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 001-33415

OREXIGEN THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**65-1178822**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*
3344 N. Torrey Pines Ct., Suite 200 La Jolla, California	**92037**
(Address of Principal Executive Offices)	*(Zip Code)*

(858) 875-8600

(Registrant's Telephone Number, Including Area Code)

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

Title of Each Class	Name of Exchange on Which Registered
Common Stock, $0.001 par value	**The NASDAQ Global Market**

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 Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☑ No ☐

Indicate by check mark 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 to 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 ☐ (Do not check if a smaller reporting company)	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 ☑

As of June 30, 2016, the aggregate market value of common stock held by non-affiliates of the registrant was approximately $48.2 million based on the closing stock price as reported by the NASDAQ Global Market for such date. Shares of common stock held by each officer and director and by each person or group who owns 5% or more of the outstanding common stock have been excluded in that such persons or groups may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

As of March 22, 2017, the Registrant had 15,227,802 shares of its $0.001 par value common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2017 Annual Meeting of Stockholders are incorporated by reference into Part III of this Report. Such proxy statement will be filed with the Securities and Exchange Commission subsequent to the date hereof but not later than 120 days after registrant's fiscal year ended December 31, 2016.

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PART 1

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the information incorporated herein by reference contain certain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or Exchange Act, and is subject to the safe harbor provisions created by that statute. Forward-looking statements are based on our management's current beliefs, expectations and assumptions and on information currently available to our management. All statements other than statements of historical facts are "forward-looking statements" for purposes of these provisions. Forward-looking statements can be identified by the use of forward-looking words such as "believes," "expects," "hopes," "may," "will," "plans," "intends," "indicates," "suggests," "assuming," "designed," "estimates," "could," "should," "would," "continue," "seeks," "aims," "projects," "predicts," "pro forma," "anticipates," "potential," "probability" or other similar expressions that are intended to identify forward-looking statements.

These statements include but are not limited to statements regarding: the potential success of marketing and commercialization of Contrave®/Mysimba® in the United States, including the recently-launched patient-focused marketing campaign; the potential for Contrave/ Mysimba to achieve commercial success globally; the potential for Orexigen and its partners to obtain regulatory approvals for Contrave/ Mysimba in additional markets outside the United States; the ability of Orexigen to enter into successful partnership arrangements for Contrave/Mysimba in additional territories outside the United States; the benefit risk profile for Contrave; the potential for past Contrave clinical trials to predict the outcome of future Contrave clinical trials; and the potential to demonstrate the real world weight loss potential of Contrave with a commercially available comprehensive lifestyle intervention program. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Actual results may differ materially from those expressed or implied in this report by the forward-looking statements due to the risk and uncertainties inherent in our business, including: the potential that the marketing and commercialization of Contrave/Mysimba will not be successful, particularly, with respect to Contrave, in the U.S. following the launch of the patient-focused marketing campaign; the potential that we will not obtain and maintain partnerships and marketing authorization globally; the potential that will not be successful in adequately informing consumers about Contrave; the potential that we will fail in our efforts to commercialize Contrave with a specialty sales force in the United States; the potential that we will not successfully complete the post-marketing requirement studies for Contrave; the capabilities and performance of various third parties on which we rely for a number of activities related to the manufacture, development and commercialization of Contrave/Mysimba; the therapeutic and commercial value of Contrave/Mysimba; competition in the global obesity market, particularly from existing and generic therapies; the potential that we will not acquire, develop and market additional product candidates or approved products; the estimates of the capacity of manufacturing and our ability to secure additional manufacturing capabilities; the potential that we will not obtain or maintain global intellectual property protection for Contrave/Mysimba; legal or regulatory proceedings against us, as well as potential reputational harm, as a result of misleading public claims about Orexigen; our ability to maintain sufficient capital to fund our operations for the foreseeable future; the potential for a Delaware court to determine that one or more of the patents are not valid or that Actavis' proposed generic product is not infringing each of the patents at issue; and the other risks and uncertainties discussed under the heading "Item 1A—Risk Factors," and elsewhere in this in this Annual Report on Form 10-K.

Given these risks and uncertainties, we urge you not to place undue reliance on these forward-looking statements, which speak only as of the date of this report. You should read this Annual Report on Form 10-K completely and with the understanding that our actual future results may be materially different from what we expect. We hereby qualify our forward-looking statements by these cautionary statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, whether as a result of new information, future events, or for any other reason.

Item 1. Business.

Overview

Orexigen® Therapeutics, Inc. ("Orexigen," "we," "our" and "us") is a biopharmaceutical company focused on the treatment of obesity. Our sole product, Contrave® (naltrexone HCl / bupropion HCl prolonged release), is approved in the United States by the U.S. Food and Drug Administration, or FDA, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index, or BMI, of 30 kg/m ^{2} or greater (obese), or 27 kg/m ^{2} or greater (overweight) in the presence of at least one weight-related comorbid condition. Contrave is a combination of generic drug components, each of which has already received regulatory approval for other indications and has been commercialized in the United States and in a majority of the member countries of the European Union.

In September 2014, the FDA approved our New Drug Application, or NDA, for Contrave. Our former collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda, commercially launched Contrave in the United States in October 2014. As part of the approval of Contrave by the FDA, we agreed to several post-marketing requirements, including studies to assess the safety and efficacy of Contrave for weight management in obese pediatric patients. We are also required to conduct a new randomized double-blind, placebo-controlled study to evaluate the effects of long-term treatment with Contrave on the incidence of major adverse cardiovascular, or CV, events in overweight and obese subjects with CV disease or multiple CV risk factors, as well as a group of short-term trials including a thorough QT study, single-dose pharmacokinetic studies in renal and hepatic impairment, and a drug-drug interaction study.

In March 2015, the European Commission, or EC, granted centralized marketing authorization, or CMA, for Contrave (under the name Mysimba®) as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index of ≥ 30 kg/m^2 (obese), or ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidemia, or controlled hypertension). This authorization applies to all 28 European Union member states, as well as Norway, Iceland and Lichtenstein.

In March 2016, we and Takeda entered into a separation agreement, which terminated our collaboration agreement. As of August 2016 all of Takeda's previous rights and obligations under that agreement were transitioned to us and we are now solely responsible for developing and commercializing Contrave within the United States and the rest of the world, including management and oversight of certain ongoing and planned post-marketing clinical trials of Contrave.

In May 2016, our commercialization partner, Kwang Dong Pharmaceutical Company, Ltd., or Kwang Dong, obtained regulatory approval and, in June 2016, it commercially launched Contrave in South Korea. In addition, Contrave/Mysimba was recently commercially launched in Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia by our partner, Valeant Pharmaceuticals, or Valeant, and in Spain by our partner, Laboratorios Farmacéuticos Rovi, S.A., or Rovi. We are currently advancing plans for the commercial launch of Contrave/Mysimba in certain other markets in Central and Eastern Europe, and Turkey with Valeant, in Italy with our partner Bruno Famaceutici, S.p.A., or Bruno, and in the United Kingdom and Ireland with our partner Consilient Health Ltd, or Consilient. We have also partnered with Valeant in Australia, New Zealand and Canada and are working with them to obtain regulatory approval of Contrave in these regions. In parallel, we are continuing partnering discussions for the rights to Contrave/Mysimba in other markets in the European Union and other territories outside the United States. Our ability to generate revenue for the foreseeable future will depend primarily on the commercial success of Contrave in the United States. Together, the Central and Eastern European countries, Turkey, Italy, Australia, New Zealand, Canada, South Korea, Spain, the United Kingdom and Ireland, are referred to in this Annual Report as the Partnered Regions.

We believe in the long-term value of our product in the United States, the European Union and elsewhere and our strategy for Contrave is to pursue marketing authorizations worldwide and pharmaceutical partnerships for global commercialization. We endeavor to continue to find high-performing partners that share our vision for Contrave and will allow us to address the obesity epidemic in a meaningful way for the entire potential patent life of our drug. With Contrave approved for marketing in the United States, we believe that we are well positioned for regulatory approvals in many other countries, and it is our goal to establish a global brand in many territories worldwide. In addition to establishing partnerships for the potential commercialization of Contrave outside the United States and the Partnered Regions, we are also exploring development opportunities to enhance the clinical profile of Contrave and advancing other early stage development programs.

We maintain an aggressive intellectual property strategy, which includes patent and trademark filings in multiple jurisdictions including the United States and other commercially significant markets. Upon FDA approval of Contrave, we received three years of exclusivity under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch Waxman Act. Moreover, we hold patents in the United States and Europe that cover the composition of Contrave (bupropion HCl ER/naltrexone HCl ER), as well as the use of Contrave for the treatment of obesity. These U.S. patents expire in 2025 and 2024, respectively. In addition, we own or have exclusive rights to numerous issued patents and patent applications currently pending in the United States

and in jurisdictions outside of the United States with respect to various compositions, methods of use and formulations relating to Contrave.

As we transition from primarily a drug development company to primarily a commercial product organization, we expect to experience changes in our strategy, business practices, culture, organizational design, and our executive team.

The Obesity Epidemic

Obesity is a serious and rising health epidemic that has been declared a disease by the American Medical Association and afflicts populations worldwide. The Obesity Action Coalition estimates that nearly 93 million Americans struggle with obesity, and it is predicted to increase to 120 million Americans within the next five years. In addition, the U.S. Center for Disease Control, or CDC, estimates that 70 percent of adults over the age of 20 years old are overweight/obese.

There are more than 40 medical conditions that are associated with obesity, according to the Obesity Action Coalition. Obesity increases the risk of heart disease, type 2 diabetes, some types of cancer, sleep apnea, and a variety of other conditions. According to a January 2012 article in the Journal of Health Economics, annual U.S. obesity-related medical costs amount to an estimated $209.7 billion, which means that approximately 20.6% of U.S. national health expenditures are spent treating obesity-related illness. A 2009 study examining the future impact of obesity on direct health care expenses projected these expenditures to increase to approximately $344 billion per year by 2018. As a result, private and governmental entities worldwide are beginning to take steps to fight against obesity.

Despite the obesity rate, increasing public interest in the obesity epidemic and significant medical repercussions and economic costs associated with obesity, we believe there continues to be a need for more effective pharmacological interventions. Almost half of adults in the US meet recommendations for anti-obesity pharmacotherapy; however, only an estimated 2-3% of those adults receive pharmacotherapy treatment. This is a large difference compared to the 8.4% of US adults with type 2 diabetes, with 86% receiving pharmacotherapy treatment.

While there has been a broad recognition of obesity as a public health crisis, we believe that the obesity epidemic will continue to be a major cause of morbidity, mortality and excess health care costs in the United States. The history of this obesity epidemic, combined with the substantial economic cost associated with obesity, we believe underscores the unmet need and the potential for novel therapeutics to continue to dramatically grow the market for obesity therapies.

The Orexigen Solution for Obesity

Contrave regulates appetite and energy expenditure through central nervous system, or CNS, activity. We believe, and our research suggests, that the CNS plays an important role in the regulation of appetite and energy expenditure. The brain, specifically the hypothalamus, plays a critical role in governing many fundamental processes throughout the body. The hypothalamus receives chemical and hormonal stimuli from various sources, including glucose, insulin, leptin and the peptides secreted by the gut as it processes food. These inputs govern a person's appetite, satiety and energy expenditure.

The brain contains numerous redundant circuits and compensatory mechanisms to maintain body weight, which is essential to survival. Such mechanisms are invoked in the presence of weight loss whether intentional (in the case of diet) or not (in the case of starvation). Moreover, in order to appropriately motivate humans to seek food, reward circuitries in the brain stimulate the urge to consume higher calorie food and in turn reward that behavior. The craving cycle is particularly intense with highly palatable foods, such as sweets.

Existing weight loss products that do not work by acting on the CNS cause some weight loss for most patients. We believe their modest effect stems from their failure to address these natural compensatory mechanisms in the body. As a result, most of these products have been vulnerable to a weight loss plateau typically seen after several months or a year of therapy. In addition, they generally do not address the behavioral elements that contribute to unhealthy eating behaviors and, ultimately, obesity. We believe Contrave sustains weight loss by preventing the body's natural tendency to counteract efforts to lose weight. In addition, we are attempting to target the underlying behavioral mechanisms of craving and reward that drive excess consumption.

Contrave (Mysimba)

Contrave is a fixed dose combination of bupropion HCl extended release, or ER, and naltrexone HCl ER. We chose these constituents based on our understanding of the circuitries in the brain that regulate appetite and energy balance. In particular, naltrexone was chosen as a complement to bupropion in order to block compensating mechanisms that attempt to prevent long-term, sustained weight loss. We hold patents in the United States that cover the composition of Contrave (bupropion HCl/naltrexone HCl

ER), as well as the use of Contrave for the treatment of obesity. We have also filed additional U.S. patents covering various aspects of Contrave. In addition, we own or have exclusive rights to numerous issued patents and patent applications currently pending in various jurisdictions outside of the United States with respect to compositions, methods of use and formulations relating to Contrave.

Naltrexone was approved in the United States in 1984 for the treatment of opioid addiction and in 1994 for the treatment of alcoholism. It is marketed under the brand names ReVia®, and in an injectable extended release formulation, Vivitrol®, which was approved in 2006 for the treatment of alcohol dependence and expanded in 2010 to include prevention of relapse to opioid dependence. Naltrexone immediate release formulation became available in generic form in the United States in 1998. Naltrexone works by blocking opioid receptors in the brain and inhibits the reinforcing aspects of addictive substances, reducing their perceived reward. Naltrexone was evaluated in the 1980s for weight loss and was shown to have negligible effects in clinical trials. Nausea is a well-known side effect associated with naltrexone immediate release that affects its tolerability. In our Contrave Phase II clinical trials, we used the generic immediate release formulation of naltrexone. In our Phase III clinical trials, naltrexone was delivered in our proprietary ER formulation in order to improve its tolerability.

Bupropion was approved for marketing in the United States in 1985 for depression, marketed under the brand name Wellbutrin®, and in 1997 for smoking cessation, marketed under the brand name Zyban®. The immediate release version became available in generic form in the United States in 1999. Bupropion SR (sustained release) became available in generic form in the United States in 2004 and bupropion XL (extended release) became available in generic form in the United States in December 2006. Bupropion is active at the neuronal uptake site for the neurotransmitters dopamine and norepinephrine. Functionally, bupropion is thought to increase the level of dopamine activity at specific receptors in the brain, which appears to lead to a reduction in appetite and increase in energy expenditure. In the 12-month period ending in August 2012, prescriptions of bupropion in the United States totaled approximately 26.6 million, according to IMS Health. Bupropion has become popular in the treatment of depression not only for its clinical efficacy, but also its attractive side effect profile relative to other antidepressants on the market. One of the reported side effects of bupropion in clinical trials for the treatment of depression was modest weight loss. Subsequently, bupropion has been studied for weight loss; results have shown approximately 3% placebo-corrected weight loss before reaching plateau, according to a study published in the October 2002 issue of Obesity Research.

Scientific Rationale

The two drug constituents of Contrave were chosen in order to leverage the brain's normal circuitry and biochemistry to reduce appetite, expend more calories, diminish food craving and food-based reward, and block compensating mechanisms that attempt to prevent long-term, sustained weight loss. Bupropion has been shown in studies to activate the proopiomelanocortin, or POMC, neurons within an area in the hypothalamus known as the arcuate nucleus. Increased firing of POMC neurons appears to lead to a reduction of appetite and an increase in energy expenditure. This is a major pathway by which naturally occurring peptides regulate body weight. Bupropion-induced stimulation of POMC activates this weight loss pathway.

Stimulation of POMC also produces beta-endorphin, an opioid occurring naturally in the body. Our early research identified a receptor on the POMC neuron that recognizes beta-endorphin. We discovered that by binding to this receptor, beta-endorphin serves as a brake on the POMC system. Left unchecked, this braking system acts to reduce POMC firing rates, thus moderating potential weight loss as a likely compensatory mechanism to preserve body mass. Based on this discovery, we chose naltrexone as the second component in Contrave because it is a potent opioid receptor antagonist which competes with beta-endorphin, thus limiting its access at the receptor on the POMC neuron. When bupropion and naltrexone are co-administered, they both induce an increase in POMC firing that is maintained for an extended duration. We expect this to translate into a greater weight loss that should be sustainable over an extended time period.

As a second attribute, both bupropion and naltrexone are known to act on the reward pathways in the brain that have been implicated in addiction to a number of substances, including food. These reward pathways are primarily regulated by dopamine and endogenous opioids. Given that both drugs are approved for addiction-related disorders, we expect that together they may attenuate food craving and reward. As a result, we anticipate that Contrave may have an additional therapeutic attribute for patients who report food craving or obsession, helping them manage their eating behavior.

The COR Program

We conducted controlled Phase II and Phase IIb clinical trials for Contrave in a total of 657 patients. Based on the results of these trials, we concluded that Contrave showed sufficient efficacy as compared to each individual monotherapy and placebo and an acceptable safety and tolerability profile to warrant continued development in pivotal Phase III clinical trials.

Our Phase III program for Contrave was comprised of four distinct clinical trials that evaluated more than 4,500 patients. Based on our Phase II and Phase IIb trial results and feedback from the FDA, these four Phase III clinical trials in our COR program were

designed to assess three doses of naltrexone ER (16mg, 32mg and 48mg) in combination with a 360mg dose of bupropion ER. All trials in the COR program were 56-week, randomized, double-blind, placebo-controlled trials.

The four Phase III clinical trials in the COR program are described as follows:

- COR-I: A trial designed to assess the safety, tolerability and efficacy of Contrave (32mg naltrexone ER plus 360mg bupropion ER) and NB16 (16mg naltrexone ER plus 360mg bupropion ER) versus placebo in 1,742 overweight/obese patients. This trial incorporated a typical diet and exercise regimen and was conducted across 34 U.S. centers.

- COR-II: A trial designed to assess the safety, tolerability and efficacy of Contrave versus placebo in 1,496 overweight/obese patients. This trial incorporated a typical diet and exercise regimen and was conducted across 36 U.S. centers. After week 28, patients not achieving at least 5% weight loss were re-randomized in a blinded fashion to assess whether increasing the dose to NB48 (48mg naltrexone ER plus 360mg bupropion ER) would result in additional weight loss.

- COR-Diabetes: A trial designed to assess the safety, tolerability and efficacy of Contrave versus placebo in 505 overweight/obese patients with Type 2 diabetes. This trial incorporated a typical diet and exercise regimen and was conducted across 53 U.S. centers.

- COR-BMOD: A trial designed to assess the safety, tolerability and efficacy of Contrave versus placebo in 793 overweight/obese patients in combination with an intensive behavior modification protocol, including dietary counseling, behavioral therapy and exercise. This trial was conducted across nine U.S. centers. This trial included the most intensive behavior modification regimen of the COR program, which resulted, as expected, in a high degree of weight loss among placebo patients.

The co-primary endpoints for all four Phase III clinical trials in the COR program were the proportion of patients achieving at least 5% weight loss and percent change in body weight compared to placebo. The co-primary endpoints for COR-I, COR-Diabetes and COR-BMOD were all measured at 56 weeks. The co-primary endpoints for COR-II were measured at 28 weeks. These endpoints were analyzed using a modified intent-to-treat, or ITT, last observation carried forward on treatment, or LOCF, of all randomized patients who had at least one post-baseline observation while on study drug. Contrave was administered twice a day with a three week escalation period in COR-I, COR-Diabetes and COR-BMOD. Contrave was administered twice a day with a four week escalation period in COR-II. All four Phase III clinical trials met their co-primary endpoints.

The 56-week results for all four clinical trials in the COR program are as follows:

	COR-I			
	ITT		Completers†	
	56 weeks		56 weeks	
	Contrave (n=471)	Placebo (n=511)	Contrave (n=296)	Placebo (n=290)
Mean Weight Loss (%)	6.1%*	1.3%	8.1%*	1.8%
Mean Weight Loss (lbs)	13.3*	3.0	17.5*	4.1
Greater than or equal to 5% weight loss (%)	48.0%*	16.4%	61.8%*	23.1%
Greater than or equal to 10% weight loss (%)	24.6%*	7.4%	34.5%*	10.7%

* Difference from placebo, $p<0.001$

† Those patients completing 56 weeks of treatment.

ITT, LOCF patients administered NB16 (n=471) experienced mean weight loss from baseline of 5.0% at 56 weeks; 39.5% of patients lost greater than or equal to 5% of their body weight at 56 weeks and 20.2% of patients lost greater than or equal to 10% of their body weight at 56 weeks.

	COR-II			
	ITT†		Completers**	
	56 weeks‡		56 weeks‡	
	Contrave (n=702)	Placebo (n=456)	Contrave (n=434)	Placebo (n=267)
Mean Weight Loss (%)	6.4%*	1.2%	8.2%*	1.4%
Mean Weight Loss (lbs)	13.8*	2.9	17.5*	3.4
Greater than or equal to 5% weight loss (%)	50.5%*	17.1%	64.9%*	21.7%
Greater than or equal to 10% weight loss (%)	28.3%*	5.7%	39.4%*	7.9%

† Co-primary endpoints for COR-II were the proportion of patients achieving at least 5% weight loss and percent change in body weight compared to placebo at 28 weeks. ITT patients (n=1,281) at 28 weeks experienced mean weight loss from

baseline of 6.5% versus 1.9% for placebo; 55.6% of patients lost greater than or equal to 5% of their body weight at 28 weeks versus 17.5% for placebo and 27.3% of patients lost greater than or equal to 10% of their body weight at 28 weeks versus 7.0% for placebo.

** Those patients completing 56 weeks of treatment.

‡ Pre-specified exploratory analysis; Contrave patients not achieving 5% weight loss double weighted because NB48 patients were excluded from efficacy analysis. There was no statistical difference between patients re-randomized to Contrave or NB48.

* Difference from placebo, p<0.001

	COR-BMOD			
	ITT		Completers†	
	56 weeks		56 weeks	
	Contrave (n=482)	Placebo (n=193)	Contrave (n=301)	Placebo (n=106)
Mean Weight Loss (%)	9.3%*	5.1%	11.5%*	7.3%
Mean Weight Loss (lbs)	20.3*	11.0	25.0*	16.0
Greater than or equal to 5% weight loss (%)	66.4%*	42.5%	80.4%*	60.4%
Greater than or equal to 10% weight loss (%)	41.5%*	20.2%	55.2%*	30.2%

* Difference from placebo, p<0.001

† Those patients completing 56 weeks of treatment.

	COR-DIABETES			
	ITT		Completers†	
	56 weeks		56 weeks	
	Contrave (n=265)	Placebo (n=159)	Contrave (n=175)	Placebo (n=100)
Mean Weight Loss (%)	5.0%*	1.8%	5.9%*	2.2%
Mean Weight Loss (lbs)	11.6*	4.2	13.5*	5.1
Greater than or equal to 5% weight loss (%)	44.5%*	18.9%	53.1%*	24.0%
Greater than or equal to 10% weight loss (%)	18.5%*	5.7%	26.3%*	8.0%

* Difference from placebo, p<0.001

† Those patients completing 56 weeks of treatment.

Secondary endpoints included multiple measures of cardiometabolic risk, food cravings and eating control. Measures of hemoglobin A1c, or HbA1c, and other measures of glycemic control were also key secondary endpoints in the COR-Diabetes trial. Secondary endpoints that demonstrated clinically and statistically significant improvements over placebo across the entire COR program included cardiometabolic risk factors such as waist circumference, HDL cholesterol and triglycerides. Patients enrolled in the COR program also experienced reductions in the frequency and strength of food cravings and an increased ability to control their eating compared to placebo. In the COR-Diabetes trial, patients administered Contrave showed a reduction in HbA1c of 0.6% from baseline, compared to a 0.1% reduction in placebo.

The overall discontinuation rates across the COR program ranged from 42% to 51% for the Contrave treated groups compared to 41% to 50% for the placebo groups. The discontinuation rates due to adverse events across the COR program ranged from 19% to 29% for the Contrave treated groups compared to 10% to 15% for the placebo groups. The most frequent adverse events leading to discontinuation for patients taking Contrave were nausea, headache, vomiting and dizziness. Nausea was the leading adverse event resulting in discontinuation; however, for the majority of patients experiencing nausea, it was mild to moderate, transient and manageable. The most frequently observed treatment-emergent adverse events were nausea, constipation and headache. Across the entire COR program, seven serious adverse events were attributed by investigators as possibly related to Contrave treatment. These consisted of cholecystitis (gallbladder inflammation) (2), seizure (2), palpitations (1), paresthesia (1) and vertigo (1). In addition, there was one death of a patient on Contrave that was not attributed by investigators as related to Contrave treatment, but rather was attributed to a cardiovascular serious adverse event. At week 56, mean blood pressure was generally unchanged from baseline for Contrave patients, compared to placebo patients who tended to experience a slight decrease (approximately 2 mm Hg) from baseline. Contrave treatment did not appear to disrupt the normal circadian pattern of blood pressure. There was a slight increase in pulse (approximately 1 beat per minute) in Contrave patients, compared to placebo patients whose pulse was generally unchanged. There were no meaningful treatment effects on ECGs or laboratory measures including liver function tests. Treatment with Contrave was not associated with increases in symptoms of depression or suicidal ideation.

We believe that our clinical trial experience with Contrave has demonstrated and replicated the validity of our scientific hypothesis, specifically, that the administration of naltrexone with bupropion enables greater weight loss than bupropion alone and

sustains weight loss beyond 24 weeks. The rate of response (greater than 5% and 10% reduction in body weight from baseline) has also favored Contrave and provides additional support for our belief that Contrave will provide a clinically relevant alternative for clinicians and obese patients.

Post-Marketing Requirements. As part of the FDA approval of Contrave, we agreed to several post-approval requirements, including studies to assess the safety and efficacy of Contrave for weight management in obese pediatric patients. There will also be a new randomized, double-blind, placebo-controlled study to evaluate the effects of long-term treatment with Contrave on the incidence of MACE in overweight and obese subjects with cardiovascular disease or multiple cardiovascular risk factors.

The Light Study

Following the results of our COR program, we submitted a New Drug Application, or NDA, for Contrave to the FDA in March 2010. In January 2011, we received a complete response letter, or CRL, from the FDA regarding our NDA for Contrave. A CRL is issued by the FDA when the review of an NDA is completed and questions remain that preclude the approval of the NDA. The CRL for Contrave indicated that the FDA could not approve the NDA in its present form primarily due to concerns regarding the cardiovascular safety profile of Contrave when used long-term in a population of overweight and obese patients. The CRL stated that before our NDA could be approved, we must conduct a randomized, double-blind, placebo-controlled trial of sufficient size and duration to demonstrate that the risk of major adverse cardiac events, or MACE, in overweight and obese patients treated with Contrave does not adversely affect the drug's benefit-risk profile.

In September 2011, following a meeting with senior officials in the FDA's Office of New Drugs, or OND, we received written correspondence from the director of the OND detailing the OND's design requirements for a randomized, double- blind, placebo-controlled cardiovascular outcomes trial, or CVOT, for Contrave that would address the CRL. We initiated the CVOT, which we refer to as the Light Study, in June 2012 and completed screening in December 2012, which resulted in approximately 8,900 patients randomized to treatment. We enrolled a patient population that we predicted would have an annualized MACE rate between 1% and 2%. The FDA previously agreed that if the interim analysis of the Light Study met the specified criteria to exclude cardiovascular risk, Contrave could be approved. The pre-specified criteria for the interim analysis was to exclude a hazard ratio of 2.0, using the upper bound of the 95% confidence interval, for excess risk MACE in patients receiving Contrave as compared to placebo. In November 2013, we announced successful results of the 25% interim analysis of the Light Study. In addition to meeting the pre-specified criteria for excluding cardiovascular risk, no new safety signals were observed in either the 25% or the later 50% interim analysis. Contrave was approved for commercial use by the FDA in September 2014. The Light Study was terminated in May 2015.

Open-Label Study for Smoking Cessation.

We conducted an exploratory, open-label 24-week clinical trial of Contrave for smoking cessation in overweight or obese patients. This trial was conducted in 30 patients across three U.S. centers. The primary endpoint for this trial was the rate of smoking cessation as defined by patient-reported continuous abstinence during weeks 4-12. Secondary endpoints, which were measured at week 12 and 24, included: rate of smoking cessation as defined by patient-reported continuous abstinence during weeks 4-24; percent change from baseline in total body weight; and a number of other key measures. Additionally, measures of safety and tolerability were evaluated. The endpoints were analyzed using ITT, LOCF.

In this trial, Contrave significantly reduced cigarette use among obese patients trying to quit smoking and was not associated with clinically meaningful weight gain. The smoking cessation rates as measured by patient-reported continuous abstinence were 48.1% and 40.7% at week 12 and 24, respectively. Improvements were also seen in a number of key secondary endpoints. The most frequent adverse events were nausea, insomnia and constipation. These tended to be transient and mild or moderate in severity. Five patients withdrew from this trial due to adverse events. No serious adverse events occurred.

Open-Label Study for Obese Depressed Patients.

We conducted an exploratory, open-label 24-week clinical trial assessing the safety and efficacy of Contrave in overweight or obese patients with major depression. This trial was a single-center trial conducted in 25 patients. The primary endpoint for this trial was the change from baseline in the Montgomery-Asberg Depression Rating Scale, or MADRS, total score at Week 12. Secondary endpoints included change from baseline in the MADRS total score at Week 24, as well a number of other key measures. Additionally, measures of safety and tolerability were evaluated. The endpoints were analyzed using ITT, LOCF.

In this trial, Contrave showed a clinically significant reduction in depressive symptoms in the study population, as evidenced by mean decreases from baseline in MADRS total scores of more than 50% at weeks 12 and 24. Improvements were also seen in a number of key secondary endpoints. The most frequent adverse events were nausea, constipation, headache and insomnia. These adverse events tended to be moderate in severity. Ten patients withdrew from the trial due to adverse events. No serious adverse events occurred during the trial that were attributed to treatment with Contrave.

The Ignite Study

In 2015 we completed a randomized, open-label clinical trial of 242 overweight or obese patients, which we refer to as the Ignite Study. The Ignite Study was designed to provide additional information regarding the real world weight loss potential of Contrave in combination with a commercially available comprehensive lifestyle intervention program (Contrave+CLI), compared to patients who receive diet and exercise advice from the study site staff but who do not receive Contrave (Usual care). Consistent with current labeling for recently approved anti-obesity medications, patients in the Ignite Study had to achieve a certain amount of weight loss (at least 5% at week 16) and not have a meaningful increase in blood pressure to remain on medication. This study was also designed to collect data beyond one year of exposure to Contrave. After a 26 week controlled treatment period, all patients entered a one year extension during which they received Contrave and lifestyle intervention.

The primary endpoint for this trial was change in body weight after 26 weeks. In the 26 week per protocol completers [Contrave+CLI (n=71), Usual care (n=82)], patients taking Contrave in combination with a lifestyle intervention program exhibited 8.5% greater weight loss compared with usual care patients (-9.5% vs. -0.9%; $p<0.001$, respectively). Weight change in ITT subjects, which included subjects discontinued from treatment [Contrave+CLI (n=152), Usual care (n=88)], was -6.2% vs -1.1% for Contrave+CLI and usual care, respectively ($p<0.001$). Secondary endpoints included the percentage of patients achieving at least 5% and 10% weight loss, waist circumference, lipids, and measures of glucose homeostasis, as well as a number of other key measures. More patients receiving Contrave+CLI achieved 5%, 10%, and 15% weight loss. Similar to the Phase III trials in the COR Program, there was also statistically significant improvement in waist circumference, triglycerides, glucose, insulin, HOMA-IR, and HDL. Treatment with Contrave+CLI was associated with significantly improved patient reported weight-related quality of life, control of eating, and sexual function. At 78 weeks upon completion on the one year extension when all patients were exposed to Contrave, weight change was similar between patients initially receiving Contrave+CLI vs usual care (-9.7% vs -10.7%). Pooling both groups, 72%, 46%, and 25% of subjects achieved ≥5%, 10%, and 15% weight loss at Week 78. Mean systolic/diastolic BP was also reduced 1-2 mmHg at Week 78, compared to baseline. The adverse event profile was similar to Phase III trials in the COR Program.

Sales and Marketing

Contrave was developed to compete in historically large therapeutic markets traditionally served by primary care physicians. In order to effectively educate and promote Contrave to these physicians and maximize the value of Contrave, in July 2015, we entered into an amended and restated collaboration agreement with Takeda to develop and commercialize Contrave in the United States. Contrave was launched commercially in the United States by Takeda in October 2014. In March 2016, we and Takeda entered into a separation agreement, which terminated our collaboration agreement in August 2016. We are now solely responsible for developing and commercializing Contrave within the United States and the rest of the world. We retain marketing rights for Contrave in the United States and outside the other Partnered Regions and are continuing partnering discussions for the rights to Contrave/Mysimba in markets in territories outside the United States and the Partnered Regions.

Maximizing the Value of Contrave in the U.S.

Our mission is to help improve the health and lives of patients struggling to lose weight. Our objective is to educate healthcare practitioners, or HCPs, and activate patients by bringing awareness and education to the role the brain plays in weight loss through an integrated patient-physician new commercial model. This innovative model is designed to enable high-quality physician consultations that improve treatment rates and success. We hope to normalize medicine as part of the weight loss treatment regimen, and maintain the position as the branded prescription product of choice for the treatment of obesity.

We implemented our new commercial model in two phases. Phase 1 is focused on education and awareness of our key messages among HCPs. Phase 2 is focused on education and activation of patients driven by our key messages.

Through strategic targeting of HCPs by our new specialty sales force and enhanced marketing mix with new messaging and HCP-centered promotions, we believe that physician awareness has reached the threshold where activated consumers are likely to encounter a receptive physician.

After achieving a high degree of physician awareness, and becoming the #1 prescribed weight-loss brand, we determined that Contrave was ready for a direct to consumer, or DTC, campaign. In December 2016, we launched a comprehensive, multimedia DTC campaign including TV, website, social media and print to drive awareness and activate patients. Our research shows patients are receptive to prescription-aided weight loss, but awareness is low. We believe activating patients is a critical step ready to be taken.

To fully maximize value, compete effectively, and further enhance the overall quality of care for the patient, we recently launched a telemedicine pilot program. According to research, many patients prefer the convenience and anonymity of telemedicine. Since Contrave is not a U.S. Drug Enforcement Administration, or DEA, scheduled, controlled substance, an opportunity exists to

accommodate patients who prefer this option. Telemedicine for Contrave offers a way for patients to efficiently connect with a certified physician via the internet which should lead to a straight forward diagnosis for appropriate patients.

Based on the existing burden of illness, the high and increasing health care cost associated with obesity and associated co-morbid diseases, the efficacy and safety profile of Contrave that was demonstrated through its clinical development program, and the health benefits associated with modest weight loss, we believe we are providing a strong value proposition to governmental authorities, private health insurers and other third-party payers. We understand that sufficient access and reasonable reimbursement are essential in order to optimize the commercial potential of Contrave.

Intellectual Property

We rely on a combination of in-licensed patent rights, our own patent rights, trademarks, trade secrets and know-how to protect Contrave. We own or have exclusive rights to several issued patents and patent application families currently pending in the United States with respect to various compositions, methods of use and formulations relating to Contrave. We also have a number of patent applications currently pending in various foreign countries that correspond to some of the pending U.S. applications. We also seek to protect our trade secrets and our know-how relating to our products and our business. These intellectual property rights are in addition to any regulatory exclusivity that we may be able to obtain.

