously filed as Exhibit 99.4 to the Company's Form S-8 Registration Statement (No. 333-188306) on May 2, 2013.
(11) Previously filed as Exhibit 10.6 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 25, 2013.
(12) Previously filed as Exhibit 10.8 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 25, 2013.
(13) Previously filed as Exhibit 10.12 to the Company's Form S-1 Registration Statement (No. 333-173154) on July 15, 2011.
(14) Previously filed as Exhibit 10.13 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.

(15) Previously filed as Exhibit 10.16 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.
(16) Previously filed as Exhibit 10.17 to the Company's Form S-1 Registration Statement (No. 333-173154) on February 27, 2013.
(17) Previously filed as Exhibit 10.22 to the Company's Form S-1 Registration Statement (No. 333-173154) on April 15, 2013.
(18) Previously filed as 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2014.
(19) Previously filed as Exhibit 4.1 to the Company's Annual Report on Form 10-K for the year ended December 31, 2014.

(20) Previously filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016.

ITEM 16. FORM 10-K SUMMARY

None.

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 31, 2017.

Insys Therapeutics, Inc.

By /s/ Dr. Santosh Vetticaden
Dr. Santosh Vetticaden
Interim Chief Executive Officer and Chief Medical Officer
(Principal Executive Officer)

By /s/ Darryl S. Baker
Darryl S. Baker
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting 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/ Dr. Santosh Vetticaden Dr. Santosh Vetticaden	Interim Chief Executive Officer and Chief Medical Officer	March 31, 2017
/s/ Darryl S. Baker Darryl S. Baker	Chief Financial Officer	March 31, 2017
/s/ Patrick P. Fourteau Patrick P. Fourteau	Director	March 31, 2017
/s/ Steven Meyer Steven Meyer	Director	March 31, 2017
/s/ Brian Tambi Brian Tambi	Director	March 31, 2017
/s/ Pierre Lapalme Pierre Lapalme	Director	March 31, 2017
/s/ Theodore H. Stanley, M.D. Theodore H. Stanley, M.D.	Director	March 31, 2017
/s/ Dr. John N. Kapoor Dr. John N. Kapoor	Director	March 31, 2017