Contrave is currently protected by U.S. patent number 7,375,111, which we refer to as the Weber/Cowley composition patent, and U.S. patent number 7,462,626, which we refer to as the Weber/Cowley methods patent. Provided maintenance fees are paid, the Weber/Cowley composition patent is expected to expire in March 2025, and the Weber/Cowley methods patent is expected to expire in July 2024. Collectively, we refer to the Weber/Cowley composition patent and the Weber/Cowley methods patent as the Weber/Cowley patents. Each of these stems from a provisional patent application that we own but that is the subject of an agreement with the Oregon Heath & Science University, or OHSU, requiring us to pay them specified royalties on sales of products covered by the patent applications. This agreement is described in further detail below. The Weber/Cowley patents cover the current composition of Contrave and methods of administering it to treat obesity. We have also filed a number of international counterparts to these patent applications in foreign countries. The European Patent Office, or EPO, has granted the European version of the Weber/Cowley patent, which published as EP1617832 B1. This EP patent has issued in numerous countries throughout the European Union and provides coverage for Contrave until at least 2024. Use of our proprietary tri-layer Contrave tablet for weight loss is protected in the United States by U.S. patent numbers 8,088,786 and 8,318,788, which are expected to expire in February 2029 and November 2027, respectively. The EPO has granted the European version of the tri-layer tablet patent, which published as EP2089005 B1. In addition, use of our proprietary sustained-release formulation of Contrave for weight loss is protected by U.S. patent numbers 8,916,195 and 9,107,837, which are expected to expire in February 2030 and June 2027, respectively. The dose escalation schedule of Contrave is protected by U.S. patent numbers 8,722,085 and 9,125,868, which are expected to expire in November 2027. U.S. patent number 8,815,889, and 9,457,005, directed to methods of treating insulin resistance using Contrave, including in obese patients, is expected to expire in July 2024. Corresponding patents have issued in several foreign countries, for example, in the European Patent Office as EP2135603 B1. U.S. patent numbers 8,969,371 and 9,119,850, which are expected to expire in July 2034, protect the use of Contrave for treating overweight or obesity in select patient populations that are at increased risk of a major adverse cardiovascular event. U.S. patent number 9,248,123, which is expected to expire in January 2032, protects the use of Contrave for treating overweight or obesity in select patient populations with major depressive disorder. Additional patent applications related to Contrave remain pending in the U.S. and throughout the world.

We have also filed patent applications in the United States and certain foreign countries under the Patent Cooperation Treaty, or PCT, which is an international treaty providing a unified procedure under which the initial filing of a single patent application can provide an effective filing date in each participating country in which appropriate steps are subsequently taken. Such steps have been taken in various foreign countries, including countries in Europe and Japan, with respect to our PCT filings directed to various treatment and formulation aspects of Contrave. Thus, we now have patent applications pending in those countries (along with our previous filings in the United States and certain non-PCT countries) that seek to provide further protection for Contrave. However, we cannot provide assurance that the claims in these patent applications will issue in their current form or at all.

We have received U.S. trademark registration number 3393576 for the mark CONTRAVE for use in connection with pharmaceutical preparations for use in the treatment of obesity and inducing weight loss. We have also obtained foreign trademark registrations for the mark CONTRAVE in Australia, Brazil, Canada, the European Union, Lebanon, Mexico, Russia, Japan, and South Korea and have pending applications in Bahrain, Canada, China, Egypt, India, Iran, Jordan, Kuwait, Oman, Qatar, Saudi Arabia, South Africa and Vietnam. In addition, applications for a Contrave logo for use in connection with pharmaceutical preparations for use in the treatment of obesity and inducing weight loss, certain printed materials and medical information services has been filed in the U.S., and is pending in Canada. The Contrave logo is also registered in Europe and Japan. An intent to use application for the mark MYSIMBA has been allowed in the United States in connection with pharmaceutical preparations, printed materials, and medical information services. We have obtained trademark registrations in the European Union, Norway, South Korea and

Switzerland for the same mark. In addition, applications for the mark MYSIMBA are pending in Albania, Australia, Bosnia and Herzegovina, Canada, Macedonia, Montenegro, Kosovo, Serbia, South Africa, Turkey and India.

We have received U.S. trademark registration number 3396021 for our corporate logo for use in connection with pharmaceutical preparations and substances for the treatment of obesity, inducement of weight loss and prevention of weight gain. We have obtained trademark registrations in Canada, the European Union and Japan for the same mark. In addition, we have received U.S. trademark registration number 3396807 for our corporate name OREXIGEN for use in connection with pharmaceutical preparations for the treatment of disorders of the CNS, printed instructional, educational and teaching materials in the field of treatment and management of disorders of the CNS, and providing medical information in the field of disorders of the CNS. We have obtained trademark registrations in Brazil, Canada, the European Union, Japan, and Russia for the same mark. We have obtained foreign trademark registrations for the corporate name Orexigen Therapeutics, Inc. in Europe and Japan.

Collaboration and Licensing Agreements

Collaboration Agreement with Takeda Pharmaceutical Company Limited

In July 2015, we entered into an amended and restated collaboration agreement with Takeda to develop and commercialize Contrave in the United States. In March 2016, we and Takeda entered into a separation agreement, which terminated our collaboration agreement, as well as the manufacturing services agreement, in August 2016. In March 2016, we paid Takeda $60 million in connection with signing the separation agreement and paid an additional $15 million in January 2017, under the terms of the separation agreement. We may also be obligated to pay Takeda milestone payments of $10 million, $20 million, $30 million and $50 million, based on the achievement of annual Contrave net sales milestones of $200 million, $300 million, $400 million and $600 million, respectively, in any year following the termination in August 2016. Each such milestone payment shall be payable only once but more than one may be payable with respect to net sales in a single year. We are now solely responsible for developing and commercializing Contrave within the United States and the rest of the world.

Oregon Health & Science University License Agreement

In June 2003, we entered into a license agreement with OHSU whereby we acquired an assignment of any rights OHSU may have to a U.S. provisional patent application that we filed, which formed the basis for the Weber/Cowley patents. These patents, as discussed above, cover the current composition of Contrave, including our ER formulation of naltrexone and methods for using that composition to effect weight loss. OHSU and the inventors have assigned all rights in the underlying invention to us. This license agreement was amended in November 2003, December 2006 and December 2007.

As consideration for this license agreement, we paid an upfront fee of $65,000 and issued 7,631 shares of our common stock to OHSU. We are also obligated to pay a royalty to OHSU on net sales for Contrave and any other products covered by the assigned patent rights.

The term of the agreement generally extends until the last of the subject patent rights expire, which is expected to occur in 2025. We may unilaterally terminate the agreement or any licenses in any country upon specified written notice to OHSU. OHSU may terminate the agreement upon delivery of written notice if we commit a material breach of our obligations and fail to remedy the breach within a specified period or may immediately terminate the agreement upon the delivery of written notice concerning the occurrence of specified bankruptcy proceedings. In addition, upon written notice and our failure to remedy any of the following breaches within a specified period, OHSU may terminate or modify the agreement: if we cannot demonstrate to OHSU's satisfaction that we have taken, or can be expected to take within a reasonable time, effective steps to achieve practical application of the licensed products and/or licensed processes; or if we have willfully made a false statement of, or willfully omitted, a material fact in any report required by the agreement; or if we commit a substantial breach of a covenant or agreement contained in the license. Under the terms of the agreement, we are responsible for all prosecution and maintenance (including all costs associated with the enforcement) of any patent applications that stem from the assigned rights, and for any patents that have or may issue with respect thereto, including the Weber/Cowley patents.

In addition to assigning us any rights it had in our provisional patent application directed to the Contrave combination of naltrexone and bupropion, OHSU has licensed to us, on an exclusive basis, the issued patent underlying the *in vitro* model that we have used for screening combination therapies for impact on neuronal activity. Our rights to this model extend through the expiration of the patent, which is expected to occur in 2024. We have the right to grant sublicenses to third parties for this patented technology, subject to our obligation to pay OHSU a royalty on revenue received by us from the sale of any products covered under such sublicensing arrangements. Under the terms of the agreement, OHSU is solely responsible for the prosecution, maintenance and enforcement (including all costs associated therewith) of this patent; however, we are required to pay 100% of the prosecution and maintenance expenses incurred by OHSU in connection with these patent rights. As of December 31, 2016, we have paid a total of approximately $118,000 in connection with the maintenance and prosecution of this patent. In addition, OHSU has the right to not file

any patent application or to abandon any patent or patent application included in the patent rights, in which case it must provide us 60 days' prior written notice and, in response, we may elect at our sole cost to pursue these actions.

Manufacturing

To date, our commercial product, as well as product used in clinical trials have been produced by outside contractors under our supervision.

In March 2010, we entered into a manufacturing services agreement with Patheon Pharmaceuticals and Patheon Inc., or collectively Patheon, pursuant to which Patheon agreed to manufacture commercial quantities of our Contrave tablet products. Under the terms of the manufacturing agreement, as amended by the parties in November 2013, we are required to purchase a certain percentage of our requirements for our Contrave tablet products intended for commercial sale, provided certain terms and conditions are met.

The initial term of the manufacturing agreement commenced on March 12, 2010 and continues in effect until December 31st of the year that is five years from the date Contrave first receives approval for marketing from the FDA or any other foreign regulatory agencies competent to grant marketing approvals for pharmaceutical products. Upon expiration of the initial term, the agreement will be automatically renewed for additional two year terms. Patheon may terminate the manufacturing agreement at any time upon specified prior written notice to us. We may also terminate the agreement with specified prior written notice to Patheon, subject to our payment of certain termination amounts. Either party may terminate the agreement effective immediately upon written notice to the other in the event that (1) the other party dissolves, is declared insolvent or bankrupt by a court of competent jurisdiction, (2) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction, or (3) the agreement is assigned for the benefit of creditors. We may terminate the agreement upon specified prior written notice if any governmental or regulatory authority, including, but not limited to, the FDA, takes any action, or raises any objection, that prevents us from importing, exporting, purchasing, or selling our Contrave tablet products. We are also required to give specified advance notice if we intend to no longer order commercial supplies of our Contrave tablet products pursuant to the manufacturing agreement due to the product's discontinuation in the market. Patheon may terminate the agreement upon specified prior written notice to us if we assign any of our rights under the agreement to an assignee that, in the opinion of Patheon acting reasonably, is (1) not a credit worthy substitute for us; or (2) a competitor of Patheon. Moreover, either party may terminate the agreement upon written notice to the other party where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under the manufacturing agreement within a specified period of time following receipt of a written notice of the breach, subject to specified terms and conditions.

Patheon has produced and will produce our bulk Contrave tablet products using naltrexone and bupropion active pharmaceutical ingredient, or API, supplied from various sources.

At this time, we use multiple API suppliers to manage our supply, and we have no material, long-term commitments or supply agreements with any of our API suppliers. Although we may seek to establish additional long-term supply commitments in the future, we may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions. We may not be able to enter into additional long-term agreements, on commercially reasonable terms, or at all.

In the future, if we are able to achieve approval in the United States or other countries to market and sell our products, we intend to continue to rely on outside contractors for the production of necessary supplies. We do not currently intend to establish our own manufacturing capabilities.

Competition

Treatments for obesity consist of behavioral modification (diet and exercise), pharmaceutical therapies, surgery and device implantation. Modifications to diet and exercise are the preferred initial treatment in obesity. However, the demands of behavioral modification alone tend to cause significant attrition over time, often resulting in regaining weight. When pharmaceutical therapies are recommended it is generally after behavioral modification alone has failed. In 2013, the American Association of Clinical Endocrinologists published treatment guidelines for obese or overweight patients with type 2 diabetes or pre-diabetes that include anti-obesity pharmacotherapy in conjunction with lifestyle modification for certain patients. Consistent with proposed labeling and as demonstrated in our clinical studies, we believe behavioral modification in combination with Contrave is effective in achieving weight loss.

The pharmaceutical market for obesity reached approximately $596 million in 2016, up 26% from 2015. Total prescriptions for 2016 reached approximately 10.7 million prescriptions, up 2.5% from the previous year. Phentermine/topiramate and lorcaserin are two of the pharmaceutical products that have been approved for the treatment of obesity in the United States. Several older agents, indicated for short-term administration, are amphetamine-like compounds including phentermine, phendimetrazine, benzphetamine and diethylpropion. Of these, phentermine is the most widely used, accounting for approximately 8.2 million prescriptions in the United

States in 2016. In June 2013, Arena commercially launched lorcaserin in the United States under the name Belviq. In 2016, Belviq accounted for approximately 420,000 prescriptions. In July 2016, the FDA approved a once-daily formulation of lorcaserin hydrochloride, which launched commercially in October 2016 under the name Belviq XR. In 2016, Belviq XR accounted for approximately 8,000 prescriptions. In September 2012, Vivus commercially launched its combination product, phentermine/topiramate, in the United States under the name Qsymia. In 2016, Qsymia accounted for approximately 455,000 prescriptions. In addition, in May 2015, Novo Nordisk launched its liraglutide injection product in the United States under the name Saxenda. In 2016, Saxenda accounted for approximately 189,000 prescriptions. Saxenda is the fifth branded pharmaceutical product approved for the treatment of obesity in the United States. Despite the large market opportunity for anti-obesity agents, there are relatively few competitive products in late stage clinical development.

In addition, we may face competition from generic suppliers. Each of bupropion and naltrexone is available in generic form. However, we have undertaken strategies which we believe may impede potential competition from generic products. Supplementing our existing composition patents and patent applications, we have developed formulations and dosages of Contrave that we believe may improve patient outcomes and provide further barriers to entry, including intellectual property protection, for potential competitors.

Third-Party Reimbursement

Despite the recognition of obesity as a chronic disease and its enormous cost to our health care system, universal coverage of and reimbursement for drugs to treat obesity by both public and private payors is lacking. However, third-party reimbursement for anti-obesity drugs appears to be evolving, including among state Medicaid programs and private commercial plans and pharmacy benefit managers.

Medicaid

The Medicaid program provides health insurance coverage for individuals who are poor and meet certain other eligibility criteria. The program is a federal and state partnership. Within broad federal parameters, each state designs and administers its own program. The federal government shares in the cost of the program by reimbursing states a percentage of their costs.

All states currently provide outpatient prescription drug coverage under their Medicaid programs. States that elect to offer outpatient prescription drug coverage must provide coverage for all FDA-approved drugs of every manufacturer that has entered into a rebate agreement with HHS under the Medicaid Rebate Program, with certain exceptions. For example, state Medicaid programs, administered by individual states for qualifying low-income individuals, are permitted to exclude coverage for weight loss drugs.

Medicare

The Medicare program provides health insurance for individuals aged 65 and over and those with serious disability or end-stage renal disease, regardless of income. However, Medicare coverage of obesity treatments is limited. In the fourth quarter of 2011, the Centers for Medicare & Medicaid Services announced that the Medicare program was adding new benefit coverage for prevention with the objective of treating obesity. The new benefit provides for screening for obesity and counseling for eligible beneficiaries by primary care providers in physician's offices. The benefit includes face to face counseling for up to 12 total months. Current policy authorizes coverage of non-pharmacologic obesity treatments but only when such treatments are an integral and necessary part of a course of treatment for a co-morbid medical condition. Pursuant to this policy, in February 2006, Medicare began covering certain designated bariatric surgical services for Medicare patients with a BMI equal to or greater than 35, who have at least one co-morbidity and have been previously unsuccessful with the medical treatment of obesity. However, the policy reiterates that treatments for obesity alone are not covered because such treatments are not considered reasonable and necessary. In addition, by statute, Medicare's prescription drug benefit does not cover either outpatient prescription weight loss drugs or over-the-counter weight loss drugs.

Private Commercial Plans

In general, private commercial plans offer coverage for oral weight loss products only if the benefit is selected by employer plan sponsors. Many plans require prior authorization. Thus, our product may not achieve broad coverage. Moreover, the amount of any coverage provided under the various plans may be minimal. Government policy is a key player in setting trends for coverage, generally and of obesity treatments, specifically. Private payors may be more likely to add coverage of weight loss products if Medicare provides such coverage. We do not expect the success of our obesity product to be entirely contingent on third-party payor coverage and reimbursement, but rather, on acceptance by physicians and people who want to lose weight and are willing to pay for the drugs out of pocket.

Outside the United States

Within the European Union, approved products are paid for by a variety of payors and governments being the primary source of payment. Governments may determine or influence reimbursement of products. Governments may also set prices or otherwise regulate pricing. Negotiating prices with governmental authorities can delay commercialization of our products, if approved. Governments may use a variety of cost-containment measures to control the cost of products, including price cuts, mandatory rebates, value-based pricing, and reference pricing (i.e., referencing prices in other countries and using those reference prices to set a price). Budgetary pressures in many European Union/European Economic Area countries are continuing to cause governments to consider or implement various cost-containment measures, such as price freezes, increased price cuts and rebates, and expanded generic substitution and patient cost-sharing. If budget pressures continue, governments may implement additional cost-containment measures.

Government Regulation

In the United States, prescription drug products are subject to extensive pre- and post-market regulation by the FDA and other state and federal authorities, including regulations that govern the testing, manufacturing, safety, efficacy, labeling, storage, record keeping, advertising and promotion of such products under the Federal Food, Drug, and Cosmetic Act, or FFDCA, and its implementing regulations, and by comparable agencies and laws in foreign countries. Failure to comply with applicable FDA or other requirements may result in civil or criminal penalties, recall or seizure of products, partial or total suspension of production or withdrawal of the product from the market.

FDA approval is required before any new drug, including a new dosage form or use of a previously approved drug, can be marketed in the United States.

New Drug Application (NDA)

An approved NDA by the FDA is generally required before a drug may be marketed in the United States. This process generally involves:

- completion of preclinical laboratory and animal testing in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug, or IND, application for human clinical testing which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug product for each intended use;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is produced to assess compliance with the FDA's current Good Manufacturing Practice, or cGMP, regulations; and
- submission to and approval by the FDA of an NDA.

The preclinical and clinical testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for any future product candidates will be granted on a timely basis, if at all.

Preclinical tests include laboratory evaluation, as well as animal studies to evaluate pharmacology and toxicity. The results of preclinical tests, together with manufacturing information and analytical data, are submitted as part of an IND application to the FDA. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, issues a clinical hold raising concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before a clinical trial can begin. Submission of an IND may not result in FDA authorization to commence a clinical trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development. Further, an independent institutional review board, or IRB, for each medical center proposing to conduct the clinical trial must review and approve the plan, protocol and informed consent forms for any clinical trial and the IRB must monitor the trial until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Clinical testing also must satisfy Good Clinical Practice, or GCP, as set forth in the FDA guidance, and related regulations, including regulations for informed consent.

For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following three or four sequential phases, which may overlap:

- *Phase I:* Studies are initially conducted in a limited population to test the product candidate for safety, dose tolerance, absorption, metabolism, distribution and excretion in healthy humans or, on occasion, in patients, such as cancer patients when the drug is too toxic to be ethically given to healthy individuals.

- *Phase II:* Studies are generally conducted in a limited patient population to identify possible adverse effects and safety risks, to determine the efficacy of the product for specific targeted indications and to determine dose tolerance and optimal dosage. Multiple Phase II clinical trials may be conducted by the sponsor to obtain information prior to beginning larger and more expensive Phase III clinical trials.

- *Phase III:* These are commonly referred to as pivotal studies. When Phase II evaluations demonstrate that a dose range of the product is effective and has an acceptable safety profile, Phase III clinical trials are undertaken in large patient populations to further evaluate dosage, to provide substantial evidence of clinical efficacy and to further test for safety in an expanded and diverse patient population at multiple, geographically-dispersed clinical trial sites.

- *Phase IV:* In some cases, FDA may condition approval of an NDA for a product candidate on the sponsor's agreement to conduct additional clinical trials after NDA approval. In other cases, a sponsor may voluntarily conduct additional clinical trials post approval to gain more information about the drug. Such post approval trials are typically referred to as Phase IV studies.

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 cost of preparing and submitting an NDA is substantial. The Prescription Drug User Fee Act, which has been reauthorized four times by Congress, requires the payment of substantial user fees with the submission of NDAs. The FFDCA provides for waiver of the application fee for the first NDA for a small business under certain circumstances. In February 2010, we were granted a waiver of this application fee for our Contrave NDA. This one time waiver will not be available to us upon submission of NDAs, if any, for our other product candidates in the future. Manufacturers and sponsors of approved drugs are subject to annual product and establishment fees. The FDA has agreed to certain performance goals in the review of NDAs. Most applications for non-priority drug products have been reviewed within ten to twelve months while most applications for priority review drugs, that is, drugs that the FDA determines represent a significant improvement over existing therapy, are reviewed in six to eight months. The review process is often extended by the submission of additional information or clarification during the review. The FDA may refer the application to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, the FDA will typically inspect one or more clinical trial sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with cGMP and GCP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied. The FDA may deny approval of an NDA if the applicable regulatory criteria are not satisfied, or it may require additional data including additional pivotal Phase III clinical trials. Even if such data are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data from clinical trials are not always conclusive and FDA may interpret data differently than we do.

Upon completion of its review of the NDA, FDA issues 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's goal is to review such resubmissions in two or 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 restrictions which can materially affect the potential market and profitability of the drug. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

The Hatch-Waxman Act

In 1984, Congress enacted the Hatch-Waxman Act. In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent with claims that cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be

therapeutically equivalent to the listed drug. ANDA applicants are not required to conduct or submit results of pre-clinical or clinical tests to prove the safety or effectiveness of their drug product, other than the requirement for bioequivalence testing. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) 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, the ANDA application will not be approved 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 automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved 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. Federal law provides a 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 provides for a period of three years of exclusivity following approval of a listed 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, during which the FDA cannot grant effective approval of an ANDA based on that listed drug.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for modifications to products previously approved by the FDA, an applicant may file an NDA under Section 505(b)(2) of the FFDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Act. This statutory provision 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 Hatch-Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness for previously approved products. 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 for which the Section 505(b)(2) applicant has submitted its own data. The FDA requires companies to perform additional studies or measurements to support the change from the approved product. As with ANDAs, described above, to the extent that a Section 505(b)(2) application relies on the FDA's finding of safety and effectiveness of a previously-approved drug, the applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." Specifically, the applicant must certify when the application is submitted that: (1) there is no patent information listed; (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 manufacture, use or sale of the product. A certification that the new product will not infringe the already approved product's Orange Book listed patents or that such patents are invalid is called a Paragraph IV certification. If the applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the patent holder and the NDA holder. In the event that the patent holder or NDA holder files a patent infringement lawsuit within 45 days of its receipt of our Paragraph IV notification, such lawsuit would automatically prevent the FDA from approving the ANDA or Section 505(b)(2) NDA until the earliest of 30 months, expiration of the patent, settlement of the lawsuit or a favorable decision in the infringement case. Any such patent infringement lawsuit could be costly, take a substantial amount of time to resolve and divert management resources.

Upon FDA approval, we received three years of Hatch-Waxman marketing exclusivity for Contrave. Under this form of exclusivity, the FDA would be precluded from approving a generic drug application or, in some cases, another 505(b)(2) application for a drug product for the protected conditions of approval (for example, a product that incorporates the change or innovation represented by our product) for a period of three years, although the FDA may accept and commence review of such applications prior to the expiration of the three-year period. However, this form of exclusivity does not prevent the FDA from approving an NDA that relies on its own clinical data to support the change or innovation.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of the completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act of 2003, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. The Best Pharmaceuticals For Children Act, or BPCA, provides sponsors with an additional 6-month period of market exclusivity on all forms of the drug containing the active moiety, if the sponsor submits results of pediatric studies specifically requested by FDA under BPCA. In order to receive the BPCA exclusivity, the drug must have other existing patent or exclusivity protection in effect.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. We and our contract manufacturers are required to comply with applicable FDA manufacturing requirements contained in the FDA's cGMP regulations. cGMP regulations require, among other things, quality control, and quality assurance as well as the corresponding maintenance of records and documentation. The manufacturing facilities for our products must meet cGMP requirements to the satisfaction of the FDA pursuant to a pre-approval inspection before we can use them to manufacture our products for commercial distribution. We and our third-party manufacturers are also subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations. In addition, prescription drug manufacturers in the United States must comply with applicable provisions of the Drug Supply Chain Security Act and provide and receive product tracing information, maintain appropriate licenses, ensure they only work with other properly licensed entities, and have procedures in place to identify and properly handle suspect and illegitimate products.

Adverse experiences associated with the use of the drug must be reported to the FDA and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

Failure to comply with statutory and regulatory requirements subjects a manufacturer to possible legal or regulatory action, including Warning Letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, and civil and criminal penalties.

The FDA can require post-approval studies and clinical trials if the FDA finds, after approving the drug, that scientific data, including information regarding related drugs, render it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicates the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

With respect to post-market product advertising and promotion, the FDA prohibits, restricts or otherwise imposes regulatory requirements on certain activities, including direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities, and promotional activities involving the internet. The FDA has very broad enforcement authority under the FFDCA, and failure to abide by these regulations can result in penalties, including the issuance of a Warning Letter directing entities to correct deviations from FDA standards, a requirement that future advertising and promotional materials be pre-cleared by the FDA, and federal civil and criminal investigations and prosecutions. State enforcement actions relating to promotional violations are also becoming more common.

Other Regulatory Requirements

The FDA can require a drug-specific Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the drug outweighs the risks. In determining whether a REMS is necessary, the FDA must consider the size of the population likely to use the drug, the seriousness of the disease or condition to be treated, the expected benefit of the drug, the duration of treatment, the seriousness of known or potential adverse events and whether the drug is a new molecular entity. If the FDA determines a REMS is

necessary, a sponsor must submit a proposed REMS as part of its application, or if the request is made post-approval, not later than 120 days after the FDA notifies the drug sponsor. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate health care providers of the drug's risks, limitations on how a drug may be prescribed or dispensed or other measures that the FDA deems necessary to assure the safe use of the drug. REMS programs must be evaluated on an ongoing basis and the FDA may require changes needed to address ongoing safety issues or corrective actions to address any noncompliance.

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the federal government has broad regulatory and enforcement powers, including the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal healthcare laws and regulations have been applied to restrict certain business and marketing practices in the pharmaceutical industry in recent years. These laws include the following:

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 Patient Protection and Affordable Care Act, or PPACA, amended the intent element of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to commit a violation. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers and formulary managers on the other. Violations of the federal Anti-Kickback Statute are punishable by imprisonment, criminal fines, civil monetary penalties and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws, including the Civil False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. 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 programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Additionally, PPACA amended the civil False Claims Act such that a violation of the federal Anti-Kickback Statute can serve as a basis for liability under the civil False Claims Act. The majority of states also have statutes or regulations similar to the federal Anti-Kickback Statute and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. Furthermore, many states have laws that govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and are not preempted by HIPAA, thus complicating compliance efforts.

Furthermore, pursuant to PPACA, the Centers for Medicare & Medicaid Services, or CMS, has issued a final rule that requires manufacturers of prescription drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to collect and report, on an annual basis, information on payments or transfers of value to physicians and teaching hospitals, as well as investment interests held by physicians and their immediate family members. The reported data are posted in searchable form on a public website. Failure to submit required information may result in civil monetary penalties. Furthermore, several states also require prescription drug companies to report certain expenses relating to the marketing and promotion of drug products and to report certain gifts and payments to individual physicians in these states. Other states prohibit various other marketing-related activities. Still other states require the posting of information relating to clinical studies and their outcomes. In addition, California, Connecticut, Massachusetts and Nevada require pharmaceutical companies to implement compliance programs and/or marketing codes. Several additional states are considering

similar proposals. Compliance with these laws is difficult and time consuming, and companies that do not comply with these state laws face civil penalties. Companies must also be registered or licensed by the federal and state governments prior to manufacturing or distributing prescription drug products.

Healthcare Reform

The United States and some foreign jurisdictions are considering or have enacted a number of 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 payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

By way of example, in March 2010, PPACA was signed into law, intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose taxes and fees on the health industry and impose additional health policy reforms. Among the provisions of PPACA of importance to our business are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's 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 certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a 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 a manufacturer's outpatient drugs to be covered under Medicare Part D;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

We expect that PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement. There have been judicial and Congressional challenges to certain aspects of PPACA, and we expect there will be additional challenges and amendments to PPACA in the future, particularly with the change in Administration.

In addition, other legislative changes have been proposed and adopted since PPACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year effective April 1, 2013 and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025 unless additional Congressional action is taken. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, 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 healthcare funding, which could have a material adverse effect on our financial operations.

European Union Drug Review and Approval

In the EEA (which is comprised of the 28 Member States of the European Union, as well as, through the Treaty of the European Economic Area, Norway, Iceland and Liechtenstein), medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of MA:

The CMA, which is issued by the EC in the form of a binding decision through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for human Use, or CHMP, of the EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer,

neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. A medicinal product can be progressively authorized in two or more EEA Member States. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in other Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

Under the above described procedures, before granting the MA, the EMA or the competent authorities of the Member States of the EEA make an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Contrave was eligible for the Centralized Procedure. In October 2013, we submitted a CMA application for Contrave, under the name Mysimba, to the European Medicines Agency, or EMA. We utilized the EMA's centralized procedure, seeking approval of Mysimba in the European Economic Area, or EEA (which is comprised of the 28 member states of the European Union, as well as Norway, Iceland and Liechtenstein), for the management of obesity, including weight loss and maintenance of weight loss, in conjunction with lifestyle modification. In March 2015, the EC granted centralized marketing authorization for Mysimba (naltrexone HCl / bupropion HCl prolonged release) as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients (≥18 years) with an initial Body Mass Index of ≥ 30 kg/m^2 (obese), or ≥ 27 kg/m^2 to < 30 kg/m^2 (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidemia, or controlled hypertension). This authorization applies to all 28 European Union member states, as well as Norway, Iceland and Liechtenstein.

Prior to submission of the CMA for Mysimba, we also established an agreed-to pediatric investigation plan with the EMA's Pediatric Committee. The EMA's Pediatric Committee also agreed to grant a waiver from the obligation to carry out pediatric clinical trials in certain subsets of the pediatric population. The EMA's Pediatric Committee's opinion was validated by an EMA decision adopted in August 2013.

DEA Regulation

Naltrexone, one of the components of Contrave, is manufactured from starting materials isolated from poppy straw and are also used in the production of opiates. Although naltrexone is not a narcotic or a controlled substance, the manufacture of naltrexone API is subject to regulation by the U.S. Drug Enforcement Administration, or DEA, because the starting material is a controlled substance. Controlled substances are those compounds that appear on one of five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA. The CSA governs, among other things, the distribution, recordkeeping, handling, security, and disposal of controlled substances. Even though Contrave is not scheduled and naltrexone is not a controlled substance, our third-party suppliers of naltrexone must be registered by the DEA in order to engage in production activities, and are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. The manufacturers must also obtain an annual quota from the DEA to obtain sufficient material to manufacture substances derived from poppy straws. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation, or a denial of renewal, of DEA registration, injunctions, or civil or criminal penalties. The failure to obtain adequate quota can also limit the manufacturing capacity of the manufacturer.

Employees

As of March 15, 2017, we had 132 full-time employees, consisting of commercial, research and development and general and administration. We consider our relations with our employees to be good.

Research and Development

Our research and development expenses totaled $38.0 million, $40.8 million and $57.4 million in the years ended December 31, 2016, 2015 and 2014, respectively.

About Orexigen

We were incorporated in Delaware in September 2002. Our principal offices are located at 3344 N. Torrey Pines Court, Suite 200, La Jolla, California 92037, and our telephone number is (858) 875-8600. Our website address is www.orexigen.com. Information found on, or accessible through, our website is not a part of, and is not incorporated into, this Annual Report on Form 10-K.

Available Information

We file electronically with the U.S. Securities and Exchange Commission our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to reports filed pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended. We make available on our website at www.orexigen.com, free of charge, copies of these reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Copies of our annual report will also be made available, free of charge, upon written request.

The public may read and copy any materials filed by us with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC at http://www.sec.gov. The contents of these websites are not incorporated into this filing. Further, our references to the URLs for these websites are intended to be inactive textual references only.

Item 1A. Risk Factors.

You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the factors described when evaluating our business.

Risks Related to Our Business and Industry

Our success for the foreseeable future is dependent solely on the success of our approved product, Contrave® (naltrexone HCI and bupropion HCI) extended release, or ER, tablets.

To date the majority of our resources have been focused on the research and development of Contrave. In September 2014, the U.S. Food and Drug Administration, or the FDA, approved our New Drug Application, or NDA, for Contrave extended-release tablets as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index, or BMI, of 30 kg/m2 or greater (obese), or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition. In March 2015, the European Commission, or the EC, granted a Centralized Marketing Authorization for Contrave (under the name Mysimba®) that is valid in all 28 European Union member states, as well as Norway, Iceland and Lichtenstein, for Mysimba to be placed on the market. The United Kingdom, or the UK, held a referendum in June 2016, which resulted in 51.9% of those who turned out to vote electing to leave the EU. According to Article 50 of Treaty of the European Union, any member state may decide to withdraw from the EU in accordance with its own constitutional requirements. When a member state decides to withdraw, it must notify the European Council of its intention. At this juncture, the UK government has not notified the European Council to trigger the Article 50 procedure. Until and unless the exit procedure provided under Article 50 is completed, the UK remains a member state of the EU and EU pharmaceutical law continues to apply to the UK and the Centralized Marketing Authorization for Mysimba will remain valid in the UK and the rest of the European Economic Area. If the exit procedure provided under Article 50 is completed, our ability to market and generate revenue from Mysimba in the UK, or elsewhere in the European Union, or Norway, Iceland and Lichtenstein will be subject to the terms of the withdrawal agreement, taking account of the framework for the future relationship between the UK and the European Union.

We are now focused on the commercialization of Contrave in the United States. Our former collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda, commercially launched Contrave in the United States in October 2014. In addition, in May 2016, our commercialization partner, Kwang Dong Pharmaceutical Company, Ltd., or Kwang Dong, obtained regulatory approval and commercially launched Contrave in South Korea in June 2016. In addition, Contrave/Mysimba was recently commercially launched in Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia by our partner, Valeant Pharmaceuticals, or Valeant, and in Spain by our partner, Laboratorios Farmacéuticos Rovi, S.A., or Rovi. We are currently advancing plans for the commercial launch of Contrave/Mysimba in certain other markets in Central and Eastern Europe, and Turkey with Valeant, in Italy with our partner Bruno Famaceutici, S.p.A., or Bruno, and in the United Kingdom and Ireland with our partner Consilient Health Ltd, or Consilient. We have also partnered with Valeant in Australia, New Zealand and Canada and are working with them to obtain regulatory approval of Contrave in these regions. In parallel, we are continuing partnering discussions for the rights to Contrave/Mysimba in other markets in the European Union and other territories outside the United States. Our ability to generate revenue for the foreseeable future will depend primarily on the commercial success of Contrave in the United States.

If Contrave does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.

The commercial success of Contrave or any other product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products by both the medical community and patient population. Coverage and reimbursement of our product by third-party payors, including government payors, generally is also necessary for optimal commercial success. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- our ability to provide acceptable evidence of safety and efficacy;
- the timing of market introduction of our products as well as competitive products;
- the relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;

- limitations or warnings contained in a product's FDA-approved labeling, including, the "black box" warning(s) and pregnancy precautions associated with the active pharmaceutical ingredients, or APIs, in Contrave and included in Contrave's product label;
- availability of alternative treatments and the potential or perceived advantages or disadvantages of such treatments, including, in the case of Contrave, a number of competitive products approved for the treatment of weight loss or expected to be commercially launched in the near future;
- pricing, discounts and cost effectiveness;
- our Risk Evaluation and Mitigation Strategy, or REMS, if any are imposed;
- the effectiveness of our, our contract sales organization's, and our collaborators' sales and marketing strategies;
- the effectiveness of our ability to distribute our products to our customers, including our ability to negotiate the terms of our agreements with third party distributors that are consistent with, or as favorable as, terms that were negotiated when we had a large pharmaceutical partner;
- our and our partners' ability to obtain sufficient third-party coverage or reimbursement; and
- the willingness of patients to pay out of pocket in the absence of third-party coverage.

If Contrave does not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from our product, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product may require significant resources and may never be successful.

We have limited sales and marketing experience and resources.

To date, the marketing of Contrave has been focused on large markets traditionally served by general and family practitioners and internists. General physicians number in the several hundred thousand in the United States and hundreds of thousands outside the United States. Traditional pharmaceutical companies employ groups of sales representatives numbering in the thousands to call on this large generalist physician population. In August 2016, we assumed full responsibility for the continued development and commercialization of Contrave in the United States from our former collaboration partner, Takeda. We have never, as an organization, commercialized a product and there is no guarantee that we will be able to do so successfully. Included in our strategy in the United States is the establishment of a specialty sales force to continue the commercialization of Contrave. While we have established our commercial team and have hired our U.S. sales force, we will need to continue to further develop the team and our marketing strategy in order to successfully market and sell Contrave in the United States which will require significant time and resources and our ability to market and sell our product and generate revenues from Contrave may be delayed or limited. Our sales organization is currently contracted through a contract sales force. Although the new contract sales force consists of sales professionals with experience in the pharmaceutical industry, including many with experience selling weight management products, we cannot assure you that their sales efforts will be effective or produce the results we expect. We will be competing with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Further, we may face difficulties or delays in obtaining and maintaining the required licenses and permits to sell Contrave in individual states and jurisdictions. If our commercialization of Contrave in the United States is unsuccessful or perceived as disappointing, our stock price could decline significantly and the long-term success of the product and our Company could be harmed.

If we do not enter into additional collaboration, distribution or co-promotion arrangements, we may not be able to effectively market and sell Contrave/Mysimba outside the United States and our ability to generate revenues may be delayed or limited.

We have entered into an agreement with a contract sales organization to sell Contrave in the United States. We have an agreement with Valeant Pharmaceuticals for the commercialization of Contrave in certain Central and Eastern European countries, Turkey, Australia, New Zealand and Canada, an agreement with Kwang Dong for commercialization of Contrave in South Korea, an agreement with Consilient for the commercialization of Mysimba in the United Kingdom and Ireland, an agreement with Bruno for commercialization in Italy, and an agreement with Rovi for commercialization of Mysimba in Spain. Together, the Central and Eastern European countries, Turkey, Australia, New Zealand, Canada, South Korea, Spain, the United Kingdom and Ireland, are referred to as the Partnered Regions. In order to expand the market opportunity for Contrave outside the Partnered Regions, we must either establish additional sales and marketing collaborations, additional distribution or co-promotion arrangements or continue to expend significant resources to develop our own sales and marketing presence. We may not be able to enter into additional collaboration, distribution or co-promotion arrangements on acceptable terms, if at all. If we are unable to enter into additional collaboration, distribution or co-promotion arrangements for Contrave/Mysimba in additional geographies and we must develop our own sales and marketing presence to address the physicians in these geographic areas, we will require additional capital and our ability to market and sell our product and generate revenues from our product may be delayed or limited. Even if we do enter into additional collaboration, distribution or co-promotion

arrangements with third parties, we will be reliant on such third parties to successfully develop and/or commercialize our product in these areas. These third parties may fail to develop or effectively commercialize our product because they cannot obtain the necessary regulatory approvals, decide to pursue a competitive potential product that may be developed outside of the collaboration or fail to devote the resources necessary to realize the full commercial potential of our product, especially in light of the resources being devoted by our competitors' collaboration and co-promotion partners. Any such failures would negatively affect our ability to generate revenues from sales of Contrave/Mysimba outside the United States.

We also face competition in our search for collaborators, co-promoters and distributors. If our competitors are able to establish collaboration, distribution or co-promotion arrangements with pharmaceutical companies who have substantially greater resources than we have, our ability to successfully commercialize Contrave/Mysimba outside the United States will be limited and as a result our competitors may be more successful in marketing and selling their products in these geographic areas.

Even though Contrave received regulatory approval from the FDA, the EC and South Korea, it will still be subject to ongoing and continued regulatory review and post-marketing requirements in these countries and elsewhere, which may result in significant expense and limit our ability to commercialize this product.

Even though U.S. regulatory approval has been obtained for Contrave, the FDA has imposed restrictions on its indicated uses and marketing and has imposed ongoing requirements for post-marketing studies and other activities. For example, the approved use of Contrave is limited as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial BMI of 30 kg/m2 or greater (obese), or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related co-morbid condition. The label also contains a "boxed" warning regarding the potential for suicidal thoughts and behaviors and neuropsychiatric reactions as a side effect of the drug. We are also required to conduct a number of post-marketing studies including a series of studies in obese pediatric patients to evaluate the safety and efficacy of Contrave for weight management in pediatric populations and a group of short-term trials, including a thorough QT study, single-dose pharmacokinetic studies in renal and hepatic impairment, and a drug-drug interaction study. Finally, although FDA approval of Contrave was based in part on 25% interim analysis data from the Light Study, which was terminated in May 2015 and which evaluated the CV safety of Contrave, the FDA determined that the Light Study would not satisfy a post-marketing requirement related to CV outcomes. As a result, the FDA is requiring us to conduct a new placebo-controlled CVOT, with a pre-specified goal to exclude a hazard ratio of 1.4, with the upper bound of the 95% confidence interval. A CVOT, which we refer as the CONVENE trial, was initiated by Takeda in February 2016, with the final study results originally expected to be available by January 2022. However, following the termination of our collaboration with Takeda, we determined that the transfer of the recently-initiated, multi-year CONVENE trial to us from Takeda would have involved substantial complexity due to the scope, size and nature of the trial. After a careful assessment, we determined that the transfer of current clinical trial operations and systems may result in a significant interruption to study conduct and possibly data integrity. As a result, Takeda terminated the CONVENE trial in April 2016. We notified the clinical trial sites and the FDA of the decision to terminate the CONVENE trial and we expect to finalize a revised protocol and plan to start a new CVOT under our IND after conferring with the FDA. We cannot assure you that a new CVOT will satisfy the FDA's post-marketing requirements related to CV outcomes or that the FDA will not require us to conduct additional studies during or after the new CVOT. Any issues relating to these restrictions or post-marketing requirements (including any additional studies which the FDA may require or a delay in conducting the post-marketing required studies) could have an adverse impact on our ability to achieve market acceptance of or continue marketing Contrave in the United States and to generate revenue from its sale in the United States. To the extent that Contrave is approved for sale in other countries in addition to the United States, the European Economic Area and South Korea, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

Contrave will also be subject to ongoing requirements established by the FDA and other regulatory authorities in the European Union and elsewhere governing the manufacturing, labeling, packaging, storage, advertising, promotion, recordkeeping and submission of safety and other post-market information, including, among other things, information related to the stability and consistency and reliability of the quality of Contrave (e.g. strength, purity and potency). These requirements include, among other things, submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice, or cGMP, regulations and good clinical practice, or GCP, requirements and related requirements in the European Union and elsewhere for any clinical trials that we conduct post-approval.

Approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. Later discovery of previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or failure to comply with regulatory requirements, may result in, among other things, restrictions on that product or on us or a partner, including:

- withdrawal of the product from the market or voluntary or mandatory product recalls;
- warning letters or untitled letters;
- civil or criminal penalties, including fines;

- withdrawal of regulatory approval;
- suspension of any ongoing clinical trials;
- refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- restrictions on operations, including restrictions on the marketing or manufacturing of the product or the imposition of costly new manufacturing requirements; or
- seizure or detention, or refusal to permit the import or export of products.

In addition, the policies of the FDA and other regulatory authorities in the European Union and elsewhere may change and additional government regulations may be enacted that could impact the marketing of Contrave/Mysimba. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained in the United States, Europe and elsewhere, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our clinical trials, including the CVOT and other post-marketing required studies, may fail to demonstrate acceptable levels of safety or efficacy of Contrave, which could prevent or significantly delay Contrave's regulatory approval in countries outside the United States, the European Union and South Korea and may adversely impact our ability to maintain regulatory approval in the United States and the European Union.

Contrave is prone to the risks of failure inherent in drug development, even following approval from the FDA. Even though U.S. and European Union regulatory approvals have been obtained for Contrave/Mysimba, the FDA has imposed ongoing requirements for post-marketing studies. Any issues relating to these post-marketing requirements (including any additional studies which the FDA may require or a delay in conducting the post-marketing required studies and issues relating to the safety or efficacy of Contrave) could have an adverse impact on our ability to receive regulatory approval outside the United States, to achieve market acceptance of or continue marketing Contrave in the United States and to generate revenue from its sale in the United States. To the extent that Contrave 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.

Before obtaining regulatory approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in adequate and well-controlled clinical trials, and, with respect to approval in other countries, similar regulatory authorities in those countries, that the product candidate is safe and effective for use for that target indication.

In addition, we may need to complete additional preclinical testing of any product candidate to evaluate safety and toxicity and the FDA may require us to conduct additional clinical trials. The results from the preclinical and clinical trials that we have completed for Contrave may not be replicated in future trials, or we may be unable to demonstrate sufficient safety and efficacy to obtain the requisite regulatory approvals for Contrave (outside the United States, the European Union and South Korea) and maintain approval for Contrave in the geographies in which we have approval today. A number of companies in the biotechnology and pharmaceutical industries have suffered significant setbacks in advanced clinical trials, including post-marketing clinical trials, even after promising results in earlier trials. If Contrave is not shown to be safe and effective in clinical trials, our clinical development program could be delayed or terminated. Any delays could also result in the need for additional financing, and our failure to adequately demonstrate the efficacy and safety of any other product candidates that we may develop, in-license or acquire would prevent receipt or maintenance of regulatory approval and, ultimately, the commercialization of that product candidate.

We expect intense competition in the obesity marketplace for Contrave and new products may emerge that provide different or better therapeutic alternatives for obesity and weight loss.

Contrave competes with well-established prescription drugs for the treatment of obesity, including Xenical® (orlistat), marketed by Genentech, Inc. Orlistat has also been launched by GlaxoSmithKline in over-the-counter form under the brand name alli®, which represents additional competition and potential negative pricing pressure. Orlistat is marketed by a pharmaceutical company with substantially greater resources than we have. In addition, a number of generic pharmaceutical products are prescribed for obesity, including phentermine, phendimetrazine, benzphetamine and diethylpropion. Some of these generic drugs, and others, are prescribed in combinations that have shown anecdotal evidence of efficacy. These products are sold at much lower prices than Contrave. The availability of a large number of branded prescription products, including drugs that are prescribed off-label, generic products and over-the-counter products could limit the demand for, and the price we or our partners are able to charge for Contrave and any future products. Vivus, Inc. commercially launched its combination product, phentermine/topiramate, in the United States under the name Qsymia in September 2012. Eisai Inc., the collaboration partner of Arena Pharmaceuticals, Inc., or Arena, commercially launched

lorcaserin in the United States under the name Belviq in June 2013. Moreover, Novo Nordisk's product, Saxenda, received FDA and European Commission approval and commercially launched in the United States in April 2015, with launches in additional markets planned in the future. These products represent additional competition and potential negative pricing pressure with respect to Contrave. Further, if safety concerns about these products' use arise after their launch, such concerns may materially and adversely affect the commercialization of Contrave. Currently, there are a number of drug products in development for obesity which could become competitors against our product.

New developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the nutritional, pharmaceutical and medical technology industries at a rapid pace. These developments may render our product less competitive. Some of our potential competitors are large pharmaceutical or device firms and have substantially greater resources than we have. These resources could be directed toward the obesity market and include:

- research and development resources, including personnel and technology;
- regulatory experience;
- drug development and clinical trial experience;
- experience and expertise in exploitation of intellectual property rights; and
- capital resources.

As a result of these factors, our competitors may more rapidly develop products than we did or may do in the future or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product. Our competitors may also develop drugs or surgical approaches that are more effective, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. In addition, our competitors may be more effective in commercializing their products. We currently outsource our manufacturing and therefore rely on third parties for that competitive expertise. There can be no assurance that we will be able to develop or contract for these capabilities on acceptable economic terms, or at all.

We and our partners are subject to uncertainty relating to reimbursement policies which, if not favorable to Contrave, could hinder or prevent Contrave's commercial success.

Our ability and our partners' ability to commercialize our approved product successfully will depend in part on the extent to which governmental authorities, private health insurers and other third-party payors establish favorable coverage and reimbursement levels for our product and related treatments. As a threshold for coverage and reimbursement, third-party payors generally require that drug products have been approved for marketing by the FDA. Third-party payors also are increasingly challenging the effectiveness of and prices charged for medical products and services. We cannot provide any assurances that we or our partners will be able to obtain adequate third-party coverage or reimbursement for our product in whole or in part.

The obesity therapy market, in particular, continues to be marked by limited coverage and reimbursement from health insurers and other payors, who have historically viewed obesity as a lifestyle issue. For example, state Medicaid programs, administered by individual states for qualifying low-income individuals, are permitted to exclude coverage for weight loss drugs. In addition, weight loss drugs are excluded from coverage under the Medicare Part D prescription drug program for eligible seniors and disabled individuals. Medicare is a federal governmental third-party payor whose policies often are emulated or adopted by other payors. Although the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program, has removed longstanding policy language that obesity itself cannot be considered an illness, the agency interprets the Part D exclusion of weight loss drugs as applying to novel obesity therapies. However, CMS has since issued a national policy covering bariatric surgery for co-morbid conditions associated with obesity, and extended coverage under the Medicare program for intensive behavioral therapy for beneficiaries with obesity. The benefit provides for screening for obesity and counseling for eligible beneficiaries by primary care providers in physician's offices. Although third-party payors' willingness to cover and reimburse obesity-related products and services appears to be changing, as exemplified by Medicare changes, we may continue to face a poor coverage and reimbursement environment.

Currently, Contrave as well as our competitors' drug products have limited third-party payor coverage. This means that individuals prescribed such drug products often either have significant out-of-pocket costs or pay for the products entirely by themselves. If Contrave does not receive adequate coverage or reimbursement, or if patients are unwilling to pay out of pocket for Contrave, the market acceptance and commercial success of Contrave may be limited.

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

As part of our corporate strategy, we may from time to time acquire, in-license, develop and/or market additional products and product candidates. Because our internal research capabilities are limited, we may be dependent upon pharmaceutical and biotechnology companies, academic scientists and other researchers to sell or license products or technology to us. The success of this strategy depends partly upon our ability to identify, select and acquire promising pharmaceutical product candidates and products.

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 and sales 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 in-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.

In addition, past and future acquisitions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- 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.

Further, any product candidate that we have or may in the future acquire may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by the FDA and applicable foreign regulatory authorities. For example, in 2015, we in-licensed from Bath University the rights to two families of opioid molecules. We are currently conducting experiments to replicate the findings of the initial academic research performed. All product candidates, including these opioid molecules, 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 products that we develop or approved products that we may acquire will be commercialized profitably or achieve market acceptance.

Delays in the commencement, the transfer and delivery of clinical trial information, the transition of clinical trials or completion of clinical trials or the requirement to conduct additional clinical trials could result in increased costs to us and delay or limit our ability to continue development programs, maintain or receive additional regulatory approvals and/or generate revenues.

Delays in the commencement, the transfer and delivery of clinical trial information, the transition of clinical trials, including the transition of any post-marketing studies from Takeda to us, or completion of clinical trials could significantly affect our product development costs or adversely impact our ability to maintain or receive additional regulatory approvals. We do not know whether clinical trials will begin on time or whether clinical trials will be completed on schedule, if at all. The commencement, transfer and delivery of clinical trial information, the transition of clinical trials and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- obtaining regulatory approval to commence a clinical trial, including regulatory approval of the design of a clinical trial;
- reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- manufacturing sufficient quantities of a product for use in clinical trials;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at a prospective site;

- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including competition from other clinical trial programs for the treatment of obesity or similar indications and the restrictions imposed by the design and length of a clinical trial;
- retaining patients who have initiated a clinical trial, but may be prone to withdraw due to side effects from the therapy, lack of efficacy or personal issues, or who are lost to further follow-up; and
- timely collection, review and analysis of our clinical trial data.

A clinical trial may be suspended or terminated by us, a development partner, the FDA (or an equivalent regulatory authority outside the United States), the IRB overseeing the clinical trial at issue, any of our clinical trial sites with respect to that site, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- lack of adequate funding or other resources to continue the clinical trial;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; and
- logistical and operational challenges inherent in complex clinical trials.

Additionally, changes in regulatory requirements and guidance for developing products for weight management may occur and we may need to initiate new clinical trials or change protocols of existing clinical trials to account for these changes. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion or termination of clinical trials, may also ultimately lead to the termination of a development program and/or the denial of regulatory approval of a product candidate, including the denial of an NDA or regulatory approval outside the United States.

Contrave may cause undesirable side effects that could delay or prevent commercialization, limit the commercial profile of an approved label, result in significant negative consequences following marketing approval or delay or prevent regulatory approval.

Undesirable side effects caused by our product could cause regulatory authorities to withdraw or limit their approval of the product or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Contrave has been evaluated in four completed Phase III clinical trials, which we refer to collectively as the Contrave Obesity Research, or COR, program. Across the entire COR program, seven patients experienced serious adverse events that were attributed by investigators as possibly related or related to Contrave treatment. These consisted of cholecystitis (gallbladder inflammation) (2), seizure (2), palpitations (1), paresthesia (1) and vertigo (1). The most frequently observed treatment-emergent adverse events were nausea, constipation, headache, vomiting, dizziness, insomnia, dry mouth and diarrhea. Nausea was the leading adverse event resulting in discontinuation; however, for the majority of patients experiencing nausea, it was mild to moderate, transient and manageable. In the Light Study 50% interim analysis, which interim analysis was completed in connection with the termination of the Light Study in 2015 and was designed only as an early and preliminary assessment of safety to support regulatory approvals of Contrave, there were no unexpected new safety signals observed. Serious adverse events and adverse events leading to discontinuation were generally consistent with the overall safety profile established in the COR program. However, a larger number of CV events are required to determine the effect of Contrave on CV outcomes and these safety conclusions may change in connection with the required post-marketing CVOT.

The safety data we have disclosed to date represents our interpretation of the data at the time of disclosure and it is subject to our further review and analysis. Serious adverse events have been reported to the FDA (and an equivalent applicable regulatory authority) and study investigators as required in accordance with current guidelines and standards. Serious adverse events that are not characterized by clinical investigators as possibly related to our study drug or adverse events that occur in small numbers may not be disclosed to the public until such time the various documents submitted to the FDA as part of the approval process are made public. We are unable to determine if the subsequent disclosure of adverse events will have an adverse effect on our stock price. In addition, our interpretation of the safety data from our clinical trials is contingent upon the review and ultimate approval of the FDA. The FDA may not agree with our methods of analysis or our interpretation of the results.

In addition, the constituent drugs of our product each has its own side effect profile that is included in the respective current product label. Contrave's label includes the side effect profiles of each of its constituent drugs, including a "boxed" warning regarding the potential for suicidal thoughts and behaviors and neuropsychiatric reactions as a side effect of the drug. Moreover, patients may experience side effects that are indicated in the constituent drugs' labels, as was the case with the side effects experienced by patients in our clinical trials of Contrave. In addition, while the constituent drugs that make up Contrave have post-marketing safety records and while we have tested these constituent drugs in combination in our clinical trials of Contrave to date, the safety of the combined

use of the constituents of Contrave is not yet fully known, and any future trials may produce side effects not observed to date. Any of the side effects of Contrave, or its individual constituent drugs, could limit the commercial profile of the approved label.

Further, if we or others, including our partners, identify undesirable side effects caused by the recently launched Contrave, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of the product;
- regulatory authorities may require the addition of labeling statements, such as an additional "boxed" warning with Contrave or an additional contraindication;
- we may be required to change the way the product is distributed or administered, to conduct additional clinical trials or to change the labeling of the product;
- we or our partners may decide to remove the products from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product; and
- our reputation may suffer.

Any of these events could prevent us and our partners from achieving or maintaining market acceptance of Contrave or any other affected product candidate and could substantially increase the costs of commercializing Contrave and significantly impact our ability and our partners' ability to successfully commercialize Contrave and generate revenues.

We rely primarily on third parties to assist us in the conduct of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to commercialize our product within our expected timeframes or at all.

We expect to use a CRO to assist us with monitoring, oversight and statistical support for the post-marketing requirements for Contrave/Mysimba, including the CVOT. The third parties with whom we contract for execution of our clinical trials play a significant role in the conduct of our clinical trials and the subsequent collection, review and analysis of data. These third parties, including CROs and investigators, are not our employees, and we have limited ability to control the amount or timing of resources that they devote to our programs. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and that our regulatory filings are consistent with regulatory requirements. Our reliance on CROs does not relieve us of our regulatory responsibilities. We and our CROs that assist us with our clinical studies are required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and regulatory authorities may not accept the clinical data in support of our marketing applications or in connection with our post-marketing commitments. We cannot assure you that upon inspection by a given regulatory authority, such authority will determine that any clinical trial complied with GCP requirements. In addition, our clinical trials must be conducted with product produced under cGMP regulations. If our CROs, consultants or independent investigators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard or fails to comply with regulatory requirements, it may adversely impact the commercialization of our product. In addition, the execution of clinical trials, the subsequent compilation, review and analysis of the data produced and the preparation of regulatory applications requires coordination among various parties. In order for these functions to be carried out effectively and efficiently, it is imperative that these parties provide the necessary resources and communicate and coordinate with one another. If these third parties are unable to provide the necessary resources or coordinate and communicate with one another, our clinical trials may be delayed or the completion and analysis of the data and the related regulatory applications may be delayed or compromised. Moreover, these third parties may also have relationships with other commercial entities, some of which may compete with us. If these third parties also contract to provide services for our competitors, it could adversely affect our business.

If the contract manufacturers upon whom we rely fail to produce our product in the volumes that we require on a timely basis, or fail to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we and our partners may face delays in the development and commercialization of Contrave.

We do not currently possess nor do we plan to implement manufacturing or packaging processes internally. We currently utilize the services of contract manufacturers to manufacture and package our clinical and commercial supplies. These supplies include the formulations of our product's APIs from our API suppliers, the tablets combining those components and the materials used to package these tablets for commercial use and use in clinical trials. If the contract manufacturers upon whom we rely fail to produce our product in the volumes required on a timely basis, we may face delays in the continued development and commercialization of Contrave.

In March 2010, we entered into a long-term manufacturing services agreement, or manufacturing agreement, with Patheon Pharmaceuticals and Patheon Inc., which we collectively refer to as Patheon, pursuant to which Patheon has agreed to manufacture commercial quantities of our Contrave tablet products. Under the terms of the manufacturing agreement, as amended by the parties in November 2013, we are required to purchase from Patheon a certain percentage of our requirements for Contrave tablet products intended for commercial sale, provided certain terms and conditions are met. The initial term of the manufacturing agreement commenced in March 2010 and shall continue in effect until December 31, 2019. Upon expiration of the initial term, the agreement will be automatically renewed for additional two year terms. Patheon may terminate the manufacturing agreement at any time upon specified prior written notice to us. We may also terminate the manufacturing agreement with specified prior written notice to Patheon, subject to our payment of certain termination amounts. Either party may terminate the manufacturing agreement effective immediately upon written notice to the other in the event that (a) the other party dissolves, or is declared insolvent or bankrupt by a court of competent jurisdiction, (b) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction, or (c) the manufacturing agreement is assigned for the benefit of creditors. We may terminate the manufacturing agreement upon specified prior written notice if any governmental or regulatory authority, including, but not limited to, the FDA, takes any action, or raises any objection, that prevents us from importing, exporting, purchasing or selling Contrave tablet products. We are also required to give specified advance notice if we intend to no longer order commercial supplies of Contrave tablet products pursuant to the manufacturing agreement due to the product's discontinuance in the market. Patheon may terminate the manufacturing agreement upon specified prior written notice to us if we assign any of our rights under the manufacturing agreement to an assignee that, in the opinion of Patheon acting reasonably, is (a) not a credit worthy substitute for us, or (b) a competitor of Patheon. Moreover, either party may terminate the manufacturing agreement upon written notice to the other party where the other party has failed to remedy a material breach of any of its representations, warranties, or other obligations under the manufacturing agreement within a specified period of time following receipt of a written notice of the breach, subject to specified terms and conditions.

If we change to other manufacturers in the future, the FDA and comparable foreign regulators must approve these manufacturers' facilities and processes prior to use, which would require new clinical studies, testing and compliance inspections, and the new manufacturers would have to be educated in or demonstrate successful technology transfer of the processes necessary for the production of our product.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up for commercial production. These problems include difficulties with production costs and yields, quality control, including stability of the product and quality assurance testing, shortages of qualified personnel and production capacity, equipment failures as well as compliance with strictly enforced federal, state and foreign regulations, which include product requirements established by the FDA or other regulatory agencies and stability requirements in other foreign countries that our current product candidate formulations may not be able to meet. If our manufacturers were to encounter any of these difficulties in the United States or in other foreign countries or otherwise fail to comply with their obligations to us, or if we do not accurately forecast our demand, our ability to support the commercial sale of Contrave or to provide product to patients in our clinical trials would be jeopardized. Moreover, our API suppliers acquire the raw materials necessary to make Contrave API from a limited number of sources. Naltrexone, in particular, comes from a very limited number of sources. Any delay or disruption in the availability of these raw materials or a change in raw material suppliers could result in production disruptions, delays or high costs with consequent adverse effects on us. Any delay or interruption in our ability to meet commercial demand for Contrave will result in the loss of potential revenues. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining a clinical trial program and, depending upon the period of delay, require us to commence new trials at significant additional expense or terminate the trials completely.

In addition, all manufacturers of our products must comply with cGMP requirements enforced by the FDA through its facilities inspection program. These requirements may be revised from time to time and include, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. Manufacturers of our products may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we are ultimately responsible for ensuring that our contract manufacturers operate in accordance with cGMP requirements and have implemented a quality oversight program, we have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval and/or commercialization, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our manufacturers' failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize Contrave or obtain regulatory approval for or successfully complete any required clinical trials, and we may be held liable for any injuries sustained as a result. Any of these factors could cause a delay in the sale of Contrave or any of its clinical trials, entail higher costs or result in our or our partners being unable to effectively commercialize Contrave. Furthermore, if our manufacturers fail to deliver the required commercial quantities on a timely basis, pursuant to provided specifications and at commercially reasonable prices, we and our partners may be unable to meet demand for Contrave and would lose potential revenues. Now that we have sole responsibility for the commercialization of Contrave in the United States, in the future we may not be able to negotiate terms that are consistent with, or as favorable as, terms that were negotiated when we had a large pharmaceutical company as our collaboration

partner. To the extent that Contrave is approved for sale in other geographies in addition to the United States, Europe and South Korea, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those geographies.

There are labeled adverse side effects to the individual use of bupropion and naltrexone.

A key constituent of Contrave is bupropion, which has been approved by the FDA for the treatment of depression and to assist smoking cessation. The FDA has directed manufacturers of all antidepressant drugs to include in their product labels a "boxed" warning and expanded warning statements regarding an increased risk of suicidal thinking and behavior in children and adolescents being treated with these drugs. The package insert for bupropion includes such a "boxed" warning statement. In December 2006, the FDA held an advisory committee meeting regarding suicidal thinking and behavior in adults being treated with antidepressant drugs. The advisory committee recommended that the "boxed" warning be extended to cover adults up to their mid-20s. The package insert for Contrave includes a "boxed" warning regarding the potential for suicidal thoughts and behaviors and neuropsychiatric reactions as a side effect of the drug. To the extent that any additional warnings or labeling changes related to suicidal thinking and behavior in adults are required, we expect that any such additional warnings or other labeling changes will also be required on labeling for Contrave. In July 2009, the FDA issued a news release announcing that it was requiring manufacturers to put a "boxed" warning on the prescribing information for smoking cessation drugs including Zyban®, which is a branded form of bupropion. The warning highlights the risk of serious mental health events including changes in behavior, depressed mood, hostility, and suicidal thoughts. Although Contrave is not intended to be promoted for or used in the treatment of major depression or smoking cessation, a similar warning is included in the labeling for Contrave, particularly because it is likely that there will be obese patients who smoke or depressed obese patients who will use Contrave.

The FDA has also directed manufacturers of antidepressant drugs to create Medication Guides to be distributed to patients regarding the risk of suicidal thinking and behavior in children and adolescents. Although we have not included children or adolescents in the Contrave clinical trials, the FDA required us to create a Medication Guide for Contrave. These warnings and other requirements may have the effect of limiting the market acceptance by targeted physicians and patients of Contrave.

The other constituent of Contrave, naltrexone, has been approved by the FDA for the treatment of alcohol and opioid dependence. The FDA has directed the manufacturers of naltrexone for these indications to include in their product labels a "boxed" warning and expanded warnings statements regarding hepatotoxicity, or liver toxicity. A similar warning statement is included in the labeling for Contrave.

Each of the constituent drugs included in the Contrave combination has in its package insert a "Category C" pregnancy precaution. This means that animal studies have shown that each of these constituent drugs has the potential to cause birth defects and that there have been no adequate and well-controlled studies of the constituent drugs in pregnant women, but that the FDA has determined that the benefits from the use of such drugs in pregnant women may be acceptable despite the potential risks. In addition, although Contrave is not known to be teratogenic, it appears from a recent FDA action, in which the FDA stated that weight loss offers no potential benefit to a pregnant woman and may result in fetal harm, that the FDA is likely to classify all weight loss pharmaceutical products as Category X. Contrave, the obesity therapeutics approved by the FDA in 2012 and Orlistat all have Category X pregnancy precautions.

Any of these known side effects and any associated warning statements or classification or categorization of risk may limit the commercial profile of the approved label for Contrave and prevent us from achieving or maintaining market acceptance of Contrave.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and we may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, resulting in damage to our reputation and business.

The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about approved drugs, such as Contrave. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling, also known as "off-label" promotion. Physicians may nevertheless use our product for their patients in a manner that is inconsistent with the approved label, as the FDA does not restrict or regulate a physician's choice of treatment within the practice of medicine. If the FDA determines that our promotional materials or training or the statements made by our sales representatives constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, which could have an adverse impact on our reputation and financial results. Moreover, in the European Union, direct-to-consumer advertising for a prescription only medicine is expressly prohibited by law.

If the suppliers upon whom we rely for API fail to produce such ingredients in the volumes that we or our partners require on a timely basis, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we or our partners may face delays in the further development or commercialization of Contrave.

We do not manufacture any of our API nor do we plan to develop any capacity to do so. Instead, we rely on suppliers of API to provide component materials to our other contract manufacturers, who produce finished pharmaceutical products incorporating the API. The failure or inability of our API suppliers to satisfy our API requirements on a timely basis could limit or halt our ability to sell Contrave in the United States, the European Union or elsewhere that we have or may receive regulatory approval for sale.

Although naltrexone itself is not addictive, synthesis of naltrexone is a multi-step process with a natural opiate starting material that has the potential for abuse and is therefore regulated as a controlled substance under the federal Controlled Substances Act or applicable foreign equivalents. As such, manufacturers of naltrexone API must be registered with the Drug Enforcement Administration, or DEA, or applicable foreign equivalents. Manufacturers making naltrexone also must obtain annual quotas from the DEA for the opiate starting material. Because of the DEA-related requirements and modest current demand for naltrexone API, there currently exist a limited number of manufacturers of this API. Therefore, API costs for naltrexone are greater than for the other constituents of our product. Demand for Contrave may require amounts of naltrexone greater than the currently available worldwide supply or our or our partners' current forecasts for the supply to us of Contrave or its components. Any lack of sufficient quantities of naltrexone would limit our ability to continue to commercialize Contrave in the United States and complete any additional required clinical trials and would limit our ability to commercialize Contrave/Mysimba outside the United States and Europe. Although we are evaluating additional possible manufacturers to supplement our current naltrexone manufacturing capacity, including those in the United States and Europe, we may not be successful in accessing additional manufacturing supply of naltrexone API or other necessary components of our product at the appropriate quantities, quality or price.

We have no material, long-term commitments or supply agreements with any of our API suppliers. Although we may seek to establish additional long-term supply commitments in the future, we may be required to agree to minimum volume requirements, exclusivity arrangements or other restrictions. We may not be able to enter into long-term agreements on commercially reasonable terms, or at all. Consequently, we and our partners may not be able to successfully commercialize Contrave if we are unable to secure long-term supply commitments for its API components. Further, now that we have sole responsibility for the commercialization of Contrave in the United States, in the future we may not be able to negotiate terms that are consistent with, or as favorable as, terms that were negotiated when we had a large pharmaceutical company as our collaboration partner.

In addition, our API suppliers must comply with cGMP requirements enforced by the FDA through its facilities inspection program and must maintain and comply with their respective DMFs on file with the FDA or other similar regulatory bodies. These requirements include, among other things, quality control, quality assurance and the generation and maintenance of records and documentation. Suppliers of our API may be unable to comply with these cGMP requirements and with other FDA, state and foreign regulatory requirements. While we are ultimately responsible for ensuring that our contract manufacturers operate in accordance with cGMP requirements and have implemented a quality oversight program, we have little control over our manufacturers' compliance with these regulations and standards. A failure to comply with these requirements may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval. If the safety of any product supplied is compromised due to our suppliers' failure to adhere to applicable laws or for other reasons, we may not be able to successfully commercialize Contrave, and we may be held liable for an injuries sustained as a result. Any of these factors could cause a delay of clinical trials or commercialization of Contrave, entail higher costs or result in our and our partners being unable to effectively commercialize our product. Furthermore, if our suppliers fail to deliver the required commercial quantities of API on a timely basis, pursuant to the required specifications set forth in their respective DMF and at commercially reasonable prices, and we are unable to timely secure and qualify additional suppliers with applicable regulatory authorities, we and our partners may not be able to successfully commercialize Contrave and/or we and our partners may be unable to meet demand for our product and would lose potential revenues. To the extent that Contrave is approved for sale in other countries in addition to the United States and Europe, we may be subject to similar restrictions and requirements imposed by laws and government regulators in those countries.

Contrave is a combination of generically-available pharmaceutical products, and our success is dependent on our ability and our partners' ability to compete against off-label generic substitutes and demonstrate the advantages of our proprietary combination products.

Off-label use occurs when physicians prescribe a drug that is approved by the FDA for one indication for a different, unapproved indication. We believe that a practitioner seeking safe and effective therapy is not likely to prescribe such off-label generics in place of Contrave because the dosage strengths, pharmacokinetic profiles and titration regimens recommended for Contrave are not available using existing generic preparations of immediate release, or IR, naltrexone and bupropion ER, and there are no oral generic ER formulations of naltrexone. However, a physician could seek to prescribe off-label generics in place of Contrave. Such off-label prescriptions could significantly diminish the market potential of our product and significantly impact our ability to generate revenues.

With regard to off-label substitution at the pharmacy level, we expect to rely on the novel dose ratios and novel pharmacokinetic properties of our product, as well as the differences in its approved indications, to provide sufficient distinction such that generic preparations are not considered therapeutic equivalents by the FDA. State pharmacy laws in many instances only permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents. Therefore, the lack of therapeutic equivalency should limit generic substitution by pharmacies and/or pharmacy benefit managers. However, we cannot be certain that pharmacists and/or pharmacy benefit managers will not seek prescriber authorization to substitute generics in place of Contrave, which could significantly diminish their market potential and significantly impact our ability and our partners' ability to successfully commercialize our product and generate revenues.

In addition, although we believe the current market prices for the generic forms of naltrexone make generic substitution by physicians, pharmacists or pharmacy benefit managers unlikely, should the prices of the generic forms decline, the motivation for generic substitution may become stronger. Wide scale generic substitution by physicians and at the pharmacy level could have substantial negative consequences to our business.

Our development and commercialization strategy depends upon access to findings of safety and effectiveness based on data not developed by us but which the FDA may reference in reviewing our U.S. marketing applications. In territories outside the United States, we must either negotiate access to these safety and effectiveness findings or develop them ourselves.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act. 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. This statutory provision expressly allows the FDA to rely, for purposes of approving an NDA, on findings of safety and effectiveness based on data not developed by the filer of the NDA. Under these guidelines, we were able to move directly into Phase II clinical trials for Contrave, because our NDA for Contrave relied, in part, upon the FDA's findings of safety and effectiveness for the previously-approved products that are incorporated into Contrave. Similar legislation for active substances with well-established medicinal use exists in the European Union under article 10a of European Directive 2001/83/EC, which allows for reference to scientific literature if active substances have been approved for at least ten years with recognized efficacy and an acceptable level of safety. There also are alleviations under article 10b of European Directive 2001/83/EC of the obligation to provide scientific references relating to individual active substances in combination products if such individual active substances have been previously authorized in the European Union, although not the obligation to provide results of new pre-clinical tests or new clinical trials relating to such combination products, which could provide an alternative pathway in Europe. In territories where data are not freely available, we may not have the ability to commercialize our products without negotiating rights from third parties to refer to their clinical data in our regulatory applications, which could require the expenditure of significant additional funds to generate our own data. We may be unable to obtain rights to the necessary clinical data and may be required to develop our own proprietary safety and manufacturing dossiers. In addition, even though we have taken advantage of Section 505(b)(2) for approval of Contrave, the FDA may also require us to perform additional studies or measurements to support changes from the previously-approved products incorporated into our product.

To the extent that a Section 505(b)(2) application relies on the FDA's finding of safety and effectiveness of a previously-approved drug, the applicant is required to make certifications to the FDA with respect to any patents listed for the approved product in the FDA's publication called "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the "Orange Book." Specifically, the applicant must certify when the application is submitted that: (1) there is no relevant patent information listed; (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 manufacture, use, or sale of the new product. A certification that the new product will not infringe the already approved product's Orange Book listed patents or that such patents are invalid is called a paragraph IV certification. If the 505(b)(2) applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA holder and patent owner. We have made paragraph IV certifications that Contrave does not infringe the bupropion ER formulation patents listed in the Orange Book, and have sent the appropriate notice to the patent holder and NDA holder.

We have received three year Hatch Waxman exclusivity in the U.S. for Contrave, but have already received patent certifications and are engaged in litigation that may permit the FDA to approve an ANDA to Contrave as early as October 2017.

We have obtained three years of Hatch-Waxman marketing exclusivity for Contrave from the date of approval by the FDA on September 10, 2014. Under this form of exclusivity, the FDA is precluded from approving a 505(b)(2) NDA or ANDA for the same drug product for the protected indication (for example, a product that incorporates the change or innovation represented by our product) for a period of three years, although the FDA may accept and commence review of such applications. In April 2015, we and Takeda received notification of a Paragraph IV certification for certain patents for Contrave which are listed in the FDA's Orange Book. The certification resulted from the filing by Actavis Laboratories FL, Inc. of an ANDA challenging such patents for Contrave. In June 2015, we and Takeda filed a lawsuit in the U.S. District Court for the District of Delaware against Actavis Laboratories Fl.,

Inc. and certain of its affiliates, which we refer to collectively as Actavis, on the basis that Actavis' proposed generic products infringe certain patents for Contrave. In accordance with the Hatch-Waxman Act, as a result of having filed a lawsuit within 45 days of the Paragraph IV certification notice, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from Takeda's receipt of the notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to our complaint, and in August 2015, we and Takeda filed an answer to Actavis' counterclaims. Moreover, in July 2015, the court ordered a stipulation between us, Takeda and Actavis in which we and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September 2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, we and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, we and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted our proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between us and Takeda, Takeda transferred to us the responsibility for management of this patent infringement lawsuit. Although we plan to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome. However, the Hatch-Waxman marketing exclusivity might not prevent the FDA from approving a 505(b)(1) NDA that relies on its own clinical data. Further, if another company obtains approval for an identical product candidate for the same new indication we are studying before we do, our approval of the new indication could be blocked until the other company's Hatch-Waxman marketing exclusivity expires, unless we conduct additional studies in support of a 505(b)(1) NDA.

We may never receive approval or commercialize our products outside of the United States, the European Union and South Korea.

In order to market any products outside of the United States, the European Union and South Korea, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety, efficacy and manufacturing. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. 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 have a negative effect on the regulatory process in others. In August 2015, we entered into a distributorship agreement with Kwang Dong through our wholly owned subsidiary. Kwang Dong began marketing Contrave in South Korea in June 2016.

Failure to obtain regulatory approval for Contrave in other countries outside of the United States, the European Union and South Korea, or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. As described above, such effects include the risks that Contrave may not be approved for all indications requested, which could limit the uses of Contrave and have an adverse effect on their commercial potential or require costly, post-marketing follow-up studies.

A variety of risks associated with operating our business and marketing our product internationally could materially adversely affect our business.

In addition to our U.S. operations, we have a subsidiary in Ireland and may establish additional international business entities in the future. We face risks associated with our international operations, including possible unfavorable regulatory, pricing and reimbursement, political, tax and labor conditions, which could harm our business. We are subject to numerous risks associated with international business activities, including:

- compliance with differing or unexpected regulatory requirements for Contrave and any future products;
- compliance with Irish laws and the maintenance of our Irish tax residency for our Irish subsidiary, which may make certain corporate actions more cumbersome, costly and time-consuming;
- difficulties in staffing and managing foreign operations;
- foreign government taxes, regulations and permit requirements;
- U.S. and foreign government tariffs, trade restrictions, price and exchange controls and other regulatory requirements;
- anti-corruption laws, including the Foreign Corrupt Practices Act, or the FCPA;
- economic weakness, including inflation, natural disasters, war, events of terrorism or political instability in particular foreign countries;

- fluctuations in currency exchange rates, which could result in increased operating expenses and reduced revenues, and other obligations related to doing business in another country;
- compliance with tax, employment, immigration and labor laws, regulations and restrictions for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- changes in diplomatic and trade relationships.

Our business activities outside of the United States are subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the U.K.'s Bribery Act 2010, or the U.K. Bribery Act. The FCPA and similar anti-corruption laws generally prohibit the offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to non-U.S. government officials in order to improperly influence any act or decision, secure any other improper advantage, or obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the company and to devise and maintain an adequate system of internal accounting controls. The U.K. Bribery Act prohibits giving, offering, or promising bribes to any person, including non-U.K. government officials and private persons, as well as requesting, agreeing to receive, or accepting bribes from any person. In addition, under the U.K. Bribery Act, companies which carry on a business or part of a business in the U.K. may be held liable for bribes given, offered or promised to any person, including non-U.K. government officials and private persons, by employees and persons associated with the company in order to obtain or retain business or a business advantage for the company. Liability is strict, with no element of a corrupt state of mind, but a defense of having in place adequate procedures designed to prevent bribery is available. Furthermore, under the U.K. Bribery Act there is no exception for facilitation payments. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the health care providers who prescribe pharmaceuticals are employed by their government and the purchasers of pharmaceuticals are government entities; therefore, any dealings with these prescribers and purchasers may be subject to regulation under the FCPA. Recently the SEC and the U.S. Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. In addition, under the Dodd–Frank Wall Street Reform and Consumer Protection Act, private individuals who report to the SEC original information that leads to successful enforcement actions may be eligible for a monetary award. We are engaged in ongoing efforts that are designed to ensure our compliance with these laws, including due diligence, training, policies, procedures and internal controls. However, there is no certainty that all employees and third-party business partners (including our distributors, wholesalers, agents, contractors, and other partners) will comply with anti-bribery laws. In particular, we do not control the actions of manufacturers and other third-party agents, although we may be liable for their actions. Violation of these laws may result in civil or criminal sanctions, which could include monetary fines, criminal penalties, and disgorgement of past profits, which could have a material adverse impact on our business and financial condition.

These and other risks associated with our international operations may materially adversely affect our business, financial condition and results of operations.

We face potential product liability exposure, and, if successful claims are brought against us, we may incur substantial liability.

The use of our product in clinical trials and the sale of our product expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health-care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. If we cannot successfully defend ourselves against product liability claims, we could incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our product;
- impairment of our business reputation;
- 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;
- loss of revenues; and
- the inability to commercialize our product.

Although we have commercial product liability insurance, which includes coverage for our ongoing and future clinical trials we perform, our insurance coverage may not be sufficient to reimburse 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 or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. 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 adversely affect our business.

Healthcare reform measures could hinder or prevent our product's commercial success.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems to contain healthcare costs and improve quality. While reform proposals often involve expanding coverage to more individuals, healthcare reform may also involve increased government price controls, additional regulatory mandates and other measures designed to lower medical and pharmaceutical costs. Within the United States, the pharmaceutical industry has been a particular focus of healthcare reform both federally and at the state level.

For example, in March 2010, the President signed into law one of the most significant health reform measures in decades. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the PPACA, substantially changes the way healthcare is financed by both governmental and private insurers, including several payment reforms that establish payments to hospitals and physicians based in part on quality measures, subjects biologic products to potential competition by lower-cost "biosimilars," and significantly impacts the pharmaceutical and medical device industries. The PPACA includes, among other things, the following measures:

- annual, non-deductible fees on any entity that manufactures or imports certain prescription branded drugs and biologics;
- increased Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program for both branded and generic drugs and expanded rebates owed by manufacturers to include rebates on Medicaid managed care utilization;
- a Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical research;
- requirements for manufacturers to discount drug prices to eligible patients in the coverage gap by 50% at the pharmacy level and for mail order services in order for their outpatient drugs to be covered under Medicare Part D;
- an extension of eligibility criteria for Medicaid programs;
- an increase in the number of entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and
- a licensure framework for follow-on biologic products.

The PPACA provisions on comparative clinical effectiveness research extend the initiatives of the American Recovery and Reinvestment Act of 2009, also known as the stimulus package, which included $1.1 billion in funding to study the comparative effectiveness of healthcare treatments and strategies. This stimulus funding was designated for, among other things, conducting, supporting or synthesizing research that compares and evaluates the risks and benefits, clinical outcomes, effectiveness and appropriateness of products. The PPACA also appropriates additional funding to comparative clinical effectiveness research. Although Congress has indicated that this funding is intended to improve the quality of healthcare, it remains unclear how the research will impact current Medicare coverage and reimbursement or how new information will influence other third-party payor policies.

In addition, the PPACA provides for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement, including obesity reduction and obesity-related services that are available to Medicaid enrollees. The PPACA also provides funding for projects designed to reduce childhood obesity.

Other legislative changes have also been proposed and adopted since the PPACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, following passage of the Bipartisan Budget Act of 2015, will stay in effect through 2025, unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals.

In the European Union and some other international markets, governments or payors have adopted local policy to contain costs for provisions of health care at low cost to consumers and regulates pharmaceutical prices, patient eligibility or reimbursement levels to control costs for the government-sponsored health care system. Many countries have announced or implemented measures to reduce health care costs to constrain their overall level of government expenditures. These measures vary by country and may include, among other things, patient access restrictions, suspensions on price increases, prospective and possibly retroactive price reductions and other recoupments and increased mandatory discounts or rebates, recoveries of past price increases, and greater importation of drugs from lower-cost countries to higher-cost countries. If our product is approved in these markets, these measures may negatively impact our revenues. In addition, certain countries set prices by reference to the prices in other countries where approved products are marketed. Thus, our inability to secure adequate prices for our products, if approved, in a particular country may not only limit the marketing of these products within that country, but may also adversely affect our ability to obtain acceptable prices in other markets. This may create the opportunity for third party cross border trade or influence our decision to sell or not to sell a product, if approved, thus adversely affecting our revenues.

We cannot predict what effect the PPACA or other healthcare reform or cost control initiatives that may be adopted in the future will have on our business. Further, there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law, and we expect there will be additional challenges and amendments to the Health Care Reform Law in the future, particularly with the change in Administration. The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care services to contain or reduce costs of health care may adversely affect:

- our ability to set a price we believe is fair for our approved product;
- our ability to generate revenues and achieve or maintain profitability; and
- the availability of capital.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management, commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses, particularly in the San Diego, California area. Our retention efforts may be particularly challenging in light of the difficult regulatory climate for obesity drugs and the recent departures among our senior management team. Our industry has experienced a high rate of turnover of management personnel in recent years. As our business continues to grow, and we continue to transition from primarily a drug development company to a commercial product organization, we expect to experience changes in our executive team, including potential departures and the addition of new executives with commercialization expertise or other necessary skill sets. We may also experience some departures from our current executive team as individuals transition to new experiences and/or retirement. If we are not able to attract, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the successful development and commercialization of Contrave/Mysimba, our ability to raise additional capital and our ability to implement our overall business strategy.

We are highly dependent on the development, regulatory, commercial and financial expertise of our senior management, particularly Michael A. Narachi, our President and Chief Executive Officer and Thomas Cannell, our Chief Operating Officer and President of Global Commercial Products. Although we have employment agreements with each of our executive officers, these agreements are terminable at will at any time with or without notice and, therefore, we may not be able to retain their services as expected. If we lose any members of our senior management team, including Messrs. Narachi and Cannell, we may not be able to find suitable replacements, and our business may be harmed as a result. We are not aware of any key personnel who has plans to retire or leave our company in the immediate future. In addition to the competition for personnel, the San Diego area in particular is characterized by a high cost of living. 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.

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

If we fail to comply with healthcare laws and regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights, among other topics, may 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, without limitation. The healthcare laws and regulations that may affect our ability to operate include:

- the federal Anti-Kickback Statute (as amended by the PPACA, which modified the intent requirement of the federal Anti-Kickback Statute so that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation), which prohibits, among other things, persons and entities from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;
- federal false claims laws, including the civil False Claims Act, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and which may apply to entities like us which promote pharmaceutical products and provide coding and billing advice to customers, and under the PPACA, 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 laws;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, and their implementing regulations, which imposes certain requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information;
- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state 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.

Additionally, the compliance environment is changing, with more states mandating implementation of compliance programs, compliance with industry ethics codes, and spending limits, and other states requiring reporting to state governments of gifts, compensation, and other remuneration to physicians. The PPACA also imposes annual reporting and disclosure requirements on certain device and drug manufacturers for which payment is available for their products under Medicare, Medicaid, or the Children's Health Insurance Program, for any "transfer of value" made or distributed to physicians and teaching hospitals. Such information is now publicly available in a searchable format. In addition, device and drug manufacturers are also required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Manufacturers were required to begin collecting requisite information on August 1, 2013, with the first reports due in 2014. Failure to submit requisite information may result in civil monetary penalties of up to an aggregate of $150,000 per year (and up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Further, under the PPACA, pharmaceutical manufacturers and distributors must provide the U.S. Department of Health and Human Services with an annual report on the drug samples they provide to physicians. The shifting regulatory environment, along with the requirement to comply with multiple jurisdictions with different compliance and/or reporting requirements, increases the possibility that a pharmaceutical company may run afoul of one or more laws.

If 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 and the curtailment or restructuring of our operations. Any penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, imprisonment, contractual damages, reputational harm, and the curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. 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 business involves the use of hazardous materials and we and our third-party manufacturers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

Our third-party manufacturers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product and other hazardous compounds. We and our manufacturers are subject to federal, state and

local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of an accident, state or federal authorities may curtail the use of these materials and interrupt our business operations. We do not currently maintain hazardous materials insurance coverage. If we are subject to any liability as a result of our third-party manufacturers' activities involving hazardous materials, our business and financial condition may be adversely affected.

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 CROs and other 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 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 drug development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for, could result in delays in our regulatory efforts and significantly increase our costs to recover or reproduce the data. 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 development of our product could be delayed.

Risks Related to Intellectual Property

Our market opportunity for Contrave may be limited by the relatively small number of issued U.S. patents and foreign patents that we own or in-license. In addition, although we have additional U.S. and international patent applications pending which seek further protection of our product, these applications may not issue on a timely basis or at all.

Contrave is currently protected by U.S. patent number 7,375,111, which we refer to as the Weber/Cowley composition patent, and U.S. patent number 7,462,626, which we refer to as the Weber/Cowley methods patent. Provided maintenance fees are paid, the Weber/Cowley composition patent is expected to expire in March 2025, and the Weber/Cowley methods patent is expected to expire in July 2024. Collectively, we refer to the Weber/Cowley composition patent and the Weber/Cowley methods patent as the Weber/Cowley patents. We own the Weber/Cowley patents, but they are subject to our license agreement with Oregon Health & Science University, or OHSU. The Weber/Cowley patents cover the current composition of Contrave and methods of administering it to treat obesity. We and/or our licensors have filed a number of international counterparts to the Weber/Cowley patents in foreign countries. A European counterpart application to the Weber/Cowley patent has issued in the European Patent Office, or EPO, as EP1617832B1, and provides protection for Contrave in the various EPO countries in which the patent has been registered. Several international counterparts to the Weber/Cowley patents have also issued in other foreign jurisdictions. However, we cannot provide assurance that other pending international counterparts will issue on a timely basis or at all. There is also no assurance that the currently pending claims in those foreign countries will not be rejected, that any such rejections and any future rejections will ultimately be overcome, nor that any claims that may issue will be sufficiently broad to protect Contrave in those foreign countries. Furthermore, we cannot be certain that the scope of any issued foreign patent will be consistent with the currently pending claims, as there is a significant likelihood that the scope of the currently pending claims will be modified. If a competitor is willing to challenge the scope or validity of the Weber/Cowley patents, the competitor could file an NDA seeking approval for three years after the date we obtained approval from the FDA of the NDA for Contrave. For example, in April 2015, we and Takeda received notification of a Paragraph IV certification for certain patents for Contrave which are listed in the FDA's Orange Book. The certification resulted from the filing by Actavis of an ANDA challenging such patents for Contrave. In June 2015, we and Takeda filed a lawsuit in the U.S. District Court for the District of Delaware against Actavis on the basis that Actavis' proposed generic products infringe certain patents for Contrave. In accordance with the Hatch-Waxman Act, as a result of having filed a lawsuit within 45 days of the Paragraph IV certification notice, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from Takeda's receipt of the notice or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to our complaint, and in August 2015, we and Takeda filed an answer to Actavis' counterclaims. Moreover, in July 2015, the court ordered a stipulation between us, Takeda and Actavis in which we and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September 2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, we and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, we and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted the Company's proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between us and Takeda, Takeda transferred to us the responsibility for management of this patent infringement lawsuit. Although we plan to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome.

We have also filed patent applications, directed to various treatment and formulation aspects of Contrave, in the United States and certain foreign countries under the Patent Cooperation Treaty, or PCT. Use of our proprietary tri-layer Contrave tablet for weight loss is protected in the United States by U.S. patent numbers 8,088,786 and 8,318,788, which are expected to expire in February 2029 and November 2027, respectively. Corresponding patents have issued in several foreign countries, for example, in the European Patent Office as EP2089005 B1. In addition, the dose escalation schedule of Contrave is protected by U.S. patent numbers 8,722,085 and 9,125,868, which are expected to expire in November 2027. U.S. patent numbers 8,815,889 and 9,457,005, directed to methods of treating insulin resistance using Contrave, including in obese patients, are expected to expire in July 2024. Corresponding patents have issued in several foreign countries, for example, in the European Patent Office as EP2135603 B1. Use of our proprietary sustained-release formulation of Contrave for weight loss is protected by U.S. patent numbers 8,916,195 and 9,107,837 which are expected to expire in February 2030 and June 2027, respectively. U.S. patent numbers 8,969,371 and 9,119,850, which are expected to expire in July 2034, protect the use of Contrave for treating overweight or obesity in select patient populations that are at increased risk of a major adverse cardiovascular event. U.S. patent number 9,248,123, which is expected to expire in January 2032, protects the use of Contrave for treating overweight or obesity in select patient populations with major depressive disorder. The PCT is an international treaty providing a unified procedure under which the initial filing of a single patent application can provide an effective filing date in each participating country in which appropriate steps are subsequently taken. Such steps have been taken in various foreign countries, including Europe and Japan, with respect to a number of our PCT filings. Thus, we now have issued patents and pending patent applications in those foreign countries, along with our previous filings in the United States and certain non-PCT countries. These filings seek to provide further protection for Contrave in the United States and overseas; however, we cannot provide assurance that the claims in the other patent applications will issue in their current form or at all.

We may face additional competition outside of the United States as a result of a lack of patent enforcement in foreign countries and off-label use of other dosage forms of the generic components in our product.

While we have filed patent applications in many countries outside the United States, and have obtained some patent coverage for Contrave in certain foreign countries, we do not currently have widespread patent protection for Contrave outside the United States and have no protection in many foreign jurisdictions. Even if international patent applications ultimately issue or receive approval, it is likely that the scope of protection provided by such patents will be different from, and possibly less than, the scope provided by our corresponding U.S. patents. The success of our international market opportunity is dependent upon the enforcement of patent rights in various other countries. A number of countries in which we have filed or intend to file patent applications have a history of weak enforcement and/or compulsory licensing of intellectual property rights. Even if we have patents issued in these jurisdictions, there can be no assurance that our patent rights will be sufficient to prevent generic competition or unauthorized use. We may face competition from the off-label use of other dosage forms of the generic components in our product. In addition, others may attempt to commercialize our product combination in the countries of the European Union, Canada, Mexico, Japan or other markets, in some of which, we do not have patent protection for our product. Due to the lack of patent protection for these combinations in some territories outside the United States and the potential for correspondingly lower prices for the drugs in those markets, it is possible that patients will seek to acquire the generic IR component of our product (naltrexone IR) in those other territories. The off-label use of the generic IR component in the United States or the importation of the generic IR component from foreign markets could adversely affect the commercial potential for our product and adversely affect our overall business and financial results.

We have in-licensed all or a portion of the rights to Contrave from third parties. If we default on any of our material obligations under those licenses, we could lose rights to our product.

We have in-licensed and otherwise contracted for rights to our product, and we may enter into similar licenses in the future to supplement our product pipeline. Under the relevant agreements, we are subject to commercialization, development, sublicensing, royalty, insurance and other obligations. If we fail to comply with any of these requirements, or otherwise breach these license agreements, the licensor may have the right to terminate the license in whole or to terminate the exclusive nature of the license. Loss of any of these licenses or the exclusive rights provided therein could harm our financial condition and operating results.

Restrictions on our patent rights relating to Contrave may limit our and our partners' ability to prevent third parties from competing against us.

Our success will depend on our and our partners' abilities to obtain and maintain patent protection for Contrave, preserve our trade secrets, prevent third parties from infringing upon our proprietary rights and operate without infringing upon the proprietary rights of others. Composition of matter patents on APIs are generally considered to be the strongest form of intellectual property protection for pharmaceutical products as they apply without regard to any method of use. Entirely new individual chemical compounds, often referred to as new chemical entities, are typically entitled to composition of matter coverage. Current law also allows novel and unobvious combinations of old compounds to receive composition of matter coverage for the combination. However, we cannot be certain that the current law will remain the same, or that our product will be considered novel and unobvious by the PTO and courts.

In addition to composition of matter patents and patent applications, we also have issued and filed method of use patents and patent applications. This type of patent protects the use of Contrave only for the specified method. However, this type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if these competitors do not actively promote their product for our targeted indication, physicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

Although we believe we and our licensors have conducted appropriate prior art searches relating to our key patents and patent applications, there is no assurance that all of the potentially relevant prior art has been found. Moreover, because the constituents of our combination product have been on the market as separate monotherapeutic products for many years, it is possible that these monotherapies have previously been used off-label in such a manner that such prior usage would affect the validity of our method of use patents.

Patent applications in the United States and most other countries are confidential for a period of time until they are published, and publication of discoveries in scientific or patent literature typically lags actual discoveries by several months or more. As a result, we cannot be certain that we and the inventors of the issued patents and applications that we in-licensed were the first to conceive inventions covered by the patents and pending patent applications or that we and those inventors were the first to file patent applications for such inventions.

We also rely upon unpatented trade secrets, unpatented know-how and continuing technological innovation to develop and maintain our competitive position, which we seek to protect, in part, by confidentiality agreements with our employees and our collaborators and consultants, some of whom assist with the development of other obesity drugs. We and our partners also have agreements with our employees and selected consultants that obligate them to assign their inventions to us. It is possible that technology relevant to our business will be independently developed by a person that is not a party to such an agreement. Furthermore, if the employees and consultants that are parties to these agreements breach or violate the terms of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets through such breaches or violations. Further, our trade secrets could otherwise become known or be independently discovered by our competitors.

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

Our commercial success depends upon our and our partners' abilities to develop, manufacture, market and sell our product 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 in which we are developing products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product and/or proprietary technologies may give rise to claims of infringement of the patent rights of others. There may be issued patents of third parties of which we are currently unaware that may be infringed by our product or proprietary technologies. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us or our partners, which may later result in issued patents that Contrave or proprietary technologies may infringe.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product and/or proprietary technologies infringe their intellectual property rights. If one of these patents is found to cover Contrave, proprietary technologies or their uses, we or our partners could be enjoined by a court and required to pay damages and could be unable to commercialize our product 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 partners 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 or our partner 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 biotechnology and pharmaceutical industries generally. If a third party claims that we or our partners 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 on 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 and fees and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

We will be obtaining our bupropion, naltrexone, our finished Contrave tablets combining these components, and the packaging for these tablets from third-party manufacturers. Each aspect of product design, formulation, manufacturing, packaging, and use has the potential to implicate third-party patent rights. We have taken various measures to reduce the potential for infringement. However, we could be exposed to potential patent infringement liability from other third parties who hold patents on various formulations of bupropion and naltrexone.

No assurance can be given that patents do not exist, have not been filed, or could not be filed or issued, which contain claims covering these or other aspects of our products, technology or methods, as implemented by us or by third-party manufacturers with whom we contract. Because of the large number of patents issued and patent applications filed in our field, we believe there is a risk that third parties may allege they have patent rights encompassing our products, technology or methods. Such third-party patent rights, if relevant, could prevent us or our partners from adopting or marketing a particular formulation or product, or could expose us to patent infringement liability.

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 the Weber/Cowley patents covering Contrave, as well as our other issued patents, are due to be paid to the PTO in several stages over the lifetimes of the patents. We have systems in place to remind us to pay these fees, and we employ an outside firm, Computer Patent Annuities, to pay annuity fees due to foreign patent agencies on our issued and pending foreign patent applications. The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and, 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.

We have not yet registered our trademarks in all of our potential markets, and failure to secure those registrations could adversely affect our business.

We have received U.S. trademark registration number 3396021 for our corporate logo for use in connection with pharmaceutical preparations and substances for the treatment of obesity, inducement of weight loss and prevention of weight gain. We have obtained trademark registrations in Canada, the European Union, and Japan for the same mark. In addition, we have received U.S. trademark registration number 3396807 for our corporate name OREXIGEN for use in connection with pharmaceutical preparations for the treatment of disorders of the central nervous system, or CNS, printed instructional, educational and teaching materials in the field of treatment and management of disorders of the CNS, and providing medical information in the field of disorders of the CNS. We have obtained trademark registrations in Brazil, Canada, the European Union, Japan and Russia for the same mark. We have obtained foreign trademark registrations for the corporate name Orexigen Therapeutics, Inc. in the European Union and Japan. We have received U.S. trademark registration number 3393576 for the mark CONTRAVE for use in connection with pharmaceutical preparations for use in the treatment of obesity and inducing weight loss. We have also obtained foreign trademark registrations for the mark CONTRAVE in Australia, Brazil, Canada, the European Union, Lebanon, Mexico, Russia, Japan, and South Korea and have pending applications in Bahrain, Canada, China, Egypt, India, Iran, Jordan, Kuwait, Oman, Qatar, Saudi Arabia, South Africa and Vietnam. In addition, applications for a Contrave logo for use in connection with pharmaceutical preparations for use in the treatment of obesity and inducing weight loss, certain printed materials and medical information services are pending in the U.S. and Canada. The Contrave logo is registered in Europe and Japan. An intent to use application for the mark MYSIMBA has been allowed in the United States in connection with pharmaceutical preparations, printed materials, and medical information services. We have obtained trademark registrations in Australia, the European Union, Norway, South Korea and Switzerland for the same mark. In addition, applications for the mark MYSIMBA are pending in Albania, Australia, Bosnia and Herzegovina, Canada, Macedonia, Montenegro, Kosovo, Serbia, South Africa, Turkey and India. However, no assurance can be given that our allowed trademark applications will actually become registered, or that our registered trademarks can be maintained or enforced. During trademark registration proceedings in the various countries, we have received and expect to receive rejections. Although we are given an opportunity to respond to those rejections, there can be no assurance that the rejections can be successfully overcome. In addition, in the PTO and in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to cancel registered

trademarks. No assurance can be given that opposition or cancellation proceedings will not be filed against our trademarks, nor can there be any assurance that our trademarks would survive such proceedings.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks Related to Our Finances and Capital Requirements

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We have focused primarily on developing our first approved product, Contrave. We have financed our operations almost exclusively through the sale of our preferred and common stock and debt and have incurred losses in each year since our inception in September 2002. As of December 31, 2016, we had an accumulated deficit of approximately $645.2 million. These losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant and increasing operating losses for the foreseeable future and such losses have had, and will continue to have, an adverse effect on our stockholders' equity. Because of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses.

We have a limited history of generating revenue from our product and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. We have a limited history of generating revenue, and we do not know when, or if, we will generate any significant revenue. Takeda commercially launched Contrave in October 2014 and our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to maintain regulatory approval of, effectively commercialize and successfully complete future clinical trials for Contrave, and our ability to:

- effectively market and sell Contrave in the United States;
- maintain regulatory approval of Contrave/Mysimba in the European Union and South Korea;
- manufacture commercial quantities of Contrave at acceptable cost levels; and
- effectively market and sell Contrave/Mysimba in the Partnered Regions and elsewhere outside the United States, if approved.

We anticipate incurring significant costs associated with the continued development and commercialization of our approved product, Contrave. We do not expect to be profitable in the near future, if ever. If we or our partners are unable to generate product revenues, we will not become sustainably profitable and may be unable to continue operations without continued funding.

We may need additional funds and/or need to enter into additional collaborative or other agreements in order to fund research and development activities, including post-marketing studies or clinical trials for Contrave/Mysimba, and commercialize Contrave in the United States and Contrave/Mysimba outside the United States, and we may be unable to raise capital when needed or enter into such an agreement, which would force us to delay, reduce or eliminate research, development, and commercialization activities.

Developing products for the obesity market, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We believe that our existing cash, cash equivalents and short-term investments will be sufficient to meet our projected operating requirements through at least the next 12 months. However, we have based these estimates 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 additional capital to:

- fund our operations and to conduct post-marketing requirements for Contrave;
- develop and commercialize Contrave/Mysimba; and
- qualify and outsource the commercial-scale of Contrave under cGMP.

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

- the successful commercialization of Contrave/Mysimba;
- the rate of progress and cost of clinical activity, including the new CVOT for Contrave, and the scope and cost of the additional post-marketing requirements for Contrave, including expenses to support the trials and milestone payments that may become payable;
- the terms and timing of any collaborative, licensing, co-promotion, distribution or other arrangements that we may establish with respect to Contrave/Mysimba;
- the costs of establishing sales, marketing and distribution capabilities in order to commercialize Contrave/Mysimba in the United States and geographies outside the United States, should we elect to do so;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of additional regulatory approvals for Contrave/Mysimba; and
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies. We currently have no commitments or agreements relating to any of these types of transactions.

Unless and until we can generate a sufficient amount of product revenue and achieve profitability, we expect to finance future cash needs through public or private equity offerings, milestone payments, debt, receivables or royalty financings, or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

Our quarterly and annual operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly and annual fluctuations. Our net loss and other operating results may be affected by numerous factors, including:

- the level of underlying demand for Contrave, wholesalers' buying patterns with respect to Contrave, discounts given to certain Contrave customers, and our ability to successfully market Contrave following the transition from Takeda;
- variations in the level of expenses, including, but not limited to, variation based on foreign currency exchange rates, related to our product or future development programs;
- regulatory developments affecting our product or those of our competitors;
- the timing of future payments, if any, we may receive under partnership, distributorship or similar agreements;
- our execution of any additional collaborative, licensing, distribution or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- addition or termination of clinical trials or funding support; and
- any intellectual property infringement lawsuit in which we may become involved.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly and annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Raising additional funds by issuing securities may cause dilution to existing stockholders and raising funds through lending and licensing arrangements may restrict our operations or require us to relinquish proprietary rights.

In March 2016, we sold $165 million aggregate principal amount of 0% Convertible Senior Secured Notes due 2020, or the Secured Notes, initially convertible into an aggregate of up to 21,999,999 shares of common stock and related warrants to purchase up to 21,999,999 shares of common stock. In September 2015, we sold 2,000,000 shares of our common stock and warrants to purchase 500,000 shares of our common stock. In December 2013, we sold $115 million aggregate principal amount of 2.75% Convertible Senior Notes due 2020, or the 2013 Notes, of which approximately $80.0 million in aggregate principal amount was outstanding as of

December 31, 2016. Any conversions or exercises of some or all of these Secured Notes, 2013 Notes, Exchange Notes or warrants, as applicable, will result in additional dilution of existing stockholders.

To the extent that we raise additional capital by issuing equity securities, our existing stockholders' ownership will be diluted. Debt, receivables and royalty financings typically contain covenants that restrict operating activities and may impair our ability to in-license potential products or product candidates. Debt, receivables and royalty financings may also be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' ownership.

If we raise additional funds through collaboration, licensing or other similar arrangements, it may be necessary to relinquish potentially valuable rights to our current product candidates, potential products or proprietary technologies, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of our product.

Our outstanding convertible notes may impact our financial results, result in the dilution of existing stockholders, and restrict our ability to take advantage of future opportunities.

In March 2016, we sold $165 million aggregate principal amount of Secured Notes and related warrants. The Secured Notes may be converted, under the conditions specified in those Secured Notes, into shares of our common stock and the warrants may be exercised, under the conditions specified in those warrants, into shares of our common stock.

In addition, in December 2013, we sold $115.0 million aggregate principal amount of 2013 Notes. In December 2016, we repurchased 2013 Notes representing an aggregate of approximately $35.0 million in principal. In February 2017 we exchanged approximately $49.6 million in aggregate of principal amount of 2013 Notes for Exchange Notes. We will be required to pay interest on the 2013 Notes and Exchange Notes until they come due, are called by us, or are converted, and the payment of that interest will reduce our net income. The sale of the 2013 Notes may also affect our earnings per share figures, as accounting requirements require that we include in our calculation of earnings per share the number of shares of our common stock into which the 2013 Notes are convertible. On June 27, 2014, our stockholders approved a flexible conversion option that allows us to pay the conversion right on these 2013 Notes in cash and/or shares. The flexible conversion right may allow us to exclude from the earnings per share calculation the shares of our common stock into which the 2013 Notes are convertible. However, we cannot guarantee that the flexible conversion option would result in the accounting treatment described above. The 2013 Notes may be converted, under the conditions and at the premium specified in those 2013 Notes, into shares of our common stock and/or into the cash equivalent of shares of our common stock.

Upon the occurrence of certain fundamental changes or, in the case of the Secured Notes, adverse events related to the regulatory approval for and commercialization of Contrave, and net sales of the Company, holders of the 2013 Notes, Exchange Notes and Secured Notes will, at their option, have the right to require the Company to repurchase for cash all or a portion of their notes, pursuant to the terms and conditions set forth in the applicable indenture.

If converted into shares, the Secured Notes, Exchange Notes and 2013 Notes will result in the dilution of our shareholders. Also when exercised, the warrants that we issued in connection with the Secured Notes will result in the dilution of our shareholders. Further, if repurchased, converted or exercised into cash, the 2013 Notes, the Exchange Notes, the Secured Notes and the related warrants may require the payment of significant additional amounts to the holders of these securities. The payment of the interest payments, the repayment of the principal, the potential payment of the conversion premium and/or cash exercise amounts and the potential repurchase of the Secured Notes, the Exchange Notes and the 2013 Notes will require the use of a substantial amount of our cash, and if such cash is not available, we may be required to sell other assets or enter into alternate financing arrangements at terms that may or may not be desirable. The existence of the Secured Notes, the Exchange Notes and the 2013 Notes and the obligations we incurred by issuing them may restrict our ability to take advantage of certain future opportunities, such as engaging in future debt or equity financing activities, which may reduce or impair our ability to acquire new businesses or invest in our existing businesses.

The Holders of our Secured Notes have the right to require us to repurchase, for cash, their Secured Notes in the case of certain fundamental changes or adverse changes related to the regulatory approval for and commercialization of Contrave and net sales of the Company.

The indenture for our Secured Notes provides that the holders of the Secured Notes will, at their option, have the right to require the Company to repurchase, for cash, all or a portion of their Secured Notes in certain circumstances, including: (a) a change in control of the company or other fundamental changes; (b) our common stock ceases to be listed or quoted on NASDAQ; and (c) following specific adverse events related to our business that include: (i) a suspension or withdrawal, by the FDA, of the marketing approval of Contrave; (ii) changes to the drug label for Contrave or the implementation of a REMS for Contrave, in any case, in a manner that would be reasonably expected to have a materially adverse impact on annual net sales of Contrave in the United States;

(iii) we cease selling Contrave in the United States, either ourselves or through affiliates, distributors, partners or licensees; (iv) approval, by the FDA, of an ANDA for a AB-rated generic version of Contrave and actual sales of such generic version in the United States; and (v) worldwide net sales for fiscal year 2017 that are less than $100 million, in aggregate. Certain of the events that would trigger the repurchase obligation are outside of our control, including certain of the events that would be classified as a change in control or fundamental change. We cannot assure you that we will avoid these events. If we are required to repurchase the Secured Notes, it will require a significant amount of cash, and if such cash is not available, we may be required to enter into alternate financing arrangements at terms that may or may not be desirable.

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

Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Domestic and international equity markets have experienced and may continue to experience heightened volatility and turmoil based on domestic and international economic conditions and concerns. In the event these economic conditions and concerns continue and the markets continue to remain volatile, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline. In addition, we maintain significant amounts of cash and cash equivalents at one or more financial institutions that are not federally insured. If economic instability continues, we cannot provide assurance that we will not experience losses on these investments.

Our foreign subsidiaries may not be able to successfully maintain advantageous tax status and resulting tax rates, which could adversely affect our business and financial condition, results of operations and growth prospects.

We anticipate being able to achieve favorable tax treatment through the performance of certain business functions and ownership of certain assets in tax-efficient jurisdictions, including Ireland, together with intra-company service and transfer pricing agreements, each on an arm's length basis. Taxing authorities, such as the U.S. Internal Revenue Service, or IRS, actively audit and otherwise challenge these types of arrangements, and have done so in the pharmaceutical industry. We expect that these challenges will continue as a result of the recent increase in scrutiny and political attention on corporate tax structures. The IRS may challenge our structure and transfer pricing arrangements through an audit or lawsuit. Responding to or defending such a challenge could be expensive and consume time and other resources, and divert management's time and focus from operating our business. We cannot predict whether taxing authorities will conduct an audit or file a lawsuit challenging this structure, the cost involved in responding to any such audit or lawsuit, or the outcome. If we are unsuccessful, we may be required to pay taxes for prior periods, interest, fines or penalties, and may be obligated to pay increased taxes in the future, any of which could require us to reduce our operating expenses, decrease efforts in support of our products or seek to raise additional funds, all of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

We may lose the ability to use our net operating loss, or NOL, carryforwards, which could prevent or delay us from offsetting future taxable income.

We have incurred substantial losses during our history and do not expect to become profitable in 2017 and may never achieve profitability. To the extent that we continue to generate taxable losses, unused losses will carry forward to offset future taxable income, if any, until such unused losses expire. Our federal and state net operating loss carryforwards begin to expire in 2027 and 2017, respectively. Additionally, the future utilization of our net operating loss carryforwards and credits to offset future taxable income is subject to annual limitations, pursuant to Sections 382 and 383 of the Internal Revenue Code, as a result of ownership changes that have occurred in prior years or may occur in the future, which could defer our ability to utilize or prevent us from fully utilizing our net operating loss carryforwards, and credits, which could have an adverse effect on our results of operations. We completed an ownership change analysis in accordance with Section 382 from inception through December 31, 2015. As a result of the study, it was determined that we experienced several ownership changes during this period with the last one occurring in December 2014. We have reduced our NOL and credit carryforwards as disclosed in our financial statement for the effect of Section 382 and 383.

Risks Relating to Securities Markets and Investment in Our Stock

The market price of our common stock has fluctuated and is likely to continue to fluctuate, which could reduce the market price of our common stock.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. Over the last several years, the overall capital markets have been highly volatile. Since the commencement of trading in connection with our initial public offering, or IPO, the publicly traded shares of our common stock have themselves

experienced significant price and volume fluctuations. During the quarter ended December 31, 2016, the price per share for our common stock on the Nasdaq Global Market has ranged from a low sale price of $1.65 to a high sale price of $3.35. This market volatility is likely to continue and could reduce the market price of our common stock, regardless of our operating performance. In addition, the trading price of our common stock could change significantly over short periods of time in response to many factors, including:

- announcements regarding the commercial sales and related revenue(s) for Contrave;
- FDA or international regulatory actions, including failure to maintain regulatory approval for Contrave in the European Union or South Korea or receive approval in other additional foreign jurisdictions;
- announcements regarding our clinical trials, including the Ignite Study, the Light Study and the post-marketing required clinical trials for Contrave;
- announcements regarding Vivus', Novo Nordisk's and Eisai's approved obesity products, including sales, safety and efficacy results, and their respective regulatory submissions and/or the results of their respective clinical trials;
- announcements regarding our other competitors' regulatory submissions and/or the results of their clinical trials;
- announcements regarding our relationships with third parties;
- announcements regarding bupropion or naltrexone;
- announcements regarding manufacturing or supply developments for Contrave;
- failure of any of our product to achieve commercial success;
- developments concerning current or future strategic collaborations;
- announcements of the introduction of new products by us or our competitors;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our products;
- actual and anticipated fluctuations in our quarterly operating results;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- healthcare reform measures and other third-party coverage and reimbursement policies;
- changes in or announcements relating to third-party coverage and reimbursement policies for Contrave/Mysimba; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

The realization of any of the risks described in these "Risk Factors" could also have a dramatic and material adverse impact on the market price of our common stock.

Future sales of our common stock may depress our stock price.

Any future sales of a substantial number of shares of our common stock in the public market, or the perception that such sales may occur, could adversely affect the price of our common stock. We cannot predict the effect, if any, that market sales of any such shares of common stock or the availability of any such shares of common stock for sale would have on the market price of our common stock.

In addition, persons who were our stockholders prior to the sale of shares in our IPO continue to hold a substantial number of shares of our common stock that they may be able to sell in the public market, subject to the limitations of Rule 144 of the Securities Act of 1933, as amended. Significant portions of these shares are held by a small number of stockholders. Sales by our current stockholders of a substantial number of shares, or the expectation that such sales may occur, could significantly reduce the market price of our common stock. For example, certain of our executive officers have established selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for the purpose of effecting specified sales of our common stock over a specified period of time.

We have also registered all common stock that we may issue under our employee benefits plans. As a result, these shares can be freely sold in the public market upon issuance, subject to restrictions under the securities laws. In addition, our directors and executive officers may in the future establish programmed selling plans under Rule 10b5-1 of the Exchange Act for the purpose of effecting sales of our common stock, in addition to the already established plans. If any of these events cause a large number of our shares to be sold in the public market, the sales could reduce the trading price of our common stock and impede our ability to raise future capital.

Our executive officers, directors, principal stockholders and their respective affiliates will exercise significant influence over stockholder voting matters in a manner that may not be in the best interests of all of our stockholders.

As of December 31, 2016, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates together controlled approximately 33.5% of our outstanding common stock, assuming no exercise of outstanding options or warrants. As a result, these stockholders will collectively be able to significantly influence all matters requiring approval of our stockholders, including the election of directors and approval of significant corporate transactions. The concentration of ownership may delay, prevent or deter a change in control of our company even when such a change may be in the best interests of some stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent;
- a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, the president or by a majority of the total number of authorized directors;
- advance notice requirements for stockholder proposals and nominations;
- a requirement of approval of not less than 66 2/3% of all outstanding shares of our capital stock entitled to vote to amend any bylaws by stockholder action, or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval.

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors, including to delay or impede a merger, tender offer or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We have never paid dividends on our capital stock, and because we do not anticipate paying any cash dividends in the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain on an investment in our stock.

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

We may become involved in securities-related litigation, including securities class action litigation, or securities-related investigations, that could divert management's attention and harm our business and could subject us to significant liabilities.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of pharmaceutical companies. These broad market fluctuations may cause the market price of our

common stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this and other types of shareholder litigation in the future. Moreover, as a public company, we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities, which would entail expenditure of additional financial and management resources. For example, in April 2015, we received a formal request from the SEC's Division of Enforcement for documentation related to, among other things, a Current Report on Form 8-K that we filed with the SEC on March 3, 2015. We intend to cooperate fully with the SEC regarding this matter. Litigation, and investigations by regulatory authorities, are often expensive and divert management's attention and resources, which could adversely affect our business.

In May 2013, we received a shareholder demand alleging that certain option grants to our President and Chief Executive Officer, Michael A. Narachi, our Chief Business Officer and acting-Chief Financial Officer, Joseph P. Hagan, and our Senior Vice President, General Counsel and Secretary, Heather D. Turner, in 2011 were granted in excess of the 1,500,000 share limit set forth in Section 3.3 of the Orexigen Therapeutics, Inc. 2007 Equity Incentive Award Plan, or Plan, as to the number of shares of our common stock with respect to which one or more stock awards may be granted to any one eligible participant during any of our fiscal years. We refer to this limit as the 162(m) Award Limit. Our board of directors established a demand review committee composed of independent directors to conduct an investigation with respect to the shareholder demand and to make recommendations to our board of directors. The demand review committee engaged independent counsel as part of its investigation and evaluated (1) the terms of the Plan, (2) the initial issuance procedures for the option grants to Mr. Narachi, Mr. Hagan and Ms. Turner during 2011, (3) the authority available to the compensation committee of our board of directors under its charter and the Plan, (4) the expectations of the award recipients and (5) the intent of our board of directors and the compensation committee regarding the availability of an exemption from the deductibility limitations of Section 162(m) of the Internal Revenue Code for such option grants. Following its investigation, the demand review committee determined that the 162(m) Award Limit first became effective as of June 2, 2011, and that, therefore, awards granted under the Plan prior to June 2, 2011, did not count toward the 162(m) Award Limit. The demand review committee determined that the awards granted to Mr. Hagan between June 2, 2011 and December 31, 2011 did not exceed the 162(m) Award Limit. The demand review committee further determined that the options granted to Mr. Narachi and Ms. Turner, including the portion of such awards in excess of the 162(m) Award Limit, were validly approved under the Plan, although the portion of those awards in excess of the 162(m) Award Limit does not qualify as performance-based compensation under Section 162(m). In September 2013, the compensation committee amended the Plan, with the approval of our board of directors, to take the following actions: (1) to clarify that the 162(m) Award Limit only applies to awards or the portion thereof intended to qualify as performance-based compensation under Section 162(m); and (2) to confirm that the compensation committee has the authority to make awards in excess of the 162(m) Award Limit, which board action we refer to as the Plan Amendment. The Plan Amendment is deemed effective as of June 10, 2011, consistent with the authority of the compensation committee as administrator of the Plan as of that date. Any grants under the Plan in excess of the 162(m) Award Limit are not intended to qualify as performance-based compensation under Section 162(m).

On December 9, 2013, the same shareholder who made a demand on the board in May 2013 filed a derivative lawsuit purportedly on behalf of us against certain of our officers and current and former members of our board of directors in the United States District Court, for the Southern District of California, captioned *Turgeman v. Narachi, et al*. The lawsuit asserts claims for breach of fiduciary duty, waste and unjust enrichment based on, among other things, the alleged grant of stock options to certain officers in excess of the 162(m) Award Limit, repricing stock options allegedly in violation of our equity incentive plan, the board of directors' conduct in responding to the May 2013 shareholder demand, and making allegedly false and misleading statements. The lawsuit seeks, among other things, declaratory relief, corporate governance reforms, rescission of certain stock option awards, rescission of the Plan Amendment, injunctive relief, damages, restitution, disgorgement and attorney's fees. On July 23, 2014, we and the individual defendants filed a motion to dismiss the *Turgeman* complaint. On March 9, 2015, the court granted the motion to dismiss with thirty days leave to amend. An amended complaint was filed on April 8, 2015. The amended complaint asserts the same derivative claims as the original complaint and asserts a putative claim on behalf of plaintiff and our shareholders for breach of contract for alleged violations of the 2007 Equity Incentive Plan. On May 8, 2015, we and the individual defendants filed a motion to dismiss the amended complaint. The court has not yet ruled on our motion.

On March 10, 2015, a purported class action lawsuit was filed against us and certain of our officers in the United States District Court, for the Southern District of California, captioned *Colley v. Orexigen, et al.* The following day, two additional putative class action lawsuits were filed in the same court, captioned *Stefanko v. Orexigen, et al.,* and *Yantz v. Orexigen, et al*., asserting substantially similar claims. On June 22, 2015, the court consolidated the lawsuits and appointed a lead plaintiff. On August 20, 2015, the lead plaintiff filed a consolidated complaint. The consolidated complaint purports to assert claims on behalf of a class of purchasers of the Company's stock between March 3, 2015 and May 12, 2015. It alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by purportedly making false and misleading statements regarding the interim results and termination of the Light Study. The consolidated complaint seeks an unspecified amount of damages, attorneys' fees and equitable or injunctive relief. On October 5, 2015, defendants filed a motion to dismiss the consolidated complaint. On May 19, 2016, the District Court granted the motion to dismiss, dismissing portions of the consolidated complaint with prejudice and portions without prejudice.

The Court granted lead plaintiff 30 days to file an amended complaint with respect to those portions not dismissed with prejudice. On June 16, 2016, lead plaintiff filed a notice of intent not to file an amended complaint but to proceed directly to an appeal of the Court's decision dismissing the consolidated complaint. As a result, the court entered judgment dismissing the consolidated complaint with prejudice on June 27, 2016. Lead plaintiff filed a Notice of Appeal with the Ninth Circuit Court of Appeals on July 26, 2016. Lead plaintiff filed their opening brief on December 2, 2016. Defendants filed their answering brief on February 2, 2017 and lead plaintiff filed a reply brief on February 16, 2017. No hearing date has been set. Although management believes that this appeal lacks merit and intends to defend against them vigorously, there are uncertainties inherent in any litigation and we cannot predict the outcome.

On June 3, 2016, plaintiff Ben Wilkin, a shareholder who had previously made a shareholder demand to inspect certain books and records of the Company, filed a derivative lawsuit purportedly on behalf of us against certain of our current and former officers and members of the board of directors in the Delaware Chancery Court, captioned *Wilkin v. Narachi, et al*. The lawsuit asserts claims for breach of fiduciary duty and waste of corporate assets based on essentially the same set of facts underlying the *Colley, Stefanko* and *Yantz* consolidated class action. The lawsuit seeks, among other things, damages, corporate governance reforms, injunctive relief, restitution, disgorgement and attorney's fees. Orexigen and the individual defendants filed a motion to dismiss on October 31, 2016, asserting that plaintiff failed to plead demand futility and otherwise failed to state a claim. Instead of opposing the motion to dismiss, on January 13, 2017, plaintiff filed an amended complaint pursuant to Chancery Rule 15(aaa). The amended complaint asserts nearly identical allegations and claims as the original complaint. Orexigen and the individual defendants' filed a motion to dismiss on March 27, 2017. Management believes that the claims lack merit and intends to defend against them vigorously.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

In December 2007, we entered into a lease agreement covering approximately 22,229 square feet of office space which we use as our corporate headquarters in La Jolla, California. In September 2008, we entered into an amendment to lease an additional 9,312 square feet bringing the total leased space to 31,541 square feet. In February 2012, we entered into a partial lease termination agreement to reduce the amount of leased office space at our corporate headquarters to a total of 22,229 square feet of leased space. In February 2013, we entered into an amendment to extend our lease to September 2017. In August 2015, we entered into an amendment to lease an additional 7,706 square feet of space in the same office complex as its corporate headquarters, bringing the total leased space to 29,935 square feet of leased space. In October 2016, we entered into an amendment to extend the lease term for our all leased office space at our corporate headquarters through February 2018. We have no laboratory, research or manufacturing facilities. We believe that our current facilities are adequate for our needs for the immediate future and that, should it be needed, suitable additional space will be available to accommodate expansion of our operations on commercially reasonable terms.

Item 3. Legal Proceedings.

In May 2013, the Company received a shareholder demand alleging that certain option grants to the President and Chief Executive Officer, Michael A. Narachi, the Chief Business Officer and acting-Chief Financial Officer, Joseph P. Hagan, and the Senior Vice President, General Counsel and Secretary, Heather D. Turner, in 2011 were granted in excess of the 1,500,000 share limit set forth in Section 3.3 of the Orexigen Therapeutics, Inc. 2007 Equity Incentive Award Plan, or Plan, as to the number of shares of the Company's common stock with respect to which one or more stock awards may be granted to any one eligible participant during any of the Company's fiscal years. The Company refers to this limit as the 162(m) Award Limit. The Company's board of directors established a demand review committee composed of independent directors to conduct an investigation with respect to the shareholder demand and to make recommendations to the board of directors. The demand review committee engaged independent counsel as part of its investigation and evaluated (1) the terms of the Plan, (2) the initial issuance procedures for the option grants to Mr. Narachi, Mr. Hagan and Ms. Turner during 2011, (3) the authority available to the compensation committee of the board of directors under its charter and the Plan, (4) the expectations of the award recipients and (5) the intent of the board of directors and the compensation committee regarding the availability of an exemption from the deductibility limitations of Section 162(m) of the Internal Revenue Code for such option grants. Following its investigation, the demand review committee determined that the 162(m) Award Limit first became effective as of June 2, 2011, and that, therefore, awards granted under the Plan prior to June 2, 2011, did not count toward the 162(m) Award Limit. The demand review committee determined that the awards granted to Mr. Hagan between June 2, 2011 and December 31, 2011 did not exceed the 162(m) Award Limit. The demand review committee further determined that the options granted to Mr. Narachi and Ms. Turner, including the portion of such awards in excess of the 162(m) Award Limit, were validly approved under the Plan, although the portion of those awards in excess of the 162(m) Award Limit does not qualify as performance-based compensation under Section 162(m). In September 2013, the compensation committee amended the Plan, with the approval of the Company's board of directors, to take the following actions: (1) to clarify that the 162(m) Award Limit only applies to awards or the portion thereof intended to qualify as performance-based compensation under Section 162(m); and (2) to confirm that the compensation committee has the authority to make awards in excess of the 162(m) Award Limit, which board action the Company refers to as the Plan Amendment. The Plan Amendment is deemed effective as of June 10, 2011, consistent with the authority of the

compensation committee as administrator of the Plan as of that date. Any grants under the Plan in excess of the 162(m) Award Limit are not intended to qualify as performance-based compensation under Section 162(m).

On December 9, 2013, the same shareholder who made a demand on the board in May 2013 filed a derivative lawsuit purportedly on behalf of the Company against certain of the officers and current and former members of the board of directors in the United States District Court, for the Southern District of California, captioned *Turgeman v. Narachi, et al*. The lawsuit asserts claims for breach of fiduciary duty, waste and unjust enrichment based on, among other things, the alleged grant of stock options to certain officers in excess of the 162(m) Award Limit, repricing stock options allegedly in violation of the Company's equity incentive plan, the board of directors' conduct in responding to the May 2013 shareholder demand, and making allegedly false and misleading statements. The lawsuit seeks, among other things, declaratory relief, corporate governance reforms, rescission of certain stock option awards, rescission of the Plan Amendment, injunctive relief, damages, restitution, disgorgement and attorney's fees. On July 23, 2014, the Company and the individual defendants filed a motion to dismiss the *Turgeman* complaint. On March 9, 2015, the court granted the motion to dismiss with thirty days leave to amend. An amended complaint was filed on April 8, 2015. The amended complaint asserts the same derivative claims as the original complaint and asserts a putative claim on behalf of plaintiff and the Company's shareholders for breach of contract for alleged violations of the 2007 Equity Incentive Plan. On May 8, 2015, the Company and the individual defendants filed a motion to dismiss the amended complaint. The court has not yet ruled on the motion.

On March 10, 2015, a purported class action lawsuit was filed against the Company and certain of the Company's officers in the United States District Court, for the Southern District of California, captioned *Colley v. Orexigen, et al*. The following day, two additional putative class action lawsuits were filed in the same court, captioned *Stefanko v. Orexigen, et al*., and *Yantz v. Orexigen, et al*., asserting substantially similar claims. On June 22, 2015, the court consolidated the lawsuits and appointed a lead plaintiff. On August 20, 2015, the lead plaintiff filed a consolidated complaint. The consolidated complaint purports to assert claims on behalf of a class of purchasers of the Company's stock between March 3, 2015 and May 12, 2015. It alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by purportedly making false and misleading statements regarding the interim results and termination of the Light Study. The consolidated complaint seeks an unspecified amount of damages, attorneys' fees and equitable or injunctive relief. On October 5, 2015, defendants filed a motion to dismiss the consolidated complaint. On May 19, 2016, the District Court granted the motion to dismiss, dismissing portions of the consolidated complaint with prejudice and portions without prejudice. The Court granted lead plaintiff 30 days to file an amended complaint with respect to those portions not dismissed with prejudice. On June 16, 2016, lead plaintiff filed a notice of intent not to file an amended complaint but to proceed directly to an appeal of the Court's decision dismissing the consolidated complaint. As a result, the court entered judgment dismissing the consolidated complaint with prejudice on June 27, 2016. Lead plaintiff filed a Notice of Appeal with the Ninth Circuit Court of Appeals on July 26, 2016. Lead plaintiff filed their opening brief on December 2, 2016. Defendants filed their answering brief on February 2, 2017 and lead plaintiff filed a reply brief on February 16, 2017. No hearing date has been set. Although management believes that this appeal lacks merit and intends to defend against it vigorously, there are uncertainties inherent in any litigation and the Company cannot predict the outcome.

On June 3, 2016, plaintiff Ben Wilkin, a shareholder who had previously made a shareholder demand to inspect certain books and records of the Company, filed a derivative lawsuit purportedly on behalf of the Company against certain of the Company's current and former officers and members of the board of directors in the Delaware Chancery Court, captioned *Wilkin v. Narachi, et al*. The lawsuit asserts claims for breach of fiduciary duty and waste of corporate assets based on essentially the same set of facts underlying the *Colley, Stefanko* and *Yantz* consolidated class action. The lawsuit seeks, among other things, damages, corporate governance reforms, injunctive relief, restitution, disgorgement and attorney's fees. Orexigen and the individual defendants filed a motion to dismiss on October 31, 2016, asserting that plaintiff failed to plead demand futility and otherwise failed to state a claim. Instead of opposing the motion to dismiss, on January 13, 2017, plaintiff filed an amended complaint pursuant to Chancery Rule 15(aaa). The amended complaint asserts nearly identical allegations and claims as the original complaint. Orexigen and the individual defendants' filed a motion to dismiss on March 27, 2017. Management believes that the claims lack merit and intends to defend against them vigorously.

At this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings described above, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorney's fees.

It is possible that additional securities class action litigation may be brought against the Company following stock price declines related to the release of information regarding Contrave or clinical trial results, including the Light Study or related to the matters alleged in the May 2013 shareholder demand and/or the Plan Amendment. Any adverse determination in such litigation could subject the Company to significant liabilities.

In April 2015, the Company and Takeda received a Paragraph IV certification notice letter regarding an abbreviated new drug application, or ANDA, submitted to the FDA by Actavis Laboratories FL, Inc., or Actavis, requesting approval to market, sell, and use a generic version of Contrave. In its notice letter, Actavis alleges that U.S. Patent Nos. 7,375,111; 7,462,626; 8,088,786; 8,318,788; 8,722,085; 8,815,889; and 8,916,195, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, for Contrave, are invalid, unenforceable and/or will not be infringed by Actavis' manufacture, use or

sale of the product described in its ANDA. In June 2015, the Company and Takeda filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Actavis and certain of its affiliates related to the ANDA previously filed by Actavis and described above. The lawsuit claims infringement of the seven patents that were the subject of Actavis' notice letter, as described above. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, as a result of having filed a patent infringement lawsuit within 45 days of receipt of Actavis' notice letter, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from the date of receipt of the notice letter or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to the Company's and Takeda's complaint, and the Company and Takeda filed an answer to Actavis' counterclaim in August 2015. Moreover, in July 2015, the court ordered a stipulation between the Company, Takeda and Actavis in which Orexigen and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September 2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, the Company and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, the Company and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted the Company's proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between the Company and Takeda, Takeda transferred the responsibility for management of this patent infringement lawsuit to the Company. Although the Company plans to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome.

Item 4. Mine Safety Disclosure.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is traded on the Nasdaq Global Market under the symbol "OREX."

The following table sets forth the high and low sales price of our common stock, as reported by the Nasdaq Global Market for the period indicated.

	High	Low
Year Ended December 31, 2016:		
Fourth Quarter	$ 3.35	$ 1.65
Third Quarter	4.75	3.15
Second Quarter	6.50	3.50
First Quarter	19.80	5.00
Year Ended December 31, 2015:		
Fourth Quarter	$ 34.40	$ 13.90
Third Quarter	50.40	18.40
Second Quarter	82.40	43.00
First Quarter	93.70	49.00

On March 23, 2017, the last reported sale price of our common stock on the Nasdaq Global Market was $4.00. As of March 23, 2017, there were 21 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock and we do not currently intend to pay any cash dividends on our common stock. We expect to retain future earnings, if any, to fund the development and growth of our business. Any future determination to pay dividends on our common stock will be at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements and contractual restrictions.

Equity Compensation Plan Information

The following table summarizes securities available under our equity compensation plans as of December 31, 2016.

Plan Category	Shares Issuable Upon Exercise of Outstanding Awards	Weighted Average Exercise Price	Number of Securities Available for Future Issuance	
Equity compensation plans approved by security holders:	6,277,552	$ 15.11	6,352,996	(1)
Equity compensation plans not approved by security holders:	213,900	4.57	36,100	(2)
Total	6,491,452	$ 14.75	6,389,096	

(1) Represents shares reserved for issuance under the 2004 Stock Plan, the 2007 Equity Incentive Award Plan, as amended, or the 2007 Plan, or the 2013 Employee Stock Purchase Plan. The 2007 Plan was adopted at the time of our initial public offering which coincided with our discontinuation of granting awards under the 2004 Stock Plan. Stock options under the 2007 Plan have an exercise price equal to the fair market value of the underlying common stock at the date of grant, generally vest over a period of four years, and have a ten-year life. The 2007 Plan contains an "evergreen" provision which allows for annual increases in the number of shares available for future issuance on January 1 of each year during the ten-year term of the plan, beginning on January 1, 2008. The annual increase in the number of shares shall be equal to the lesser of (i) 15% of our outstanding common stock on the applicable January 1, (ii) 600,000 shares of common stock, or (iii) a lesser amount determined by our board of directors. The 2007 Plan provides that the maximum number of shares that may be granted pursuant to the exercise of incentive stock options granted under the plan is 4,000,000 shares. The 2007 Plan was amended and restated in July 2016 to, among other things, eliminate the "evergreen" provision. The 2013 Employee Stock Purchase Plan was adopted in June 2013.

(2) Represents shares reserved for issuance under the 2007 Plan to individuals not previously an employee or non-employee director of ours (or following a bona fide period of non-employment with us), as an inducement material to each individual's entering into employment with us, or the Inducement Reserve, within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules, or Rule 5635(c)(4). The 2007 Plan was amended in October 2009 to provide for the reservation of 50,000 shares of our

common stock to be issued pursuant to the Inducement Reserve without stockholder approval, as permitted under Rule 5635(c)(4). The 2007 Plan was further amended without stockholder approval in February 2010 to reserve an additional 200,000 shares of our common stock to be issued pursuant to the Inducement Reserve.

Sales of Unregistered Securities

None.

Repurchases of Equity Securities

None.

Item 6. Selected Financial Data

The following selected financial data should be read together with our financial statements and related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Annual Report on Form 10-K.

	Years Ended December 31,				
	2016	2015	2014	2013	2012
	(In thousands, except per share amounts)				
Statement of Operations Data:					
Revenues:					
Collaborative agreement	$ 5,795	$ 13,865	$ 54,229	$ 3,428	$ 3,428
Royalties	5,931	10,594	1,292	—	—
Net product sales	21,983	—	—	—	—
Total revenues	33,709	24,459	55,521	3,428	3,428
Cost of product sales	7,995	—	—	—	—
Operating expenses:					
Research and development	38,023	40,750	57,412	56,748	73,680
Selling, general and administrative	118,583	43,762	28,639	23,878	19,987
Pre-existing settlement gain	(80,229)	—	—	—	—
Amortization expense of intangible assets	3,307	-	-	-	-
Change in fair value of contingent consideration	3,000	—	—	—	—
Total operating expenses	82,684	84,512	86,051	80,626	93,667
Loss from operations	(56,970)	(60,053)	(30,530)	(77,198)	(90,239)
Other income (expense):					
Interest income	622	227	88	65	147
Interest expense	(7,850)	(7,446)	(7,083)	(538)	(2)
Foreign currency loss net	(3,880)	(39)	—	—	—
Change in fair value of financial instruments	25,400	—	—	—	—
Gain on extinguishment of debt	18,287	—	—	—	—
Total other income (expense)	32,579	(7,258)	(6,995)	(473)	145
Net loss before income taxes	(24,391)	(67,311)	(37,525)	(77,671)	(90,094)
Income taxes	(133)	(1,376)	—	—	—
Net loss	$ (24,524)	$ (68,687)	$ (37,525)	$ (77,671)	$ (90,094)
Basic and diluted net loss per share (1)	$ (1.68)	$ (5.24)	$ (3.17)	$ (8.05)	$ (12.74)
Shares used to calculate net loss per share (1)	14,576	13,113	11,824	9,649	7,074

(1) See Note 2 of Notes to Financial Statements for an explanation of the method used to calculate the net loss per share and the number of shares used in the computation of the per share amounts.

	As of December 31,				
	2016	2015	2014	2013	2012
	(In thousands)				
Balance Sheet Data:					
Cash, restricted cash and investments, and investment securities, available-for-sale	$ 193,998	$ 214,011	$ 205,537	$ 176,996	$ 137,403
Working capital	159,101	201,654	181,612	155,429	113,780
Total assets	304,589	236,330	212,981	180,121	139,154
Long-term convertible debt	166,179	87,870	83,908	80,031	—
Accumulated deficit	(645,211)	(620,687)	(552,000)	(514,475)	(436,804)
Total stockholders' equity	57,044	33,378	22,344	41,862	75,469

Item 7. Management's Discussion And Analysis Of Financial Condition And Results Of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. In addition to historical information, this discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including but not limited to those set forth under "Item 1A - Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Overview

Background

We are a biopharmaceutical company focused on the treatment of obesity. Our sole product, Contrave, is approved in the United States by the U.S. Food and Drug Administration, or FDA, as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index, or BMI, of 30 kg/m 2 or greater (obese), or 27 kg/m 2 or greater (overweight) in the presence of at least one weight-related comorbid condition. Contrave is a combination of generic drug components, each of which has already received regulatory approval for other indications and been commercialized in the United States and in a majority of the member countries of the European Union.

In September 2014, the FDA notified us that it had approved our NDA for Contrave extended-release. Our former collaboration partner, Takeda Pharmaceutical Company Limited, or Takeda, commercially launched Contrave in the United States in October 2014. As part of the approval of Contrave by the FDA, we agreed to several post-marketing requirements, including studies to assess the safety and efficacy of Contrave for weight management in obese pediatric patients, a new randomized double-blind, placebo-controlled study to evaluate the effects of long-term treatment with Contrave on the incidence of major adverse cardiovascular, or CV, events in overweight and obese subjects with CV disease or multiple CV risk factors, and a group of short-term trials including a thorough QT study, single-dose pharmacokinetic studies in renal and hepatic impairment, and a drug-drug interaction study. We are now focused on the commercialization of Contrave.

In March 2015, the European Commission granted centralized marketing authorization for Contrave (under the name Mysimba™) (naltrexone HCl / bupropion HCl prolonged release) as an adjunct to a reduced-calorie diet and increased physical activity, for the management of weight in adult patients ($\geq$ 18 years) with an initial Body Mass Index of $\geq$ 30 kg/m 2 (obese), or $\geq$ 27 kg/m 2 to < 30 kg/m 2 (overweight) in the presence of one or more weight-related co-morbidities (e.g., type 2 diabetes, dyslipidemia, or controlled hypertension). This authorization applies to all 28 European Union member states, as well as Norway, Iceland and Lichtenstein.

In March 2016, we and Takeda entered into a separation agreement, which terminated our collaboration agreement. As of August 2016, all of Takeda's previous rights and obligations under that agreement were transitioned to us and we are now solely responsible for developing and commercializing Contrave within the United States and the rest of the world, including management and oversight of certain ongoing and planned post-marketing clinical trials of Contrave.

In May 2016, our commercialization partner, Kwang Dong Pharmaceutical Company, Ltd., or Kwang Dong, obtained regulatory approval and, in June 2016, commercially launched Contrave in South Korea. In addition, Contrave/Mysimba was recently commercially launched in Bulgaria, Croatia, the Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Slovakia and Slovenia by our partner, Valeant Pharmaceuticals, or Valeant, and in Spain by our partner, Laboratorios Farmacéuticos Rovi, S.A., or Rovi. We are currently advancing plans for the commercial launch of Contrave/Mysimba in certain other markets in Central and Eastern Europe, and Turkey with Valeant, in Italy with our partner Bruno Famaceutici, S.p.A., or Bruno, and in the United Kingdom and Ireland with our partner Consilient Health Ltd, or Consilient. We have also partnered with Valeant in Australia, New Zealand and Canada and are working with them to obtain regulatory approval of Contrave in these regions. In parallel, we are continuing partnering discussions for the rights to Contrave/Mysimba in other markets in the European Union and other territories outside the United States. Our ability to generate revenue for the foreseeable future will depend primarily on the commercial success of Contrave in the United States. Together, the Central and Eastern European countries, Turkey, Italy, Australia, New Zealand, Canada, South Korea, Spain, the United Kingdom and Ireland, are referred to in this Annual Report as the Partnered Regions.

In March 2016, we closed an offering, or the Offering, of $165.0 million aggregate principal amount of 0% Convertible Senior Secured Notes due 2020, or the 2016 Notes, and related warrants, or the Warrants, to purchase up to 21,999,999 shares of our common stock, par value $0.001 per share, or the Common Stock, and 219,994 shares of Series Z Non-Convertible Non-Voting Preferred Stock, par value $0.001 per share, or the Series Z Preferred Stock and, together with the 2016 Notes, Warrants and Common Stock underlying the 2016 Notes and Warrants, the Securities, to qualified institutional buyers and accredited investors, or the Purchasers, pursuant to a securities purchase agreement, dated March 15, 2016, or the Securities Purchase Agreement, by and among us and the Purchasers. The Offering was led by funds managed by The Baupost Group, L.L.C., which, prior to the Offering, was the holder of approximately 18.1% of the Company's outstanding Common Stock.

Our primary activities since incorporation have been organizational activities, including recruiting personnel, conducting research and development, including clinical trials, and raising capital. In connection with terminating our collaboration agreement with Takeda, our organizational activities have been updated and expanded to include the build out of a sales and marketing team and related quality, regulatory, safety and compliance teams for the takeover of commercial sales of Contrave in the United States that occurred in August 2016. We have incurred significant net losses since our inception. As of December 31, 2016, we had an accumulated deficit of $645.2 million. These losses have resulted principally from costs incurred in connection with research and development activities, primarily costs of clinical trial activities associated with our current product and product candidates, performing manufacturing-related activities, and selling, general and administrative expenses. We expect to continue to incur losses for the next several years. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support our cost structure, and until that time, we may need to continue to raise additional equity or debt financing.

Revenues

We generated approximately $33.7 million in revenue for 2016, resulting primarily from the sublicensing of technology and amounts earned under our collaboration agreement with Takeda and product sold directly by the Company. In September 2010, we entered into a collaboration agreement with Takeda to develop and commercialize Contrave in the United States, Canada and Mexico. Under the collaboration agreement, we received an upfront, nonrefundable cash payment of $50.0 million from Takeda and this amount is being recognized ratably over the estimated life of the agreement. In September 2014, we also recognized two regulatory/development milestones, consisting of $20.0 million due to us upon regulatory approval in the United States and $10.0 million due to us upon the delivery of launch supplies to Takeda as these payments were determined to meet the definition of a substantive milestone. In October 2014, we earned and were paid a $70.0 million milestone from Takeda for the shipment of Contrave to pharmacy wholesalers in preparation for the commercial launch. This milestone payment was determined to not meet the definition of a substantive milestone. As a result, we recognized $20.8 million in 2014 with $49.2 million deferred which was to be recognized over the remaining estimated life of the agreement. Takeda accounted for approximately 34%, 99% and 100% of revenue for the years ended December 31, 2016, 2015 and 2014, respectively.

In March 2016, we and Takeda entered into a separation agreement, which terminated our collaboration agreement in August 2016. We are now solely responsible for developing and commercializing Contrave within the United States. Subsequent to the transition from Takeda in August 2016, we recorded net sales of $17.3 million of Contrave in the U.S. for the five months ended December 31, 2016.

In 2016, we recorded net product sales of approximately $2.8 million of Contrave to our commercialization partner, Kwang Dong Pharmaceutical Company, Ltd., or Kwang Dong, in South Korea. We also recorded net product sales of approximately $1.9 million to our commercialization partner, Valeant Pharmaceuticals International, Inc., or Valeant, in Central and Eastern Europe in 2016.

Other than net product sales to Kwang Dong, Valeant and other international partners, our ability to generate revenue in the near term will depend solely on the success of our sales of Contrave in the United States. Given the early stage of commercialization, it is difficult to predict the amount of future sales of Contrave or the related revenues we will generate. Future sales of Contrave will depend on, among other factors, the availability and use of Contrave, our ability to continue to market and sell Contrave, and coverage and reimbursement by third-party payors.

Research and Development Expenses

Our research and development expenses consisted primarily of costs associated with clinical trials managed by contract research organizations, or CROs, product development efforts, raw materials, inventory, and manufacturing-related expenses. License fees, salaries and related employee benefits for certain personnel, and costs associated with certain non-clinical activities such as regulatory expenses, are also included in this amount. Our most significant costs to date are expenses incurred in connection with the clinical trials for Contrave. The clinical trial expenses included payments to vendors such as CROs, investigators, suppliers of clinical drug materials and related consultants. We charge all research and development expenses to operations as incurred because the underlying technology associated with these expenditures relates to our research and development efforts and has no alternative future uses.

Our internal research and development resources are not directly tied to any individual research project and are primarily deployed across our Contrave and other programs. We have developed Contrave in parallel with other projects and, due to the fact that we use shared resources across projects, we do not maintain information regarding our internal costs incurred for our research and development programs on a program-specific basis. We use external service providers to manage our clinical trials, to manufacture the product supplies used in these trials and for formulations development, consulting and other activities.

The following table summarizes our research and development expenses for the year ended December 31, 2016. Costs that are not attributable to a specific research program are included in the "Other" category (in thousands):

Costs of external service providers:		
Obesity	$	23,041
Other		1,701
Subtotal		24,742
Internal costs		10,847
Stock-based compensation		2,434
Total research and development costs	$	38,023

At this time, due to the risks inherent in the drug development process, we are unable to estimate with any certainty the costs we will incur for the post-marketing requirements of Contrave and any additional clinical trials required for post-marketing requirements of Contrave, under the name Mysimba, by the EMA. Future development expenses will depend on the conduct of the new CVOT and any other additional clinical trials for Contrave, if any, our financial resources and ongoing assessments as to Contrave's commercial potential. Clinical development timelines, the probability of success and development costs can differ materially from expectations. The lengthy process of completing our clinical trials, and seeking regulatory approval for our product candidates requires the expenditure of substantial resources. Any failure by us or delay in completing our clinical trials, or in obtaining regulatory approvals, could cause a delay in the commencement of product revenues and cause our research and development expenses to increase and, in turn, have a material adverse effect on our results of operations.

Selling, General and Administrative

Our selling, general and administrative expenses consist primarily of salaries and related costs for personnel in executive, commercial and internal support functions, as well as professional fees for legal, consulting and accounting services. In addition, selling, general and administrative expenses include our outsourced sales representatives and other sales and marketing costs necessary for commercializing Contrave. We anticipate selling, general and administrative expenses to increase substantially as we establish our sales and marketing capabilities in the United States

Interest and Other (Expense), Income net

Other Income (Expense) consists principally of interest expense incurred on the 2013 Notes, offset by our change in the fair value of our financial instruments on our 2016 convertible debt and warrant liability, income earned on marketable securities and foreign currency gains and losses. A portion of our business is conducted outside of the U.S. through our Irish foreign subsidiary. The foreign subsidiary keeps its accounting records in its functional currency, the Euro.

Income Taxes

At December 31, 2016, we have federal, state and foreign net operating loss carryforwards of approximately $445.4 million, $417.4 million and $39.0 million, respectively, not considering the IRC Section 382 annual limitation discussed below. The federal loss carryforwards begin to expire in 2027, unless previously utilized. At December 31, 2016, we have federal and state research and development tax credit carryforwards of $21.8 million and $7.0 million, respectively. The federal research and development tax credit carryforwards begin to expire in 2024 unless previously utilized. The state research and development tax credits and foreign net operating losses carry forward indefinitely. The California net operating loss carryforwards are scheduled to begin to expire in 2017. Approximately $12.2 million of the net operating loss carryforwards relates to excess tax deductions for stock compensation, the income tax benefit of which will be recorded as additional paid in capital if and when realized.

Additionally, the utilization of the net operating loss and research and development tax credit carryforwards is subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state tax provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes limit the amount of the net operating loss and research and development tax credit carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has completed an ownership change analysis in accordance with Section 382 from inception through December 31, 2016. As a result of the analysis, it was determined that the Company experienced several ownership changes during this period with the last one occurring in December 2014. The analysis to determine the limitation of NOLs and federal credits as a result of the ownership changes has not been finalized. Based on the preliminary analysis of the limitation of our net operating losses and federal credits, deferred tax assets for net operating losses of $189.4 million and $162.5 million for federal and state, respectively, and federal research and development credits of $12.0 million have been removed from the deferred tax asset

schedule. A corresponding decrease to the valuation allowance has also been recorded. Due to the existence of the valuation allowance, future changes in the deferred tax assets related to these tax attributes will not impact the effective tax rate.

During 2015, we expanded our operations internationally. We fully funded our Irish subsidiary with equity and debt and transferred the rights to exploit our intellectual property in markets outside of North America to our Irish subsidiary in exchange for a note. We also entered into a cost sharing arrangement, an intercompany services agreement and other related agreements with our Irish subsidiary which enable it to function as our foreign trading company. During 2015, we recognized a gain on the transfer of intellectual property to our Irish subsidiary in the amount of $69.7 million. This gain was eliminated in consolidation for financial reporting purposes, but recognized for US federal income tax purposes, and offset by NOL carryforwards for federal income tax purposes. We incurred federal alternative minimum tax of $1.3 million as a result of the gain and the results of operations in the US, which we recorded to current tax expense for 2015. We did not incur US federal income tax for 2016 and incurred $133,000 of state income tax expense for 2016. Our Irish subsidiary generated a tax loss of $26.6 million during 2016 which was fully offset by a valuation allowance.

Critical Accounting Policies and Estimates

Management's discussion and analysis of our financial condition and results of operations are based upon our financial statements, which are prepared in accordance with accounting principles that are generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities, related disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. We continually evaluate our estimates and judgments, the most critical of which are those related to accounting for research and development expenses, net product sales and stock-based compensation costs. We base our estimates and judgments on historical experience and other factors that we believe to be reasonable under the circumstances. Materially different results can occur as circumstances change and additional information becomes known.

We believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue Recognition

Collaborative agreement revenue

Prior to the revised multiple element and milestone method of revenue recognition guidance adopted by the Company on January 1, 2011, nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by the Company under the agreements were recognized as revenue upon the earlier of when payments were received or collection was assured, but were deferred if the Company had continuing performance obligations. If the Company had continuing involvement through contractual obligations under such agreements, such up-front fees were deferred and recognized over the period for which the Company continued to have a performance obligation.

Effective January 1, 2011, for multiple element agreements entered into or materially modified after December 31, 2010, the Company follows the provisions of Accounting Standards Update, or the ASU, No. 2009-13. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. A delivered item is considered a separate unit of accounting when the delivered item has value to the partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using vendor-specific objective evidence, or VSOE, of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company use its best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of drug products, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, the Company's price to the partner is fixed or determinable, and collectability is reasonably assured.

Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have a material impact on the amount of revenue recognized in a given period.

The Company accounts for milestone payments under its agreements using the milestone method of accounting. The Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following three criteria: 1) the consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, 2) the consideration relates solely to past performance, and 3) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. Any milestone payments that do not satisfy these revenue recognition criteria are recorded over the remaining life of the agreements with a cumulative catch up adjustment for the portion of the milestone earned from the inception of the agreement to the expected term of the agreement. The excess of the milestone paid and the amount recognized in the cumulative catch up adjustment is recorded as deferred revenue and recognized over the remaining expected term of the agreement.

Royalty revenue

Royalties to be received based on sales of the Company's licensed products by partners are recognized as earned.

Product Sales, Net

The Company's net product sales consist of U.S. sales of Contrave as well as product sales to our distributors in other countries. The Company recognizes product revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, net product revenue from the sale of Contrave/Mysimba is generally recognized upon transfer of title of the product to our third-party customers, provided that no significant obligations remain.

Effective August 1, 2016, the Company reacquired the commercial rights of Contrave from Takeda and began selling Contrave in the U.S. The Company commenced shipments of Contrave to its wholesalers in mid-August 2016. The Company has determined it does not currently have the necessary volume of activity to reasonably estimate certain sales allowances at the time title and risk of loss transfers to the wholesalers. Accordingly, the price is not considered fixed or determinable at that time. Therefore, the Company recognizes revenue when the wholesalers sell Contrave to the dispensing institutions (i.e. pharmacies, hospitals) at which point it has developed sufficient historical experience and data to reasonably estimate future returns and chargebacks. As of December 31, 2016, the Company had a deferred revenue balance of approximately $1.0 million related to Contrave net product sales.

Upon recognition of revenue from product sales of Contrave in the U.S., the Company records certain sales reserves and allowances as a reduction to gross revenue. These reserves and allowances include:

Rebates:

The Company records provisions for U.S. Medicaid, and commercial managed care contract rebates at the time revenue is recognized based upon our estimated rebate claims attributable to a sale. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. For commercial managed care contract rebates, the Company considers current contract terms, such as changes in formulary status and agreed to discount rates, along with historical utilization rates. Orexigen also considers outstanding rebate claims, rebate payments, forecasted sales, and levels of inventory in the distribution channel and adjusts estimates each period to reflect actual experience. There can be a significant time lag between recording estimates and actual payments.

Chargebacks:

The Company provides predetermined discounts under certain government programs, including the Veterans Administration Federal Supply Schedule, or FSS, and Public Health Service 340B, whereby the pharmacies or health care facilities affiliated with these programs purchase Contrave from wholesalers at reduced prices. A chargeback represents the difference between the invoice price to the wholesaler and the contractual discounted price offered by the Company under the respective program. Our estimate for

these chargeback fees takes into consideration contractual terms, historical utilization rates along with payor mix, and our expectations regarding future utilization rates.

Cash Discounts:

The Company offers certain wholesalers cash discounts as an incentive for meeting certain payment terms. The Company estimates prompt payment discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. As the prompt pay discounts are applied against wholesaler purchases of Contrave, the Company records its initial estimate at the point in which that sales occurs.

Distribution Fees:

The distribution fees, based on contractually determined rates, arise from contractual agreements the Company has with certain wholesalers for distribution services they provide with respect to Contrave. These fees are generally a fixed percentage of the price of the product purchased by the wholesalers.

Savings Card Program:

The Company offers certain discount programs to patients under which the patient receives a discount on his or her prescription. The Company reimburses pharmacies for this discount through a third-party vendor. The discounts, which are recorded as a reduction of sales at the point of revenue recognition, reflect an estimate based on historical utilization rates, expectations surrounding future utilization, and user mix in relation to the discount offering.

Sales Returns:

The Company allows the wholesalers to return product that is damaged or received in error. In addition, the Company accepts unused product to be returned beginning six months prior to and ending twelve months following product expiration. Additional specific rights of return are also extended to certain customers. The Company believes that its estimated product returns for Contrave requires a high degree of judgement and is subject to change based on our experience and certain quantitative and qualitative factors. Because of the shelf life of Contrave and the lengthy return period, there may be a significant period of time between when the product is shipped and when the Company issues credits on returned product. In order to develop a methodology to reliably estimate future returns, the Company analyzes many factors, including, without limitation: (1) actual Contrave product return history, taking into account product expiration dating at the time of shipment, (2) re-order activities of the wholesalers as well as their customers and (3) levels of inventory in the wholesale channel. The Company considers the dating of product at the time of shipment into the distribution channel and changes in the estimated levels of inventory within the distribution channel to estimate our exposure to returned product. The Company also considers current contract prices and projected future prices to estimate the exposure to returned product. Given the exposure to returns and the Company's limited history of selling Contrave in the U.S., the Company recognizes product sales allowances based on these estimates as a reduction of product sales in the same period the related revenue is recognized, upon sale of Contrave from the wholesalers to the pharmacies, hospitals, etc. The Company believes this reduces its exposure to returns and allows us to more reasonably justify the estimate. Should actual product return results differ from our estimates, however, the Company will be required to make adjustments to these allowances in the future, which could have an effect on product sales revenue and earnings in the period of adjustments.

Research and Development Expenses

All research and development costs are charged to expense as incurred and consist principally of costs related to clinical trials, license fees and salaries and related benefits. Clinical trial costs are a significant component of research and development expenses. These costs are accrued based on estimates of work performed, and require estimates of total costs incurred based on patients enrolled, progress of clinical studies and other events. Clinical trial costs are subject to revision as the trials progress and revisions are charged to expense in the period in which they become known.

Fair Value Option

The Company has elected the fair value option to account for its convertible notes that were issued during the quarter ended March 31, 2016 and records these convertible notes at fair value with changes in fair value recorded in the statement of operations. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in earnings as incurred and not deferred.

Fair Value of Contingent Consideration

As part of the Separation Agreement between the Company and Takeda, the Company recorded a current contingent consideration liability and a long-term contingent consideration liability that have been classified as Level 3 inputs in the fair value hierarchy. The contingent consideration represents the estimated fair value of future payments due to Takeda based on: (i) Orexigen achieving annual net sales targets in certain years and (ii) Takeda performing certain obligations, as outlined in the Separation Agreement. The initial fair value of the long-term portion of the contingent consideration based on net sales was estimated through the use of a Monte Carlo simulation model. The Monte Carlo simulation model utilized the following assumptions: (i) expected term; (ii) risk-adjusted net sales; (iii) risk-free interest rate; and (iv) expected volatility. The initial fair value of the current portion of the contingent consideration based on Takeda performing certain obligations was estimated using a probability weighted approach. The probability was applied to the contingent consideration based on Takeda performing certain obligations and discounted to present value. The fair value of the Company's contingent consideration liability is revalued to fair value each period and any increase or decrease is recorded into earnings. The fair value of the contingent consideration is impacted by certain unobservable inputs, most significantly with regards to the discount rates, probability of scenario occurrence, expected volatility, historical and projected net sales performance, and expected scenario timing. Significant changes to these inputs in isolation could result in a significantly different fair value measurement.

Purchased Intangibles

Acquired assets and assumed liabilities recognized in an acquisition are recorded on the basis of their estimated fair values determined by management at the date of acquisition. The fair value of intangible assets (developed technology intangible and tradename) was determined primarily using the "income method," which starts with a forecast of all expected future cash flows. Some of the more significant assumptions inherent in the intangible asset values, from the perspective of a market participant, include: the amount and timing of projected future cash flows (including net revenue, cost of product sales, research and development costs, sales and marketing expenses, capital expenditures and working capital requirements) as well as estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, among other factors.

The Company reviews its finite-lived intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of finite-lived intangible asset may not be recoverable. Recoverability of a finite-lived intangible asset is measured by a comparison of its carrying amount to the undiscounted future cash flows expected to be generated by the asset. If the asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no indicators of impairment during the period ended December 31, 2016.

Stock-Based Compensation

We account for stock-based compensation to employees in accordance with the fair value method of accounting for stock-based compensation arrangements which requires us to expense the estimated fair value of non-cash, stock-based payments to employees. Share-based payment transactions with employees are recognized in the financial statements based on their fair value and recognized as compensation expense over the vesting period.

We grant options to purchase our common stock to our employees, directors and non-employees under our 2007 equity incentive award plan. Stock-based compensation expense for the years ended December 31, 2016, 2015 and 2014 was $10.3 million, $15.2 million and $15.3 million, respectively. At December 31, 2016, total unrecognized estimated stock-based compensation expense related to non-vested stock options granted prior to that date was $21.6 million, which is expected to be recognized over a weighted-average period of 3.2 years.

We calculate the fair value of stock option grants using the Black-Scholes option-pricing model. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our expected stock price volatility over the term of the awards, risk-free interest rate and the expected term of the awards.

The weighted average expected life of an award is based on historical forfeiture experience, exercise activity, and on the terms and conditions of the stock awards. For options granted during the year ended December 31, 2016, we have calculated a weighted average expected term of 5.5 years. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of the stock awards. For purposes of estimating the fair value of stock options granted during 2016 using the Black-Scholes model, we used an estimated weighted average stock price volatility of 95.4%.

The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued (weighted-average risk-free interest rate of 1.3% for the

year ended December 31, 2016). The assumed dividend yield was based on our expectation of not paying dividends in the foreseeable future.

For 2016, 2015 and 2014, we have reduced stock-based compensation expense recognized in the Consolidated Statement of Operations to reflect estimated forfeitures. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated to be approximately 10.0% for all years ended December 31, 2016, 2015 and 2014 based on historical experience.

Equity instruments issued to non-employees are recorded at their fair value and are periodically revalued as the equity instruments vest and are recognized as expense over the related service period.

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates which will be in effect when the differences reverse. We provide a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized.

We follow the provisions of the Income Taxes Topic of the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, that defines a recognition threshold and measurement attributes for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The topic also provides guidance on de-recognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. Under the topic, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Results of Operations

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

Revenues. Revenues increased to $33.7 million for the year ended December 31, 2016 from $24.5 million in 2015, and primarily represent revenues recognized for the net sales of Contrave. The increase of approximately $9.2 million in 2016 was due primarily to Orexigen recording net sales of Contrave starting August 2016 as a result of acquiring the U.S. rights to Contrave from Takeda, which amounted to an increase of $22.0 million in net sales of Contrave when compared to 2015. This increase was partially offset by a decrease of $8.1 million of milestone revenues and $4.7 million of royalty revenues for sales of Contrave by Takeda in 2016 as compared to 2015 as a result of the Separation Agreement.

Cost of Sales. Cost of sales was approximately $8.0 million for the year ended December 31, 2016. There were no product sales for the year ended December 31, 2015, and therefore, no cost of sales in the same period of 2015.

Research and Development Expenses. Research and development expenses decreased to $38.0 million for the year ended December 31, 2016 from $40.8 million in 2015. This decrease of approximately $2.8 million was due primarily to a decrease in expenses in connection with our Contrave CVOT, related proprietary product formulation work and related consulting activities of $2.9 million and a decrease in stock-based compensation expense of $1.9 million. This decrease was partially offset by an increase in other consulting activities of $1.4 million and an increase in salaries and other personnel related costs of $500,000.

Selling, General and Administrative Expenses. Selling, general and administrative (SG&A) expenses increased to $118.6 million for the year ended December 31, 2016 from $43.8 million in 2015. Specifically, sales and marketing costs were $79.5 million and $13.2 million for the year ended December 31, 2016 and 2015, respectively. General and administrative costs were $39.1 million and $30.6 million for the year ended December 31, 2016 and 2015, respectively. This overall SG&A increase of approximately $74.8 million was due primarily to an increase in sales and marketing department costs of $66.3 million to establish sales, marketing and distribution capabilities in order to commercialize Contrave in the United States. This increase in sales and marketing department costs included an increase of $45.3 million in contract sales, promotion and advertising expenses, an increase in salaries and personnel related costs of $11.2 million, an increase in professional fees of $3.5 million and an increase in marketing materials related expenses of $1.8 million.

The general and administrative expenses increased by approximately $8.5 million including an increase in legal and other fees related to the March 2016 debt offering of $7.1 million, an increase in salaries and personnel related costs of $3.2 million, and an increase of professional and consulting costs of $1.1 million. These increases were partially offset by a decrease in stock-based compensation expense of approximately $3.4 million.

Pre-existing Settlement Gain. Pre-existing settlement gain was approximately $80.2 million for the year ended December 31, 2016. As a result of the Separation Agreement and the settlement of a pre-existing relationship with Takeda, the Company recorded a settlement non-cash gain of $80.2 million representing the existing Contrave deferred revenue.

Amortization Expense of Intangible Assets. As a result of the intangible assets acquired in the Contrave business combination, the Company recorded amortization expense over the estimated useful life of the assets. Amortization expense of intangible assets was approximately $3.3 million for the year ended December 31, 2016.

Change in Fair Value of Contingent Consideration. The change in fair value of contingent consideration related to the Takeda business combination was $3.0 million for the year ended December 31, 2016.

Interest Income. Interest income increased to $622,000 for the year ended December 31, 2016 from $227,000 in 2015. This increase of approximately $395,000 was primarily due to an increase in average investment balances and higher interest rates as compared to 2015.

Interest and Other Expense, net. Interest and other expense, net increased to $7.9 million for the year ended December 31, 2016 from $7.5 million in 2015. This increase of approximately $400,000 was primarily due to an increase in the amortization of the discount of the liability component of the 2013 Notes.

Foreign Currency Gain (Loss) net. Foreign currency loss increased to $3.9 million for the year ended December 31, 2016 from $39,000 in 2015. This increase was primarily due to the fluctuation in the Euro.

Change in Fair Value of Financial Instruments. The change in fair value of financial instruments was $25.4 million for the year ended December 31, 2016 reflecting the change in fair value of the convertible debt and warrant liability issued in March 2016.

Gain on Extinguishment of Debt. In December 2016, the Company purchased approximately $35.0 million in face value of the outstanding 2013 Notes for approximately $10 million. As a result of the note repurchase, the Company recorded a gain on extinguishment of debt of approximately $18.3 million during the year ended December 31, 2016, determined as the difference between the purchase price and the net carrying value of the 2013 Notes that were purchased.

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

Revenues. Revenues decreased to $24.5 million for the year ended December 31, 2015 from $55.5 million in 2014, and represent revenue recognized under our collaboration agreement with Takeda. The decrease of approximately $31.0 million in 2015 was due primarily to recognition of two regulatory/development milestones in 2014, consisting of $20.0 million payable upon regulatory approval of Contrave in the United States and $10.0 million payable upon the delivery of Contrave launch supplies to Takeda, partially offset by $10.3 million of deferred revenue recognized in 2015. Also in 2014, we recognized $20.8 million of a $70.0 million milestone we received from Takeda for the shipment of Contrave to pharmacy wholesalers in preparation for the commercial launch. This was partially offset by an increase of $9.3 million of royalty revenues for sales of Contrave by Takeda in 2015 as compared to 2014.

Research and Development Expenses. Research and development expenses decreased to $40.8 million for the year ended December 31, 2015 from $57.4 million in 2014. This decrease of approximately $16.6 million was due to a decrease in pre-launch expenses for Contrave including raw materials, inventory, and manufacturing-related expenses of $10.1 million and a decrease in expenses of $5.9 million in connection with our Contrave clinical costs, related proprietary product formulation work and consulting activities.

General and Administrative Expenses. General and administrative expenses increased to $43.8 million for the year ended December 31, 2015 from $28.6 million in 2014. This increase of approximately $15.2 million was due primarily to an increase in marketing and market research costs of $9.2 million, an increase in recruiting costs of $1.9 million, an increase in consulting and professional fees of $1.7 million and an increase in salaries and other personnel related costs of $744,000.

Interest Income. Interest income increased to $227,000 for the year ended December 31, 2015 from $88,000 in 2014. This increase of approximately $139,000 was primarily due to an increase in average investment balances and higher interest rates as compared to 2014.

Interest and Other Expense, net. Interest and other expense, net increased to $7.3 million for the year ended December 31, 2015 from $7.1 million in 2014. This increase of approximately $300,000 was primarily due to an increase in the amortization of the discount of the liability component of the 2013 Notes.

Foreign Currency Gain (Loss) net. Foreign currency gain (loss) net increased to $39,000 for the year ended December 31, 2015 from zero in 2014. This increase was primarily due to the fluctuation in the Euro.

Liquidity and Capital Resources

Since inception, our operations have been financed primarily through the issuance of equity and debt securities. Through December 31, 2016, we received net proceeds of approximately $798.3 million from the issuance of equity and debt securities as follows:

- from September 12, 2002 to December 31, 2006, we issued and sold a total of 105,357 shares of common stock for aggregate net proceeds of $14,801;
- in March 2004, we issued and sold a total of 932,204 shares of Series A redeemable convertible preferred stock for aggregate net proceeds of $9.2 million and the conversion of promissory notes and interest thereon totaling $1.7 million;
- from April 2005 to May 2005, we issued and sold 1,483,051 shares of Series B redeemable convertible preferred stock for aggregate net proceeds of $34.9 million;
- in November 2006, we issued and sold a total of 877,193 shares of Series C convertible preferred stock for aggregate net proceeds of $29.9 million;
- in May 2007, we issued and sold a total of 805,000 shares of common stock for aggregate net proceeds of $87.9 million;
- in January and February 2008, we issued and sold a total of 732,644 shares of common stock for aggregate net proceeds of $74.9 million;
- in July 2009, we issued and sold a total of 1,150,000 shares of common stock for aggregate net proceeds of $81.6 million;
- in December 2011, we issued and sold a total of 564,617 shares of common stock and common stock warrants to purchase up to 5,646,173 shares for aggregate net proceeds of $86.9 million;
- in October 2012, we issued and sold a total of 1,100,000 shares of common stock for aggregate net proceeds of $56.5 million;
- in December 2013, we issued the 2013 Notes for aggregate net proceeds of $110.5 million;
- in September 2015, we issued and sold a total of 2.0 million shares of common stock and common stock warrants to purchase 500,000 shares of our common stock for aggregate net proceeds of $59.8 million; and
- in March 2016, we issued the 2016 Notes, warrants to purchase up to 21,999,999 shares of common stock and 219,994 shares of Series Z Preferred Stock for aggregate net proceeds of $164.3 million.

As of December 31, 2016, we had $92.5 million in cash and cash equivalents, $11.5 million in investment securities, available-for-sale and restricted investments of $90.0 million. As of December 31, 2016, our holdings primarily consisted of treasury-backed money market funds, treasuries and other instruments that are insured, guaranteed or supported by the U.S. federal government, and corporate debt obligations. We maintain established guidelines relating to diversification and maturities of our investments to preserve principal and maintain liquidity. The Company had $90.2 million in restricted cash and investments as of December 31, 2016 as required by our 2016 financing agreements. The required restricted cash and investments amounts are $90.0 million and $40.0 million until March 21, 2017 and June 21, 2017, respectively.

Net cash used in operating activities was $109.7 million and $54.5 million for 2016 and 2015, respectively. Net cash used in operating activities was primarily a result of sales and marketing expenses, external research and development expenses, clinical trial costs, personnel-related costs, third-party supplier and manufacturer expenses and professional fees.

Net cash used in investing activities was $107.1 million for 2016 and net cash provided by investing activities was $41.4 million for 2015. In 2016, restricted cash and investments increased by $90.2 million as required by the issuance of the 2016 Notes. In 2016, we made a $60.0 million payment to Takeda for the acquisition of the Contrave business. Also, these amounts are the result of the net purchases and maturities of investment securities.

Net cash provided by financing activities was $154.6 million and $64.3 million for 2016 and 2015, respectively. In 2016, we received approximately $164.3 million net proceeds from the issuance of convertible debt, warrants and preferred stock. The net cash provided by financing activities for 2015 was primarily as a result of the issuance of 2.0 million shares of our common stock in a private placement for aggregate net proceeds of $59.8 million.

We cannot be certain what extent we will receive cash inflows from the commercialization of our product candidates beyond the net product sales related to Contrave.

We have entered into a license agreement for the rights to develop and commercialize Contrave. Pursuant to this agreement, we obtained exclusive and non-exclusive licenses to the patent rights and know-how for selected indications and territories. Pursuant to our agreement with Oregon Health & Science University, we issued 7,632 shares of our common stock in December 2003 and paid an upfront fee of $65,000. We are also obligated to pay royalties on any net sales of the applicable licensed product(s), including Contrave. Our royalty payable to OHSU at December 31, 2016 for Contrave sales was approximately $175,000.

Our future capital uses and requirements depend on numerous factors. These factors include but are not limited to the following:

- the successful commercialization of Contrave;
- the scope and cost of the post-marketing requirements for Contrave in the U.S. and Mysimba in the E.U.;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish with respect to Contrave;
- the costs of establishing sales, marketing and distribution capabilities in order to commercialize Contrave should we elect to do so;
- the costs involved in enforcing or defending patent claims or other intellectual property rights;
- the costs and timing of additional regulatory approvals for Contrave, if at all; and
- the extent to which we in-license, acquire or invest in other indications, products, technologies and businesses.

Although it is difficult to predict future liquidity requirements, we believe that our existing cash and cash equivalents and investment securities, available-for-sale, and anticipated product revenue, will be sufficient to meet our projected operating requirements through the next 12 months.

Until we can generate significant cash from our operations, we expect to continue to fund our operations with existing cash resources, proceeds of potential offerings of our equity securities, debt, receivables or royalty financings and potential future corporate collaborations and licensing arrangements. However, we cannot be sure that our existing cash and investment resources and future product revenue will be adequate, 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 development programs and/or our pre-commercialization and commercialization activities, relinquish some or even all rights to product candidates or renegotiate less favorable terms than we would otherwise choose. Failure to obtain adequate financing also may adversely affect our ability to operate as a going concern. If we raise additional funds by issuing equity securities, substantial dilution to existing stockholders would likely result. Debt, receivables and royalty financings may be coupled with an equity component, such as warrants to purchase stock, which could also result in dilution of our existing stockholders' We cannot be certain if, when or to what extent we will receive cash inflows from the commercialization of our product candidates beyond the sales of Contrave. As a result of the termination of our collaboration with Takeda, we are solely responsible for developing and commercializing Contrave within the United States and the rest of the world and are responsible for the functions previously the responsibility of Takeda, including management and oversight of certain ongoing and planned post-marketing clinical trials of Contrave, including the new CVOT. We will incur substantial costs as we establish sales, marketing and distribution capabilities in order to commercialize Contrave. We will incur substantial additional development expenses to pay for the new CVOT for Contrave.

Any turbulence in the U.S. and international markets and economies may adversely affect our ability to access the capital markets and obtain additional financing on terms acceptable to us, or at all.

Contractual Obligations and Commitments

The following table describes our long-term contractual obligations and commitments as of December 31, 2016 (in thousands):

	Payments Due by Periods				
	Total	Less Than 1 Year	1-3 Years	4-5 Years	After
Debt obligations	$ 245,000	$ —	$ —	$ 245,000	$ —
Interest on debt obligations (1)	8,617	2,200	4,400	2,017	—
Purchase obligations	2,937	2,937	—	—	—
Operating lease obligations	1,762	1,508	254	—	—
Total	$ 258,316	$ 6,645	$ 4,654	$ 247,017	$ —

(1) Interest on the 2013 Notes calculated at 2.75%

We have not included certain license obligations which may require additional payments due upon the occurrence of certain milestones related to regulatory or commercial events. We are required to pay royalties on any net sales of the licensed products. License payments may increase based on the timing of various milestones and the extent to which the licensed technologies are pursued for other indications. These milestone payments and royalty payments under our license agreements are not included in the table above because we cannot, at this time, determine when or if the related milestones will be achieved or the events triggering the commencement of payment obligations will occur.

We also enter into agreements with third parties to manufacture our product candidates, conduct our clinical trials and perform data collection and analysis. Our payment obligations under these agreements depend upon the progress of our development programs. Therefore, we are unable at this time to estimate with certainty the future costs we will incur under these agreements.

Recently Issued Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, "*Revenue from Contracts with Customers*," which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASU 2014-09 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new standard will be effective for the Company starting in the first quarter of fiscal 2018. The FASB will permit entities to adopt one year earlier if they choose (i.e., the original effective date). The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The Company is in the process of performing a preliminary assessment of the impact of ASU 2014-09 on the Consolidated Financial Statements, and is considering all items outlined in the standard. In assessing the impact, the Company will identify all revenue generating activities, map those activities to deliverables and map those deliverables to the standard. The Company will be assessing what impact the change in standard will have on those deliverables. Based on the Company's preliminary assessment to date, the Company expects that the new standard will impact the estimation of sales allowances for the Company's U.S. product revenues and the timing of revenue recognition which could be earlier than that what the Company is currently recognizing U.S. product revenue. The Company will continue to evaluate the impact of ASU 2014-09 and related amendments on the Consolidated Financial Statements and related disclosures throughout 2017. The Company plans to adopt the new standard beginning January 2018 using the modified retrospective method.

In April 2015, the FASB issued ASU No, 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which simplifies the presentation of debt issuance costs by requiring debt issuance costs to be presented as a deduction from the corresponding debt liability, consistent with the presentation of debt discounts or premiums. Previous guidance generally required entities to present debt issue costs separately as deferred charges. The Company adopted the new guidance in the first quarter of 2016, and prior year amounts were reclassified to conform to the current year presentation. The adoption of this guidance resulted in the reclassification of approximately $259,000 of unamortized debt issuance costs principally from other noncurrent assets to a reduction of long term debt on our consolidated balance sheet as of December 31, 2015. At December 31, 2016, debt issuance costs of approximately $147,000 were netted against long term debt on our consolidated balance sheet under the new guidance.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU No. 2016-2 requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet for all leases and to disclose key information about leasing arrangements. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. ASU No. 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the impact of adoption of ASU No. 2016-02 on the consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "*Compensation – Stock Compensation* (Topic 718): Improvements to Employee Share-Based Payment Accounting", or ASU 2016-09. The amendment is to simplify several aspects of the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in ASU 2016-09 are effective for interim and annual reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of ASU 2016-09 on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on

expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available for sale debt securities. The ASU is effective for the Company beginning in the first quarter of 2020, with early adoption permitted. The Company is currently evaluating the impact of ASU 2016-13 on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments,* which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of this new pronouncement on its consolidated statements of cash flows and related disclosures.

In August 2014, the FASB issued ASU 2014-15, "*Presentation of Financial Statements - Going Concern*," which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and provide related footnote disclosures. ASU 2014-15 was effective for the Company for the year ended December 31, 2016 and for interim reporting periods thereafter. The adoption of this new standard did not have an impact on our consolidated financial statements at December 31, 2016 but may require additional disclosures in our consolidated financial statements in future quarters.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows* (Topic 230) - Restricted Cash, which outlines that a statement of cash flows explains the change during the period in total cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 is effective for public business entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2017, and early application is permitted. The Company is currently evaluating the impact this standard will have on its consolidated financial statements.

In January 2017, the FASB issued an ASU 2017-01, *Business Combinations* (Topic 805) Clarifying the Definition of a Business. The amendments in this Update is to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company is currently evaluating the impact of adopting this guidance.

Off-Balance Sheet Arrangements

We have not engaged in any off-balance sheet activities.

Item 8. Financial Statements and Supplementary Data

Index to Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of
Orexigen Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Orexigen Therapeutics, Inc. as of December 31, 2016 and 2015, and the related consolidated statements of operations, comprehensive loss, 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. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Orexigen Therapeutics, Inc. at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

San Diego, California
March 29, 2017

OREXIGEN THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS
(In thousands, except share and par value amounts)

	December 31,	
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	$ 92,494	$ 155,422
Accounts receivable, net	1,102	6,828
Investment securities, available-for-sale	11,499	58,589
Restricted cash and investments	90,005	—
Inventory	23,193	10,802
Prepaid expenses and other current assets	6,168	2,254
Total current assets	224,461	233,895
Property and equipment, net	1,044	1,284
Intangible assets	76,061	—
Other long-term assets	2,835	1,013
Restricted cash	188	138
Total assets	$ 304,589	$ 236,330
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 15,210	$ 6,485
Accrued clinical trial expenses	—	5,820
Accrued expenses	30,412	10,323
Contingent consideration	15,000	—
Deferred revenue, current portion	4,738	9,613
Total current liabilities	65,360	32,241
Long-term contingent consideration	6,800	—
Long-term convertible debt	64,279	87,870
Long-term convertible debt, at fair value	101,900	—
Deferred revenue, less current portion	5,863	82,691
Other long-term liabilities	—	150
Commitments and contingencies		
Series Z preferred stock, $.001 par value, 219,994 and no shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	3,343	—
Stockholders' equity:		
Preferred stock, $0.001 par value, 10,000,000 shares authorized at December 31, 2016 and 2015, 219,994 shares and no shares issued and outstanding at December 31, 2016 and 2015, respectively	—	—
Common stock, $0.001 par value, 300,000,000 shares authorized at December 31, 2016 and 2015; 14,616,751 and 14,554,492 shares issued and outstanding at December 31, 2016 and 2015, respectively	15	15
Additional paid-in capital	698,229	653,835
Accumulated other comprehensive income	4,011	215
Accumulated deficit	(645,211)	(620,687)
Total stockholders' equity	57,044	33,378
Total liabilities and stockholders' equity	$ 304,589	$ 236,330

See accompanying notes.

OREXIGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)

	Years Ended December 31,		
	2016	2015	2014
Revenues:			
Collaborative agreement	$ 5,795	$ 13,865	$ 54,229
Royalties	5,931	10,594	1,292
Net product sales	21,983	—	—
Total revenues	33,709	24,459	55,521
Cost of product sales	7,995	—	—
Operating expenses:			
Research and development	38,023	40,750	57,412
Selling, general and administrative	118,583	43,762	28,639
Pre-existing settlement gain	(80,229)	—	—
Amortization expense of intangible assets	3,307	—	—
Change in fair value of contingent consideration	3,000	—	—
Total operating expenses	82,684	84,512	86,051
Loss from operations	(56,970)	(60,053)	(30,530)
Other income (expense):			
Interest income	622	227	88
Interest expense	(7,850)	(7,446)	(7,083)
Foreign currency loss net	(3,880)	(39)	—
Change in fair value of financial instruments	25,400	—	—
Gain on extinguishment of debt	18,287	—	—
Total other income (expense)	32,579	(7,258)	(6,995)
Net loss before income taxes	(24,391)	(67,311)	(37,525)
Income taxes	(133)	(1,376)	—
Net loss	$ (24,524)	$ (68,687)	$ (37,525)
Net loss per share — basic and diluted	$ (1.68)	$ (5.24)	$ (3.17)
Shares used to compute basic and diluted net loss per share	14,576	13,113	11,824

See accompanying notes.

OREXIGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Years Ended December 31,		
	2016	**2015**	**2014**
Net loss	$ (24,524)	$ (68,687)	$ (37,525)
Other comprehensive income (loss)			
Foreign currency translation gain	3,807	224	—
Unrealized gains (losses) on investment securities	(12)	18	(23)
Other comprehensive income (loss)	3,795	242	(23)
Comprehensive loss	$ (20,729)	$ (68,445)	$ (37,548)

See accompanying notes.

OREXIGEN THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2013	10,497	$ 10	$ 556,330	$ (3)	$ (514,475)	$ 41,862
Net exercise of warrants	1,730	2	15	—	—	17
Exercise of common stock options	111	—	2,286	—	—	2,286
Issuance of common stock for Employee Stock Purchase Plan	8	—	431	—	—	431
Stock-based compensation expense	—	—	15,296	—	—	15,296
Unrealized loss on securities, available-for-sale	—	—	—	(23)	—	(23)
Net loss					(37,525)	(37,525)
Balance at December 31, 2014	12,346	12	574,358	(26)	(552,000)	22,344
Net exercise of warrants	57	0	1	—	—	1
Issuance of common stock for private placement	2,000	2	59,801	—	—	59,803
Exercise of common stock options	139	1	4,098	—	—	4,099
Issuance of common stock for Employee Stock Purchase Plan	13	—	356	—	—	356
Stock-based compensation expense	—	—	15,221	—	—	15,221
Unrealized gain on securities, available-for-sale	—	—	—	18	—	18
Cumulative translation adjustment	—	—	—	224	—	224
Net loss					(68,687)	(68,687)
Balance at December 31, 2015	14,555	15	653,835	216	(620,687)	33,379
Reclassification of warrants to equity	—	—	33,700	—	—	33,700
Exercise of common stock options	2	—	36	—	—	36
Issuance of common stock for Employee Stock Purchase Plan	60	—	152	—	—	152
Stock-based compensation expense	—	—	10,506	—	—	10,506
Unrealized loss on securities, available-for-sale	—	—	—	(12)	—	(12)
Cumulative translation adjustment	—	—	—	3,807	—	3,807
Net loss					(24,524)	(24,524)
Balance at December 31, 2016	14,617	$ 15	$ 698,229	$ 4,011	$ (645,211)	$ 57,044

See accompanying notes.

OREXIGEN THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)

	Years Ended December 31,		
	2016	**2015**	**2014**
Operating activities			
Net loss	$ (24,524)	$ (68,687)	$ (37,525)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Amortization of premium on investment securities, available-for-sale	245	763	751
Accretion of debt discount	4,564	4,221	3,877
Change in fair value of financial instruments	(25,400)	—	—
Gain from pre-existing settlement	(80,229)	—	—
Change in fair value of contingent consideration	3,000	—	—
Amortization of intangible assets	3,307	—	—
Gain from extinguishment of debt	(18,287)	—	—
Depreciation	428	223	139
Unrealized foreign currency loss	4,307	197	—
Stock-based compensation	10,330	15,220	15,296
Other non-cash adjustments	586	63	43
Changes in operating assets and liabilities:			
Accounts receivable, net	5,668	(4,257)	(2,494)
Inventory	1,453	(9,610)	(1,198)
Prepaid expenses and other current assets	(3,913)	(781)	(175)
Restricted cash	—	39	—
Accounts payable and accrued expenses	11,814	1,026	2,107
Other assets	(1,843)	(713)	112
Deferred rent and lease incentives	(150)	(203)	124
Deferred revenue	(1,069)	8,026	45,771
Net cash provided by (used) in operating activities	(109,713)	(54,473)	26,828
Investing activities			
Purchases of investment securities, available-for-sale	(23,599)	(119,595)	(130,390)
Maturities and sales of investment securities, available-for-sale	70,604	161,555	107,196
Purchase of Contrave - net	(63,504)	—	—
Restricted cash	(50)	—	—
Purchase of restricted investments	(90,178)	—	—
Purchases of property and equipment	(330)	(538)	(246)
Net cash provided by (used in) investing activities	(107,057)	41,422	(23,440)
Financing activities			
Proceeds from convertible debt issuance	120,000	—	—
Proceeds from issuance of warrants	41,000	—	—
Proceeds from issuance of Series Z Preferred	3,343	—	—
Proceeds from issuance of common stock and warrants in private placement financing	—	59,803	—
Repayment of debt	(9,974)	—	—
Proceeds from issuance of common stock and warrants	188	4,456	2,734
Net cash provided by financing activities	154,557	64,259	2,734
Effect of exchange rate changes on cash	(715)	(29)	—
Increase (decrease) in cash and cash equivalents	(62,928)	51,179	6,122
Cash and cash equivalents at beginning of period	155,422	104,243	98,121
Cash and cash equivalents at end of period	$ 92,494	$ 155,422	$ 104,243
Supplemental Disclosure of Cash Flow Information:			
Interest paid	$ 3,221	$ 3,163	$ 3,119
Taxes paid	$ 1,347	$ 28	$ —
Unrealized gain (loss) on investment securities, available-for-sale	$ (12)	$ 18	$ (23)
Supplemental Disclosure of Non-Cash Investing Information:			
Liability incurred to purchase Contrave	$ 3,414	$ —	$ —
Purchases of equipment included in accounts payable	$ —	$ 108	$ 120

See accompanying notes.

1. Organization and Basis of Presentation

Orexigen Therapeutics, Inc., or the Company, a Delaware corporation, is a biopharmaceutical company focused on the development and commercialization of pharmaceutical product candidates for the treatment of obesity. The Company was incorporated in September 2002 and commenced operations in 2003.

The Company's primary activities since incorporation have been organizational activities, including recruiting personnel, conducting research and development, including clinical trials, raising capital, and preparing for the marketing and commercialization of its sole product, Contrave®, in the United States. Contrave was launched commercially in the United States by the Company's former partner, Takeda Pharmaceutical Company Limited, or Takeda, in October 2014. In August 2016, the collaboration agreement between the Company and Takeda was terminated and the Company is now solely responsible for developing and commercializing Contrave within the United States and the rest of the world. The Company has experienced losses since its inception, and as of December 31, 2016, had an accumulated deficit of $645.2 million. The Company expects to continue to incur losses for at least the next several years. Successful transition to attaining profitable operations is dependent upon achieving a level of revenues adequate to support the Company's cost structure, and until that time, the Company may need to continue to raise additional equity or debt financing.

For the year ended December 31, 2016, the Company has adopted, as required FASB Accounting Standard Codification (ASC) Topic 205-40, Presentation of Financial Statements – Going Concern, which requires that management evaluate whether there are relevant conditions and events that in aggregate raise substantial doubt about the entity's ability to continue as a going concern and to meet its obligations as they become due within one year from the date that the financial statements are issued.

The Company has a board approved plan which projects that the Company's existing working capital can fund its operations for one year after the financial statements are issued. This plan is based on management's best estimate and assumptions for U.S. sales of Contrave, for which the Company reacquired the rights to sell in August 2016, and sales of Contrave or Mysimba outside the U.S. for which there is limited history or no history. Due to the inherent uncertainty in achieving the forecasted global revenues in the plan, the Company has identified certain forecasted expenses that can be reduced during the second half of 2017 and through the first quarter of 2018 if revenues are less than forecasted or if the Company is not able to raise additional equity or debt financing during the interim period.

The identified cost cutting actions could include a reduction of certain discretionary sales, general and administrative expenses. Management has evaluated that, if required, the cost cutting measures described above could be effectively implemented during the second half of 2017 and through the first quarter of 2018, and that when implemented, would allow the Company to reduce its working capital requirements. Thus, management has concluded that there is not substantial doubt that the Company can meet its obligations as they become due within one year after the financial statements are issued.

The financial statements of the Company's foreign subsidiary with a functional currency other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates for operating results. Translation gains and losses are included in accumulated other comprehensive income (loss) in stockholders' equity. Foreign currency transaction gains and losses are included in the results of operations in other income and expense.

Reverse Stock Split

In July 2016, the Orexigen Board of Directors and stockholders approved a 1-for-10 reverse stock split of all of the outstanding shares of Orexigen's common stock. On the effective date (July 12, 2016) of the reverse stock split, every 10 shares of the Company's issued and outstanding common stock, par value $0.001, was consolidated into one outstanding share of common stock, par value $0.001. The reverse stock split reduced the number of shares of the Company's outstanding common stock from approximately 145.9 million to approximately 14.6 million. Proportional adjustments were made to the Company's outstanding convertible debt, stock options, warrants, and equity incentive plan. The effect of this event has been reflected in all the share quantities and per share amounts in these financial statements. The shares of common stock authorized remained at 300 million shares and retained a par value of $0.001.

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of Orexigen Therapeutics Inc. and our wholly owned subsidiary, Orexigen Therapeutics Ireland, Ltd. All intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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 expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents.

Investment Securities, Available-for-Sale

The Company classifies all investment securities as available-for-sale, as the sale of such securities may be required prior to maturity. These investment securities are carried at fair value, with unrealized gains and losses reported as accumulated other comprehensive income (loss) until realized. The cost of debt securities is adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization and accretion, as well as interest and dividends, are included in interest income. Realized gains and losses from the sale of available-for-sale securities, if any, are determined on a specific identification basis and are also included in interest income.

The Company reviews all available-for-sale securities at each period end to determine if they remain available-for-sale based on then current intent and ability to sell the security if it is required to do so. Marketable securities are subject to a periodic impairment review. The Company may recognize an impairment charge when a decline in the fair value of investments below the cost basis is determined to be other-than-temporary. There were no marketable securities deemed to be impaired as of December 31, 2016 or 2015.

Restricted Cash and Investments

All cash and investments that are legally restricted from use are recorded in restricted cash and investments on the balance sheet. The convertible senior secured notes due 2020 issued in March 2016 (See Note 9) require the Company to maintain a minimum account balance which is considered to be restricted cash and investments. The required restricted cash and investment amounts are $90.0 million and $40.0 million until March 21, 2017 and June 21, 2017, respectively.

Fair Value of Financial Instruments

The carrying amount of cash and cash equivalents, account receivable, restricted cash, accounts payable and accrued expenses are considered to be representative of their respective fair value because of the short-term nature of these items. Investment securities, available-for-sale, are carried at fair value.

Segment Reporting

The Company operates in one segment based upon the Company's organizational structure, the way in which the operations and investments are managed and evaluated by the chief operating decision maker ("CODM") as well as the lack of availability of discrete financial information at a lower level. The Company's CODM reviews revenue at the product line level, and commercial, manufacturing, operating income and expenses, and net income at the Company wide level to allocate resources and assess the Company's overall performance. The Company shares common, centralized support functions, including finance, human resources, legal, information technology, and corporate marketing, all of which report directly or indirectly to the CODM. Accordingly, decision-making regarding the Company's overall operating performance and allocation of Company resources is assessed on a consolidated basis.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and available-for-sale investment securities. The Company maintains deposits in federally insured financial institutions in excess of federally insured limits. However, management believes the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which these deposits are held. Additionally, the Company has established guidelines regarding the diversification of its investments and their maturities, which are designed to maintain safety and liquidity.

Property and Equipment

Property and equipment is stated at cost and depreciated over the estimated useful lives of the assets (three to five years) using the straight-line method. Leasehold improvements are stated at cost and amortized over the shorter of their useful lives or the lease term.

Impairment of Long-Lived Assets

The Company will record impairment losses on long-lived assets used in operations when events and circumstances indicate that assets might be impaired and the undiscounted cash flows estimated to be generated by those assets are less than the carrying amount of those assets. The Company has not recognized any impairment losses during the years ended December 31, 2016 and 2015.

Research and Development Costs

All research and development costs are charged to expense as incurred and consist principally of costs related to clinical trials, license fees and salaries and related benefits. Clinical trial costs are a significant component of research and development expenses. These costs are accrued based on estimates of work performed, and require estimates of total costs incurred based on patients enrolled, progress of clinical studies and other events. Clinical trial costs are subject to revision as the trials progress and revisions are charged to expense in the period in which they become known.

Patent Costs

All costs related to filing and pursuing patent applications are expensed as incurred as recoverability of such expenditures is uncertain.

Inventory

Inventories are stated at the lower of cost (using a first-in, first-out basis) or market. Inventory costs including raw materials, work in process and finished goods that may be associated with its products prior to regulatory approval are charged to research and development expense prior to such approval on a country-specific basis.

Fair Value Option

The Company has elected the fair value option to account for its convertible notes that were issued during the year ended December 31, 2016 and records these convertible notes at fair value with changes in fair value recorded in the statement of operations. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in earnings as incurred and not deferred.

Preferred Stock

When issued, the Company classifies conditionally redeemable preferred shares, which includes preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control, as temporary equity. The Company's Series Z Preferred Stock features a contingent right to receive payment from the Company in the event of certain fundamental changes, some of which are not within the Company's control. Accordingly, the Series Z Preferred Stock is presented as a component of temporary equity.

Accounting for Warrants at Fair Value

The Company classifies as liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside the control of the Company) or (ii) gives the counterparty a choice of net-cash settlement or settlement in shares (physical settlement or net-share settlement).

The Company assessed the classification of warrants issued in March 2016 and associated with the 2016 convertible notes as of the date of the offering and determined that such instruments met the criteria for liability classification due to a cash settlement feature. Accordingly, the Company classified the warrants issued in 2016 as a liability at their fair value and adjusts the instruments to fair value at each balance sheet date until the cash settlement feature expires, the warrants are exercised or expired. At the 2016 Annual Meeting of Stockholders on July 8, 2016, the stockholders approved an amendment to increase the authorized shares of common stock. On such date, the cash settlement feature expired and therefore the Company adjusted the liability to fair value on that date and reclassified the warrants from a liability to equity in Additional Paid in Capital and no longer being marked to market.

Convertible Senior Notes

In December 2013, the Company issued $115.0 million in aggregate principal amount of 2.75% convertible senior notes due 2020, or the 2013 Notes. The convertible debt may be settled in shares or cash upon conversion at the Company's option. The cash settlement feature of the 2013 Notes required the Company to account for the liability (debt) and equity (conversion option) components separately. The carrying amount of the liability component was estimated by measuring the fair value of a similar liability that does not have an associated conversion feature. To measure the fair value of the liability component, the Company used an income approach, discounting the future contractual cash flows due under the 2013 Notes by a market interest rate. The market interest rate was determined to be 8.69%. Assumptions used in the estimate represent what market participants would use in pricing the liability component, including market interest rates, credit standing, and yield curves, all of which are defined as Level 2 observable inputs. The estimated implied interest rate was applied to the 2013 Notes, which resulted in a fair value of the liability component of $79.7 million upon issuance, calculated as the present value of implied future payments based on the $115.0 million aggregate principal amount. The difference between the cash proceeds and the estimated fair value of the liability component was recorded in additional paid-in capital as the 2013 Notes. The liability component will be accreted to redemption value over the term of the 2013 Notes.

Purchased Intangibles

Acquired assets and liabilities assumed in an acquisition are recorded on the basis of their estimated fair values determined by management at the date of acquisition. The Company determines the estimated economic lives of the acquired intangible assets for amortization purposes.

Intangible assets consist of developed technology and trade-names acquired in the Contrave business combination under the purchase method of accounting are recorded at fair value net of accumulated amortization since the acquisition date. Amortization is calculated using the straight line method over the estimated useful lives at the following annual rates:

	Useful Lives
Developed technology	10 years
Trade-name	10 years

The Company reviews its finite-lived intangible assets for impairment when events or changes in circumstances indicate that the carrying amount of finite-lived intangible asset may not be recoverable. Recoverability of a finite-lived intangible asset is measured by a comparison of its carrying amount to the undiscounted future cash flows expected to be generated by the asset. If the asset is considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the asset exceeds the fair value of the asset. There were no indicators of impairment during the period ended December 31, 2016.

Income Taxes

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities using enacted tax rates which will be in effect when the differences reverse. The Company provides a valuation allowance against net deferred tax assets unless, based upon the available evidence, it is more likely than not that the deferred tax asset will be realized.

The Company follows the provisions of the Income Taxes Topic of the FASB Accounting Standards Codification that defines a recognition threshold and measurement attributes for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. Under the Income Taxes Topic, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained.

Revenue Recognition

Collaborative agreement revenue

Prior to the revised multiple element and milestone method of revenue recognition guidance adopted by the Company on January 1, 2011, nonrefundable, up-front license fees and milestone payments with standalone value that are not dependent on any future performance by the Company under the agreements were recognized as revenue upon the earlier of when payments were received or collection was assured, but were deferred if the Company had continuing performance obligations. If the Company had continuing involvement through contractual obligations under such agreements, such up-front fees were deferred and recognized over the period for which the Company continued to have a performance obligation.

Effective January 1, 2011, for multiple element agreements entered into or materially modified after December 31, 2010, the Company follows the provisions of ASU No. 2009-13. In order to account for the multiple-element arrangements, the Company identifies the deliverables included within the agreement and evaluates which deliverables represent separate units of accounting. Analyzing the arrangement to identify deliverables requires the use of judgment, and each deliverable may be an obligation to deliver services, a right or license to use an asset, or another performance obligation. A delivered item is considered a separate unit of accounting when the delivered item has value to the partner on a standalone basis based on the consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research capabilities of the partner and the availability of research expertise in this field in the general marketplace. Arrangement consideration is allocated at the inception of the agreement to all identified units of accounting based on their relative selling price. The relative selling price for each deliverable is determined using VSOE of selling price or third-party evidence of selling price if VSOE does not exist. If neither VSOE nor third-party evidence of selling price exists, the Company use its best estimate of the selling price for the deliverable. The amount of allocable arrangement consideration is limited to amounts that are fixed or determinable. The consideration received is allocated among the separate units of accounting, and the applicable revenue recognition criteria are applied to each of the separate units. Changes in the allocation of the sales price between delivered and undelivered elements can impact revenue recognition but do not change the total revenue recognized under any agreement. Upfront license fee payments are recognized upon delivery of the license if facts and circumstances dictate that the license has standalone value from the undelivered items, which generally include research and development services and the manufacture of drug products, the relative selling price allocation of the license is equal to or exceeds the upfront license fee, persuasive evidence of an arrangement exists, the Company's price to the partner is fixed or determinable, and collectability is reasonably assured.

Upfront license fee payments are deferred if facts and circumstances dictate that the license does not have standalone value. The determination of the length of the period over which to defer revenue is subject to judgment and estimation and can have a material impact on the amount of revenue recognized in a given period.

The Company accounts for milestone payments under its agreements using the milestone method of accounting. The Company recognizes consideration that is contingent upon the achievement of a milestone in its entirety as revenue in the period in which the milestone is achieved only if the milestone is substantive in its entirety. A milestone is considered substantive when it meets all of the following three criteria: 1) the consideration is commensurate with either the entity's performance to achieve the milestone or the enhancement of the value of the delivered item(s) as a result of a specific outcome resulting from the entity's performance to achieve the milestone, 2) the consideration relates solely to past performance, and 3) the consideration is reasonable relative to all of the deliverables and payment terms within the arrangement. A milestone is defined as an event (i) that can only be achieved based in whole or in part on either the entity's performance or on the occurrence of a specific outcome resulting from the entity's performance, (ii) for which there is substantive uncertainty at the date the arrangement is entered into that the event will be achieved and (iii) that would result in additional payments being due to the Company. Any milestone payments that do not satisfy these revenue recognition criteria are recorded over the remaining life of the agreements with a cumulative catch up adjustment for the portion of the milestone earned from the inception of the agreement to the expected term of the agreement. The excess of the milestone paid and the amount recognized in the cumulative catch up adjustment is recorded as deferred revenue and recognized over the remaining expected term of the agreement.

Royalty revenue

Royalties to be received based on sales of the Company's licensed products by partners are recognized as earned.

Product Sales, Net

The Company's net product sales consist of U.S. sales of Contrave as well as product sales to our distributors in other countries. The Company recognizes product revenue when all four of the following criteria are met: (i) persuasive evidence that an arrangement exists; (ii) delivery of the products and/or services has occurred; (iii) the selling price is fixed or determinable; and (iv) collectability is reasonably assured. Specifically, net product revenue from the sale of Contrave/Mysimba is generally recognized upon transfer of title of the product to our third-party customers, provided that no significant obligations remain.

Effective August 1, 2016, the Company reacquired the commercial rights of Contrave from Takeda and began selling Contrave in the U.S. The Company commenced shipments of Contrave to its wholesalers in mid-August 2016. The Company has determined it does not currently have the necessary volume of activity to reasonably estimate certain sales allowances at the time title and risk of loss transfers to the wholesalers. Accordingly, the price is not considered fixed or determinable at that time. Therefore, the Company recognizes revenue when the wholesalers sell Contrave to the dispensing institutions (i.e. pharmacies, hospitals) at which point it has developed sufficient historical experience and data to reasonably estimate future returns and chargebacks. As of December 31, 2016, the Company had a deferred revenue balance of approximately $1.0 million related to Contrave net product sales in the U.S.

Upon recognition of revenue from product sales of Contrave in the U.S., the Company records certain sales reserves and allowances as a reduction to gross revenue. These reserves and allowances include:

Rebates:

The Company records provisions for U.S. Medicaid, and commercial managed care contract rebates at the time revenue is recognized based upon our estimated rebate claims attributable to a sale. U.S. Medicaid rebate accruals are generally based on historical payment data and estimates of future Medicaid beneficiary utilization applied to the Medicaid unit rebate formula established by the Center for Medicaid and Medicare Services. For commercial managed care contract rebates, the Company considers current contract terms, such as changes in formulary status and agreed to discount rates, along with historical utilization rates. Orexigen also considers outstanding rebate claims, rebate payments, forecasted sales, and levels of inventory in the distribution channel and adjusts estimates each period to reflect actual experience. There can be a significant time lag between recording estimates and actual payments.

Chargebacks:

The Company provides predetermined discounts under certain government programs, including the Veterans Administration FSS and Public Health Service 340B, whereby the pharmacies or health care facilities affiliated with these programs purchase Contrave from wholesalers at reduced prices. A chargeback represents the difference between the invoice price to the wholesaler and the contractual discounted price offered by the Company under the respective program. Our estimate for these chargeback fees takes into consideration contractual terms, historical utilization rates along with payor mix, and our expectations regarding future utilization rates.

Cash Discounts:

The Company offers certain wholesalers cash discounts as an incentive for meeting certain payment terms. The Company estimates prompt payment discounts based on contractual terms, historical utilization rates, as available, and our expectations regarding future utilization rates. As the prompt pay discounts are applied against wholesaler purchases of Contrave, the Company records its initial estimate at the point in which that sales occurs.

Distribution Fees:

The distribution fees, based on contractually determined rates, arise from contractual agreements the Company has with certain wholesalers for distribution services they provide with respect to Contrave. These fees are generally a fixed percentage of the price of the product purchased by the wholesalers.

Savings Card Program:

The Company offers certain discount programs to patients under which the patient receives a discount on his or her prescription. The Company reimburses pharmacies for this discount through a third-party vendor. The discounts, which are recorded as a reduction of sales at the point of revenue recognition, reflect an estimate based on historical utilization rates, expectations surrounding future utilization, and user mix in relation to the discount offering.

Sales Returns:

The Company allows the wholesalers to return product that is damaged or received in error. In addition, the Company accepts unused product to be returned beginning six months prior to and ending twelve months following product expiration. Additional specific rights of return are also extended to certain customers. The Company believes that its estimated product returns for Contrave requires a high degree of judgement and is subject to change based on our experience and certain quantitative and qualitative factors. Because of the shelf life of Contrave and the lengthy return period, there may be a significant period of time between when the product is shipped and when the Company issues credits on returned product. In order to develop a methodology to reliably estimate future returns, the Company analyzes many factors, including, without limitation: (1) actual Contrave product return history, taking

into account product expiration dating at the time of shipment, (2) re-order activities of the wholesalers as well as their customers and (3) levels of inventory in the wholesale channel. The Company considers the dating of product at the time of shipment into the distribution channel and changes in the estimated levels of inventory within the distribution channel to estimate our exposure to returned product. The Company also considers current contract prices and projected future prices to estimate the exposure to returned product. Given the exposure to returns and the Company's limited history of selling Contrave in the U.S., the Company recognizes product sales allowances based on these estimates as a reduction of product sales in the same period the related revenue is recognized, upon sale of Contrave from the wholesalers to the pharmacies, hospitals, etc. The Company believes this reduces its exposure to returns and allows us to more reasonably justify the estimate. Should actual product return results differ from its estimates, however, the Company will be required to make adjustments to these allowances in the future, which could have an effect on product sales revenue and earnings in the period of adjustments.

Stock-Based Compensation

The Company measures and recognizes compensation expense for all stock-based payment awards made to employees, non-employee directors and consultants, including stock options and employee stock purchases related to the Company's 2013 Employee Stock Purchase Plan, or the ESPP, based on estimated fair values. Compensation costs related to all equity instruments granted are recognized at the grant-date fair value of the awards. Additionally, the Company includes an estimate of the number of awards that will be forfeited in calculating compensation costs, which is recognized over the requisite service period of the awards on a straight-line basis. No related tax benefits of the share-based compensation costs have been recognized since the Company's inception.

The fair value of each option award was estimated on the date of grant using the Black-Scholes option valuation model. The following weighted-average assumptions were utilized for the calculations during each period:

	Years Ended December 31,		
	2016	2015	2014
Expected life (in years)	5.5	5.6	5.6
Expected volatility	95.4%	93.9%	107.3%
Risk-free interest rate	1.3%	1.6%	1.8%
Expected dividend yield	0.0%	0.0%	0.0%
Per share grant-date fair value	$ 3.37	$ 35.37	$ 50.11

The weighted average expected life of an award is based on historical forfeiture experience, exercise activity, and on the terms and conditions of the stock awards. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period commensurate with the estimated expected term of the stock awards. The risk-free interest rate assumption was based on the United States Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the award being valued. The expected dividend yield is determined to be 0% given that the Company has never declared or paid cash dividends on its common stock and does not anticipate paying such cash dividends.

Total stock-based compensation expense recognized during the years ended December 31, 2016, 2015 and 2014 was comprised of the following (in thousands):

	Years Ended December 31,		
	2016	2015	2014
Cost of goods sold	$ 170	$ —	$ —
Selling, general and administrative	7,726	10,826	10,842
Research and development	2,434	4,394	4,454
	$ 10,330	$ 15,220	$ 15,296

At December 31, 2016, the Company had capitalized into inventory approximately $176,000 of stock-based compensation related to stock options granted to employees involved with the manufacturing of Contrave/Mysimba. At December 31, 2016, total unrecognized estimated share-based compensation expense related to non-vested stock options granted prior to that date was $21.6 million, which is expected to be recognized over a weighted-average period of 3.2 years.

Comprehensive Loss

The Company records all components of comprehensive income, including net income, in the financial statements in the period in which they are recognized. Comprehensive loss consists of net loss and certain changes in stockholders' equity that are excluded from net loss, including unrealized gains and losses on investments and also gains and losses from foreign currency translations.

Comprehensive loss for each of the years ended December 31, 2016, 2015 and 2014 has been reflected in the Consolidated Statements of Comprehensive Loss. Accumulated other comprehensive income (loss), which is included as a separate component of stockholders' equity, represents unrealized gains and losses on investment securities, available-for-sale.

Net Loss Per Share

The Company computes basic loss per share by dividing the net loss available to common stockholders by the weighted average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss assumes the conversion, exercise or issuance of all potential common stock equivalents, unless the effect of inclusion would be anti-dilutive. For purposes of this calculation, common stock equivalents include the Company's stock options and ESPP, warrants and the shares to be issued upon the conversion of the convertible senior notes. No shares related to the assumed conversion of the 2013 or 2016 convertible senior notes were included in the diluted net loss calculation for the years ended December 31, 2016, 2015 and 2014 because the inclusion of such shares would have had an anti-dilutive effect. The shares to be issued upon exercise of certain outstanding stock options, performance stock units and common stock warrants were excluded from the diluted net loss calculation for all periods presented because such shares are anti-dilutive.

(In thousands, except per share amounts)	Years Ended December 31,		
	2016	2015	2014
Historical			
Numerator:			
Net loss	$ (24,524)	$ (68,687)	$ (37,525)
Denominator:			
Weighted average common shares outstanding	14,576	13,113	11,824
Denominator for basic and diluted net loss per share	14,576	13,113	11,824
Net loss per share — basic and diluted	$ (1.68)	$ (5.24)	$ (3.17)

Historical outstanding anti-dilutive securities not included in the diluted net loss per share calculation include the following (in thousands):

	As of December 31,		
	2016	2015	2014
Shares underlying 2013 convertible senior notes	976	1,404	1,404
Shares underlying 2016 convertible senior notes	22,000	—	—
Common stock warrants outstanding	22,500	500	57
Common stock options and PSU's outstanding	6,491	1,987	1,796
	51,967	3,891	3,257

Recently Issued Accounting Standards

In May 2014, the FASB issued ASU No. 2014-09, "*Revenue from Contracts with Customers*," which outlines a comprehensive revenue recognition model and supersedes most current revenue recognition guidance. The new standard requires a company to recognize revenue upon transfer of goods or services to a customer at an amount that reflects the expected consideration to be received in exchange for those goods or services. ASU 2014-09 defines a five-step approach for recognizing revenue, which may require a company to use more judgment and make more estimates than under the current guidance. The new standard will be effective for the Company starting in the first quarter of fiscal 2018. The FASB will permit entities to adopt one year earlier if they choose (i.e., the original effective date). The new standard allows for two methods of adoption: (a) full retrospective adoption, meaning the standard is applied to all periods presented, or (b) modified retrospective adoption, meaning the cumulative effect of applying the new standard is recognized as an adjustment to the opening retained earnings balance. The Company is in the process of performing a preliminary assessment of the impact of ASU 2014-09 on the Consolidated Financial Statements, and is considering all items outlined in the standard. In assessing the impact, the Company will identify all revenue generating activities, map those activities to deliverables and map those deliverables to the standard. The Company will be assessing what impact the change in standard will have on those deliverables. Based on the Company's preliminary assessment to date, the Company expects that the new standard will impact the estimation of sales allowances for the Company's U.S. product revenues and the timing of revenue recognition which could be earlier than that what the Company is currently recognizing U.S. product revenue. The Company will continue to evaluate the impact of ASU 2014-09 and related amendments on the Consolidated Financial Statements and related disclosures throughout 2017. The Company plans to adopt the new standard beginning January 2018 using the modified retrospective method.

In April 2015, the FASB issued ASU No, 2015-03, *Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs*, which simplifies the presentation of debt issuance costs by requiring debt issuance costs to be

presented as a deduction from the corresponding debt liability, consistent with the presentation of debt discounts or premiums. Previous guidance generally required entities to present debt issue costs separately as deferred charges. The Company adopted the new guidance in the first quarter of 2016, and prior year amounts were reclassified to conform to the current year presentation. The adoption of this guidance resulted in the reclassification of approximately $259,000 of unamortized debt issuance costs principally from other noncurrent assets to a reduction of long term debt on our consolidated balance sheet as of December 31, 2015. At December 31, 2016, debt issuance costs of approximately $147,000 were netted against long term debt on our consolidated balance sheet under the new guidance.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*. ASU No. 2016-2 requires an entity to recognize right-of-use assets and lease liabilities on its balance sheet for all leases and to disclose key information about leasing arrangements. Lessees and lessors are required to disclose qualitative and quantitative information about leasing arrangements to enable a user of the financial statements to assess the amount, timing and uncertainty of cash flows arising from leases. ASU No. 2016-02 is effective for fiscal years, and interim periods within those years, beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the impact of adoption of ASU No. 2016-02 on the consolidated financial statements and related disclosures.

In March 2016, the FASB issued ASU No. 2016-09, "*Compensation – Stock Compensation* (Topic 718): Improvements to Employee Share-Based Payment Accounting", or ASU 2016-09. The amendment is to simplify several aspects of the accounting for share-based payment transactions including the income tax consequences, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The amendments in ASU 2016-09 are effective for interim and annual reporting periods beginning after December 15, 2016. The Company is currently assessing the impact of ASU 2016-09 on the consolidated financial statements and related disclosures.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which amends the impairment model by requiring entities to use a forward-looking approach based on expected losses to estimate credit losses on certain types of financial instruments, including trade receivables and available for sale debt securities. The ASU is effective for the Company beginning in the first quarter of 2020, with early adoption permitted. The Company is currently evaluating the impact of ASU 2016-13 on its consolidated financial statements.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments,* which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of this new pronouncement on its consolidated statements of cash flows and related disclosures.

In August 2014, the FASB issued ASU 2014-15, " *Presentation of Financial Statements - Going Concern*," which requires management to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and provide related footnote disclosures. ASU 2014-15 was effective for the Company for the year ended December 31, 2016 and for interim reporting periods thereafter. The adoption of this new standard did not have an impact on our consolidated financial statements at December 31, 2016 but may require additional disclosures in our consolidated financial statements in future quarters.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows* (Topic 230) - Restricted Cash, which outlines that a statement of cash flows explains the change during the period in total cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 is effective for public business entities for annual periods, including interim periods within those annual periods, beginning after December 15, 2017, and early application is permitted. The Company is currently evaluating the impact this standard will have on its consolidated financial statements.

In January 2017, the FASB issued an ASU 2017-01, *Business Combinations* (Topic 805) Clarifying the Definition of a Business. The amendments in this Update is to clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company is currently evaluating the impact of adopting this guidance.

3. Investment Securities, Available-for-Sale

The Company invests its excess cash in investment securities, principally debt instruments of financial institutions, corporations with investment grade credit ratings and government agencies. The Company's available-for-sale securities are classified as current as they are available for use in current operations or may be used in other strategic initiatives during the next twelve months. A summary of the estimated fair value of investment securities, available-for-sale, is as follows at December 31, 2016 and December 31, 2015 (in thousands):

			Unrealized		
December 31, 2016	**Maturity in Years**	**Amortized Cost**	**Gains**	**Losses**	**Fair Value**
U.S. Treasury securities	Less than 1	$ 100,026	-	$ (21)	$ 100,005
Corporate debt securities	Less than 1	1,498	1	-	1,499
Total investment securities		$ 101,524	$ 1	$ (21)	$ 101,504

			Unrealized		
December 31, 2015	**Maturity in Years**	**Amortized Cost**	**Gains**	**Losses**	**Fair Value**
U.S. government agency securities	Less than 1	$ 36,748	$ 7	$ (12)	$ 36,743
Corporate debt securities	Less than 1	9,803	—	(2)	9,801
U.S. Treasury securities	Less than 1	12,046	—	(1)	12,045
Total investment securities		$ 58,597	$ 7	$ (15)	$ 58,589

A portion of the investments at December 31, 2016 are restricted investments as described in Note 2. Gross realized gains and losses on available-for-sale securities were immaterial during the years ended December 31, 2016, 2015 and 2014.

4. Contrave Acquisition

In March 2016, the Company entered into a separation agreement with Takeda (the "Separation Agreement"), which terminated the Restated Collaboration Agreement between the Company and Takeda, and the manufacturing services agreement between the Company and Takeda. The Separation Agreement provided for the transfer of certain rights and assets to the Company and provided for the transition of activities under the collaboration agreement from Takeda to the Company during the transition period. On August 1, 2016, the transition period under the Separation Agreement between the Company and Takeda terminated and the Company reacquired all commercial rights to Contrave in the United States. The Company made an initial payment of $60.0 million (the "Initial Payment") to Takeda in March 2016 and paid an additional $15.0 million to Takeda in January 2017 (the "January 2017 Payment"). The source of funds for the Initial Payment and the January 2017 Payment was from the Company's cash on hand. The Company may also be obligated to pay Takeda milestone payments of $10 million, $20 million, $30 million and $50 million, based on the achievement of annual Contrave net sales milestones of $200 million, $300 million $400 million and $600 million, respectively, in any future year. Each such milestone payment shall be payable only once but more than one may be payable with respect to net sales in a single year. The contingent consideration liability will be re-measured to fair value at each reporting date until the contingencies are resolved and any changes in fair value are recognized in earnings. See Note 5 for valuation methodology of contingent consideration. As a result of the Separation Agreement and the settlement of a pre-existing relationship with Takeda, the Company recorded a settlement gain of $80.2 million representing the existing Contrave deferred revenue on August 1, 2016.

Purchase Consideration

The estimated fair value of the total consideration at the date of acquisition (August 1, 2016) is as follows (in thousands):

Prepaid purchase price payment to Takeda in March 2016	$ 60,000
Fair value of contingent consideration due to Takeda	18,800
Payment due to Takeda for Contrave inventory	7,762
Estimated payment due to Takeda for charge-backs and rebates	823
Cash received from Takeda for estimated returns as of August 1, 2016	(1,667)
Total Purchase Price	$ 85,718

On the acquisition date, the estimated fair value of net assets acquired was $85.7 million. The preliminary allocation of the total consideration to the fair value of the assets acquired and liabilities assumed is subject to finalization of estimating the fair value of the assets acquired and liabilities assumed. The estimated fair values of the assets acquired and liabilities assumed, including the fair value of purchased intangibles, are preliminary estimates pending the finalization of our valuation analyses. The allocation as of the date of the acquisition is as follows (in thousands):

Developed technology intangible	$	74,967
Tradename		4,400
Inventory		14,261
Assumption of accrued expenses (savings card program)		(5,687)
Assumption of accrued expenses (returns reserve)		(2,223)
Total Fair Value of Assets Acquired and Liabilities Assumed	$	85,718

The fair value of intangible assets (developed technology intangible and tradename) is determined primarily using the "income method," which starts with a forecast of all expected future cash flows. Some of the more significant assumptions inherent in the intangible asset values, from the perspective of a market participant, include: the amount and timing of projected future cash flows (including net revenue, cost of product sales, research and development costs, sales and marketing expenses, capital expenditures and working capital requirements) as well as estimated contributory asset charges; the discount rate selected to measure the risks inherent in the future cash flows; and the assessment of the asset's life cycle and the competitive trends impacting the asset, among other factors.

The estimated amortization expense related to the intangible assets recorded in connection with the Contrave acquisition for 2016 through 2020 and thereafter is as follows (in thousands):

Year ended December 31,		
2017	$	7,938
2018		7,938
2019		7,938
2020		7,938
2021		7,938
Thereafter		36,370
	$	76,060

Pro forma

The following unaudited pro forma financial information presents results as if the acquisition of Contrave had occurred on January 1, 2015 (in thousands):

	Year ended December 31,			
	2016		2015	
Revenues	$	53,966	$	51,488
Net loss		(173,549)		(177,637)
Net loss per share - basic and diluted	$	(11.91)	$	(15.70)

For purposes of the pro forma disclosures above, the primary adjustments for the year ended December 31, 2016 include the amortization of the intangible assets, reversal of collaborative and royalty revenue. For purposes of the pro forma disclosures above, the primary adjustments for the year ended December 31, 2015 include the amortization of the intangible assets, reversal of collaborative and royalty revenue and the elimination of existing Contrave deferred revenue.

5. Fair Value Measurements

The fair values of the Company's financial instruments are recorded using a hierarchal disclosure framework based upon the level of subjectivity of the inputs used in measuring assets and liabilities. The following table presents information about the Company's financial assets measured at fair value on a recurring basis as of December 31, 2016 and 2015, and indicates the fair value hierarchy of the valuation techniques utilized by the Company to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that the Company has the ability to access. The Company classifies money market funds as Level 1 assets. Fair values determined by Level 2 inputs utilize inputs other

than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. Level 2 inputs include quoted prices for similar assets and liabilities in active markets, and inputs other than quoted prices that are observable for the asset or liability, such as interest rates and yield curves that are observable at commonly quoted intervals. The Company classifies commercial paper holdings, U.S. Treasury securities, U.S. government agency securities and asset-backed security holdings as Level 2 assets. Level 3 inputs are unobservable inputs for the assets or liabilities, and include situations where there is little, if any, market activity for the asset or liability. In certain cases, the inputs used to measure fair value may fall into different levels of the fair value hierarchy. In such cases, the level in the fair value hierarchy within which the fair value measurement in its entirety falls has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires judgment, and considers factors specific to the asset or liability.

Assets and liabilities measured at fair value that have recurring measurements are shown below (in thousands):

		Fair Value Measurement at Reporting Date Using		
Description	**Balance as of December 31, 2016**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Financial instruments owned:				
Money market funds	$ 65,081	$ 65,081	$ —	$ —
U.S. Treasury securities	100,005	—	100,005	—
Corporate debt securities	1,499		1,499	
Total assets measured at fair value	$ 166,585	$ 65,081	$ 101,504	$ —
Liabilities:				
Contingent consideration - current	$ 15,000	$ —	$ —	$ 15,000
Contingent consideration - long-term	6,800			6,800
Convertible debt	101,900	—	—	101,900
Total liabilities measured at fair value	$ 123,700	$ —	$ —	$ 123,700

		Fair Value Measurement at Reporting Date Using		
Description	**Balance as of December 31, 2015**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Other Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**
Financial instruments owned:				
Money market funds	$ 47,196	$ 47,196	$ —	$ —
U.S. government agency securities	67,421	—	67,421	—
U.S. Treasury securities	12,045	—	12,045	—
Corporate debt securities	9,801	—	9,801	—
Total financial instruments owned	$ 136,463	$ 47,196	$ 89,267	$ —

There were no transfers between Levels 1, 2 or 3 during the years ended December 31, 2016 and 2015.

The following table presents additional information about Level 3 liabilities measured at fair value. Both observable and unobservable inputs may be used to determine the fair value of positions that the Company has classified within the Level 3 category. As a result, the unrealized gains and losses for liabilities within the Level 3 category may include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in unobservable long-dated volatilities) inputs.

Changes in Level 3 liabilities measured at fair value for the year ended December 31, 2016 (in thousands):

Contingent consideration—January 1, 2016	$	—
Fair value of contingent consideration (August 1, 2016)	$	18,800
Change in fair value of contingent consideration (recognized in earnings)		3,000
Contingent consideration at fair value – December 31, 2016	$	21,800
Convertible debt—January 1, 2016	$	—
Fair value of convertible debt on date of issuance (March 21, 2016)	$	120,000
Change in fair value of convertible debt (recognized in earnings)		(18,100)
Convertible debt at fair value – December 31, 2016	$	101,900
Warrant liabilities – January 1, 2016	$	—
Fair value of warrant liability on date of issuance (March 21, 2016)	$	41,000
Change in fair value of warrant liability (recognized in earnings)		(7,300)
Reclassification to equity		(33,700)
Fair value of warrant liability—December 31, 2016	$	—

As part of the Separation Agreement between the Company and Takeda, the Company recorded a current contingent consideration liability and a long-term contingent consideration liability that have been classified as Level 3 inputs in the fair value hierarchy. The contingent consideration represents the estimated fair value of future payments due to Takeda based on: (i) Orexigen achieving annual net sales targets in certain years and (ii) Takeda performing certain obligations, as outlined in the Separation Agreement. The initial fair value of the long-term portion of the contingent consideration based on net sales was estimated through the use of a Monte Carlo simulation model. The Monte Carlo simulation model utilized the following assumptions: (i) expected term; (ii) risk-adjusted net sales; (iii) risk-free interest rate; and (iv) expected volatility. The initial fair value of the current portion of the contingent consideration based on Takeda performing certain obligations was estimated using a probability weighted approach. The probability was applied to the contingent consideration based on Takeda performing certain obligations and discounted to present value. The fair value of the Company's contingent consideration liability is revalued to fair value each period and any increase or decrease is recorded into earnings. The fair value of the contingent consideration was impacted by certain unobservable inputs, most significantly with regards to the discount rates, probability of scenario occurrence, expected volatility, historical and projected net sales performance, and expected scenario timing. Significant changes to these inputs in isolation could result in a significantly different fair value measurement.

In March 2016, the Company issued $165.0 million in aggregate principal amount of 0.0% convertible senior notes, which included the principal amount of the convertible note, a conversion feature, warrant coverage, and preferred shares.

To measure the fair value of the principal amount, the Company used an income approach, discounting the principal amount due under the convertible note by market interest rates by potential scenario. To measure the fair value of the conversion feature of the convertible note, a Black-Scholes option pricing model was utilized. The Black-Scholes option pricing model utilized the following assumptions: (i) expected term; (ii) common stock price; (iii) risk-free interest rate; and (iv) expected volatility. Assumptions used in the estimates represent what market participants would use in pricing the liability components, including market interest rates, credit standing, yield curves, volatilities, and risk-free rates, all of which are defined as Level 2 observable inputs. The estimated implied interest rates were applied to the principal amount of the convertible note by scenario and were weighted based on the probability of each scenario occurring. The estimated volatilities and the risk-free rates were incorporated into the Black-Scholes option pricing models for the conversion feature of the convertible note by scenario and were weighted based on the probability of each scenario occurring. Scenarios and probabilities were based on Company management estimates and were incorporated into the determination of the fair values of the principal amount and the conversion feature of the convertible note.

To measure the fair value of the warrant coverage component, a Black-Scholes option pricing model was utilized. The Black-Scholes option pricing model utilized the following assumptions: (i) expected term; (ii) common stock price; (iii) risk-free interest rate; and (iv) expected volatility. Assumptions used in the estimates represent what market participants would use in pricing the component, including volatilities and risk-free rates, which are defined as Level 2 observable inputs. The estimated volatilities and the risk-free rates were incorporated into the Black-Scholes option pricing models for the warrants by scenario and were weighted based on the probability of each scenario occurring. Scenarios and probabilities were based on Company management estimates and were incorporated into the determination of the fair value of the warrant coverage.

The fair values of the principal amount of the convertible note, the conversion feature of the convertible note and the warrant coverage were impacted by certain unobservable inputs, most significantly with regards to the discount rates, probabilities of certain scenarios occurring, expected volatility, share price performance, and expected scenario timing. Significant changes to these inputs in isolation could result in a significantly different fair value measurement.

6. Inventory

Inventory consists of the following (in thousands):

	December 31,	
	2016	2015
Raw materials	$ 6,678	$ 8,619
Work in process	1,036	708
Finished goods	15,479	1,475
	$ 23,193	$ 10,802

7. Property and Equipment

Property and equipment consists of the following (in thousands):

		December 31,	
	Useful Life in Years	2016	2015
Furniture and fixtures	5	$ 1,209	$ 1,202
Computer equipment and software	3 to 5	1,157	553
Leasehold improvements	5	644	644
Manufacturing equipment	5	664	664
Asset under construction		0	437
		3,674	3,500
Accumulated depreciation		(2,630)	(2,216)
Property and equipment, net		$ 1,044	$ 1,284

Depreciation expense was $428,000, $223,000 and $139,000 for each of the years ended December 31, 2016, 2015 and 2014, respectively.

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31,	
	2016	2015
Product sales reserves and allowances	$ 9,998	$ —
Accrued compensation related expenses	7,169	4,115
Inventory received, not invoiced	5,398	2,032
Accrued income taxes	133	1,346
Accrued marketing and market research expenses	5,201	559
Accrued research and development expenses	864	889
Accrued interest on convertible notes	184	264
Accrued legal and professional expenses	984	353
Other accrued expenses	481	765
	$ 30,412	$ 10,323

9. Convertible Debt

0% Convertible Senior Secured Notes due 2020

On March 21, 2016, the Company closed an offering, or the Offering, of $165.0 million aggregate principal amount of 0% Convertible Senior Secured Notes due 2020, or the 2016 Notes, and related warrants, or the Warrants, to purchase up to 21,999,999 shares of the Company's common stock, par value $0.001 per share, or the Common Stock, and 219,994 shares of Series Z Non-Convertible Non-Voting Preferred Stock, par value $0.001 per share, or the Series Z Preferred Stock, and, together with the 2016

Notes, Warrants and Common Stock underlying the 2016 Notes and Warrants, the Securities, to qualified institutional buyers and accredited investors, or the Purchasers, pursuant to a securities purchase agreement, dated March 15, 2016, or the Securities Purchase Agreement, by and among the Company and the Purchasers. The Offering was led by funds managed by The Baupost Group, L.L.C., collectively, Baupost, which, prior to the Offering, was the holder of approximately 18.1% of the Company's outstanding Common Stock.

The 2016 Notes will mature on July 1, 2020, unless earlier repurchased, redeemed or converted in accordance with the Indenture. The 2016 Notes shall only be convertible into shares of Common Stock of the Company at the Conversion Rate. In the event of a change of control transaction at any time, the 2016 Notes will be convertible for a period beginning on the closing of such change of control transaction and ending 35 Trading Days after the closing of such transaction.

The Conversion Rate is 133.333 shares of Common Stock for each $1,000 principal amount of 2016 Notes, which represents a conversion price of $7.50 per shares of Common Stock. The Conversion Rate and the corresponding conversion price will be subject to adjustment for certain events, but will not be adjusted for accrued and unpaid interest.

If one or more Events of Default occurs, then unless the principal of all of the 2016 Notes shall have already become due and payable, either the Trustee or the holders of at least 25% in aggregate principal amount of the 2016 Notes then outstanding, by notice in writing to the Company (and to the Trustee if given by holders), may declare 100% of the principal of, and accrued and unpaid interest, if any, on, all the 2016 Notes to be due and payable immediately, and upon any such declaration the same will become and will automatically be immediately due and payable. If an Event of Default resulting from a voluntary or involuntary liquidation, reorganization, or other relief occurs and is continuing, 100% of the principal of, and accrued and unpaid interest, if any, on, all 2016 Notes shall become and shall automatically be immediately due and payable.

Upon the occurrence of certain fundamental changes or adverse events related to the regulatory approval for and commercialization of Contrave, and net sales of the Company, as described in the Indenture, holders of the 2016 Notes will, at their option, have the right to require the Company to repurchase for cash all or a portion of their 2016 Notes at a repurchase price equal to 100% of the aggregate principal amount of 2016 Notes. The 2016 Notes were not redeemable by the Company, in whole or in part, prior to the receipt of the required stockholder approvals, or the Stockholder Approval, which the Company obtained at its 2016 annual meeting of stockholders in July 2016. From and after the receipt of the Stockholder Approval, the 2016 Notes are not redeemable, in whole or in part, without the consent of the holders of not less than 70% in aggregate principal amount of the 2016 Notes at the time outstanding.

In March 2016, the Company entered into a Security Agreement by and among the Company, the guarantors party thereto from time to time and U.S. Bank National Association, as the collateral agent, pursuant to which the Company granted a first-priority security interest in substantially all of the Company's current and future assets, subject to customary exclusions, to secure the Company's obligations under the Indenture. The security interests shall be released once less than 25% of the original principal amount of 2016 Notes issued on the date of the Indenture remains outstanding.

The Purchasers received Warrants exercisable for a number of shares of Common Stock equal to the aggregate principal amount of the 2016 Notes acquired by the Purchasers, multiplied by the Conversion Rate. The exercise price of the Warrants is $15.00 per share and the Warrants expire on September 21, 2026. From and after the Stockholder Approval, the Warrants became only exercisable for a number of shares of Common Stock of the Company at the Exercise Price. In the event of a change of control transaction at any time, the Warrants will be exercisable for a period beginning on closing of such change of control transaction and ending 35 days after such transaction.

Due to the complexity and number of embedded features within the convertible note and as permitted under accounting guidance, the Company elected to account for the convertible notes and all the embedded features, collectively, the hybrid instrument, under the fair value option. The Company recognizes the convertible debt at fair value rather than at historical cost with changes in fair value recorded in the consolidated statements of operations. Direct costs and fees incurred to issue the convertible notes were recognized in earnings as incurred and not deferred. On the initial measurement date of March 21, 2016, the fair value of the hybrid instrument was estimated at $120.0 million, which was $45.0 million lower than the principal amount of $165.0 million. Upfront costs and fees related to items for which the fair value option is elected was $5.3 million and was recorded as a component of selling, general and administrative expense for the year ended December 31, 2016.

In connection with the Offering the Company issued 219,994 shares of Series Z Preferred Stock.

The Series Z Preferred Stock is not convertible and does not pay or accrete dividends. The Series Z Preferred Stock is entitled to a liquidation preference upon a Fundamental Change, which includes a change of control. Upon a Fundamental Change, the Company must pay each holder an amount equal to the lesser of (i) the amount by which $975 exceeds the amount received by holders of each

100 shares of Common Stock and (ii) $225; provided however that, if $975 does not exceed the amount received by holders of each 100 shares of Common Stock, then the Fundamental Change Amount will be $0.

The Series Z Preferred Stock expires on the earlier to occur of (a) December 31, 2020 or (b) upon receipt of the consent of the holders of at least seventy percent (70%) of the outstanding shares of Series Z Preferred Stock, voting as a separate class. Expiration requires no cash outlay by the Company. The Series Z Preferred Stock is classified outside of permanent equity, since all of the contingent events requiring payment are not solely within the Company's control. The gross proceeds received on March 21, 2016, in the Offering, net of fees paid directly to the note holders, were be allocated to the initial fair value of the Warrants and Notes with the residual amount of approximately $3.3 million allocated to the Series Z Preferred Stock.

2.75% Convertible Senior Notes due 2020

In December 2013, the Company issued $115.0 million in aggregate principal amount of 2.75% convertible senior notes due 2020, or the 2013 Notes, in an offering to qualified institutional buyers conducted in accordance with Rule 144A under the Securities Act of 1933, as amended. Debt issuance costs of approximately $488,000 were primarily comprised of legal, accounting and other professional fees, the majority of which were recorded as a reduction to the 2013 Notes on the consolidated balance sheet and are being amortized to interest expense over the seven-year term of the 2013 Notes.

The Company has the option to settle the 2013 Notes through payment or delivery, as the case may be, of cash, shares of the Company's common stock or a combination thereof, at the Company's election. The conversion rate for the 2013 Notes is 12.21225 shares per $1,000 principal amount, which is equivalent to a conversion price of approximately $81.88 per share of common stock, and is subject to adjustment under the terms of the 2013 Notes.

The 2013 Notes will mature on December 1, 2020, unless earlier repurchased or converted in accordance with their terms prior to such date. Prior to the close of business on the business day immediately preceding September 1, 2020, holders may convert all or a portion of their 2013 Notes only under the following circumstances: (1) during any fiscal quarter commencing after March 31, 2014, if, for at least 20 trading days (whether or not consecutive) during the 30 consecutive trading day period ending on the last trading day of the immediately preceding fiscal quarter, the last reported sale price of the Company's common stock on such trading day is greater than or equal to 130% of the applicable conversion price on such trading day; (2) during the five consecutive business day period immediately following any ten consecutive trading day period (the "measurement period") in which, for each trading day of that measurement period, the trading price per $1,000 principal amount of notes for such trading day was less than 98% of the product of the last reported sale price of the Company's common stock on such trading day and the applicable conversion rate on such trading day, or (3) upon the occurrence of specified corporate transactions. On and after September 1, 2020 until the close of business on the business day immediately preceding the maturity date, holders may convert all or a portion of their 2013 Notes at any time, regardless of the foregoing circumstances. Holders of the Notes will have the right to require the Company to repurchase all or some of their Notes at 100% of their principal amount, plus any accrued and unpaid interest, upon the occurrence of certain events.

The Company pays 2.75% interest per annum on the principal amount of the 2013 Notes semi-annually in arrears in cash on June 1 and December 1 of each year. If a designated event, as defined in the indenture for the 2013 Notes, including, but not limited to, a change in control, certain mergers or liquidation, occurs prior to the maturity date, subject to certain limitations, holders of the Notes may require the Company to repurchase all or a portion of their 2013 Notes for cash at a repurchase price equal to 100% of the principal amount of the 2013 Notes to be repurchased, plus any accrued and unpaid interest to, but excluding, the repurchase date.

The Company accounts separately for the liability and equity components of the 2013 Notes in accordance with authoritative guidance for convertible debt instruments that may be settled in cash upon conversion. The guidance requires the carrying amount of the liability component to be estimated by measuring the fair value of a similar liability that does not have an associated conversion feature. Because the Company has no outstanding non-convertible public debt, the Company determined that senior, unsecured corporate bonds traded on the market represent a similar liability to the 2013 Notes without the conversion option. The Company estimated the implied interest rate of its 2013 Notes to be 8.69%, assuming no conversion option. Assumptions used in the estimate represent what market participants would use in pricing the liability component, including market interest rates, credit standing, and yield curves, all of which are defined as Level 2 observable inputs. The estimated implied interest rate was applied to the 2013 Notes, which resulted in a fair value of the liability component of $79.7 million upon issuance, calculated as the present value of implied future payments based on the $115.0 million in aggregate principal amount. The $31.3 million difference between the cash proceeds and the estimated fair value of the liability component was recorded in additional paid-in capital as the 2013 Notes were not considered redeemable.

In December 2016, the Company purchased approximately $35.0 million in face value of the outstanding 2013 Notes for approximately $10 million. As a result of the note repurchase, the Company recorded a gain on extinguishment of debt of approximately $18.3 million during the year ended December 31, 2016, determined as the difference between the purchase price and

the net carrying value of the 2013 Notes that were purchased. No portion of the purchase price was ascribed to the equity component of the 2013 Notes as the purchase price was equal to the then fair value of the liability component of the 2013 Notes.

A summary of the liability and equity components of the 2013 Notes is as follows at December 31, 2016 and 2015, respectively (in thousands):

	December 31,	
	2016	2015
Principal amount of senior convertible notes outstanding	$ 79,903	$ 115,000
Unamortized discount of liability component	(15,477)	(26,871)
Unamortized debt issuance costs	(147)	(259)
Long term convertible debt	$ 64,279	$ 87,870
Carrying value of equity component, net of issuance costs	$ 31,178	$ 31,178
Remaining amortization period of discount on the liability component	4.0 years	5.0 years

10. Operating Leases

In December 2007, the Company entered into an operating lease agreement for office facilities (corporate headquarters) in San Diego, California. The term of the lease began in April 2008 and was for an initial term of 64 months. In February 2013, the Company entered into an amendment to extend its lease to September 2017. In August 2015, the Company entered into an amendment to lease additional space in the same office complex as its corporate headquarters. In October 2016, the Company entered into an amendment to extend the lease term for all leased office space at the corporate headquarters through February 2018. The monthly rental payments are adjusted on an annual basis. As security for the lease, the landlord required a letter of credit, which is collateralized by a certificate of deposit of $88,000, which is included in restricted cash in the accompanying balance sheet at December 31, 2016. Rent expense is being recorded on a straight-line basis over the life of the lease.

Future minimum payments under the operating leases as of December 31, 2016 are as follows (in thousands):

Years Ending December 31,	
2017	$ 1,508
2018	254
2019	—
2020	—
2021	—
	$ 1,762

Total rent expense for each of the years ended December 31, 2016, 2015 and 2014 was approximately $1.4 million, $1.0 million and $911,000, respectively.

11. Technology, License and Distribution Agreements

Takeda Pharmaceutical Company Limited

In September 2010, the Company entered into a collaboration agreement with Takeda to develop and commercialize Contrave in the United States, Canada and Mexico. Effective in September 2013, the Company and Takeda entered into an amendment to the collaboration agreement pursuant to which Takeda assumed from the Company the responsibility to package Contrave for commercial sale in the United States, Canada and Mexico. Under the terms of the original collaboration agreement, the Company received from Takeda a nonrefundable upfront cash payment of $50.0 million and additional payments totaling $100.0 million that were achieved between the execution of the collaboration agreement and the first commercial sale of Contrave in the United States. The Company was eligible to receive additional payments of over $1.0 billion upon achieving certain anniversary, regulatory/development and sales-based milestones. The Company was also eligible to receive tiered royalty payments ranging from a minimum of 20% to a maximum of 35%, subject to customary reductions, on increasing levels of net sales in the United States.

In July 2015, the Company entered into an amended and restated collaboration agreement with Takeda (the "Restated Collaboration Agreement") which amended and restated the original agreement that the parties entered into in September 2010. The Restated Collaboration Agreement was substantially the same as the prior agreement subject to the following key changes:

(a) The territory covered by the collaboration was revised to only include the United States, returning all rights for the countries of Mexico and Canada to the Company.

(b) The responsibilities for the costs of development activities for Contrave from and after August 1, 2015 were restructured.

(i) The Company was responsible for the cost of the randomized, double-blind, placebo-controlled cardiovascular outcomes clinical trial (the "CVOT") to be conducted by Takeda up to the currently-projected total cost of such CVOT, above which the parties would have generally shared the costs of such CVOT equally, with certain exceptions.

(ii) Takeda was to be responsible for 100% of remaining costs for the terminated Light Study.

(iii) Takeda and the Company were to be responsible for 75% and 25% of expenses, respectively, of any other post-approval development costs, including all other post-marketing requirement studies other than the CVOT.

(c) The Company was then eligible to receive up to an additional $105 million of potential milestone payments upon achievement of a combination of factors related to superiority claims reflected in approved labeling for Contrave, a lack of generic competition and net sales.

The termination provisions of the Restated Agreement were not changed from the prior agreement. In addition to the Restated Collaboration Agreement, the parties also simultaneously agreed to a mutual release to, among other things, any claims or potential claims related to the prior dispute among the parties.

The upfront payment of $50.0 million was determined not to have standalone value and was deferred and was being recognized over the estimated term of the agreement of 14.5 years. In addition to the upfront payment, the Company earned milestones of $30.0 million for the FDA approval of Contrave and for delivery of launch supplies to Takeda in 2014. This milestone payment was determined to meet the definition of a substantive milestone and was recognized at the time the milestone was earned. Also, in October 2014, the Company earned and was paid a $70.0 million milestone for the shipment of Contrave, by Takeda, to pharmacy wholesalers in preparation for the commercial launch. This milestone payment was determined to not meet the definition of a substantive milestone. As a result, the Company recognized $20.8 million in 2014 and deferred $49.2 million which was to be recognized over the remaining estimated life of the agreement.

In March 2016, the Company entered into a separation agreement with Takeda, or the Separation Agreement, which terminated the Restated Collaboration Agreement between the Company and Takeda, and the manufacturing services agreement between the Company and Takeda. The termination was effective on August 1, 2016. The Separation Agreement provided for the transfer of certain rights and assets to the Company and provided for the transition of activities under the collaboration agreement from Takeda to the Company during the transition period. In connection with the Separation Agreement, the Company made a $60.0 million payment for the acquisition of the Contrave business and paid an additional $15.0 million in January 2017. The Company may also be obligated to pay Takeda milestone payments of $10 million, $20 million, $30 million and $50 million, based on the achievement of annual Contrave net sales milestones of $200 million, $300 million $400 million and $600 million, respectively, in any year following the end of the transition period. Each such milestone payment shall be payable only once but more than one may be payable with respect to net sales in a single year. The Company recorded a contingent consideration liability associated with these sales milestones, as disclosed in Note 5, *Fair Value Measurements*. The acquisition date was August 1, 2016.

For the year ended December 31, 2016, the Company recognized revenues under the Restated Collaboration Agreement of approximately $11.4 million, including approximately $6.0 million in royalties earned for the sale of Contrave by Takeda and approximately $5.4 million in continued recognition of the up front and non-substantive milestone payments. As a result of the Separation Agreement and the settlement of a pre-existing relationship with Takeda, the Company recorded a settlement gain of $80.2 million representing the existing Contrave deferred revenue.

Kwang Dong Pharmaceutical Company, Ltd.

In July 2015, the Company's wholly owned subsidiary, Orexigen Therapeutics Ireland, Ltd., and Kwang Dong Pharmaceutical Company, Ltd., or Kwang Dong, entered into an exclusive distribution agreement for South Korea for Contrave. Under the terms of the agreement, Kwang Dong will be responsible for seeking regulatory approval and for all commercialization activity and expenses. The Company will supply Contrave tablets to Kwang Dong. The Company received a $7.0 million upfront payment and will be entitled to potential sales-based milestones of $6.0 million and other potential payments totaling $10.0 million. In May 2016, the Company paid $300,000 to Kwang Dong when they obtained regulatory approval for Contrave in South Korea. Kwang Dong began

marketing Contrave in June 2016. The upfront payment was determined not to have standalone value. As a result, the $7.0 million was deferred. The $300,000 payment by the Company upon regulatory approval was deemed to be a contingent portion of the $7.0 million upfront payment. Therefore, the non-contingent portion of the upfront payment of $6.7 million is being recognized over the term of the agreement. In 2016, the Company recognized revenues under this agreement of $3.2 million, including approximately $2.8 million in product sales and approximately $400,000 in amortization of deferred revenue.

Laboratorios Farmacéuticos Rovi, S.A.

In August 2016, the Company's wholly owned subsidiary, Orexigen Therapeutics Ireland, Ltd., and Laboratorios Farmacéuticos Rovi, S.A., or ROVI, entered into a commercialization and distributorship agreement for Mysimba in Spain. Under the terms of the agreement, ROVI will be responsible for all commercialization activity and expenses. Orexigen will supply Mysimba tablets to ROVI for an upfront payment, a transfer price, and various potential commercial milestone payments. ROVI began marketing Mysimba in January 2017.

The upfront payment, 450,000 Euros, was determined not to have standalone value. As a result, the upfront payment was deferred. Therefore, the upfront payment is being recognized over the term of the agreement. In 2016, the Company recognized revenues under this agreement of approximately $38,000.

Valeant Pharmaceuticals International, Inc.

In March 2016, the Company's wholly owned subsidiary, Orexigen Therapeutics Ireland, Ltd., and Valeant Pharmaceuticals International, Inc., or Valeant, entered into a commercialization and distributorship agreement for Mysimba in Central and Eastern Europe. Under the terms of the agreement, Valeant will be responsible for commercialization activities in all 19 countries and for obtaining regulatory approvals in the non-EU countries. Orexigen will retain regulatory affairs responsibilities in EU countries. Orexigen will supply Mysimba tablets to Valeant at an agreed transfer price. In 2016, the Company recognized revenues under this agreement of approximately $1.9 million.

Oregon Health & Science University

In June 2003, the Company entered into a license agreement with Oregon Health & Science University, or OHSU, whereby the Company acquired an assignment of any rights OHSU may have to a U.S. provisional patent application that the Company filed, which formed the basis for the Company's subsequently issued patents. This license agreement was amended in November 2003, December 2006 and December 2007. As consideration for this license agreement, the Company paid an upfront fee of $65,000 and issued 7,632 shares of the Company's common stock to OHSU. The Company is also obligated to pay a royalty to OHSU on net sales for Contrave and any other products covered by the assigned patent rights. The royalty expense is recorded as a general and administrative expense. The Company recorded a royalty payable of $219,000 and $258,000 as of December 31, 2016 and 2015, respectively, under this agreement. The Company is also responsible for all prosecution and maintenance (including all costs associated with the enforcement) of any patent applications, that stem from these assigned rights, and for any patents that have or may issue with respect thereto.

OHSU has also licensed to the Company, on an exclusive basis, the issued patent underlying the in vitro model that the Company has used for screening combination therapies for impact on neuronal activity. With respect to these rights, the Company was required to make a payment of $20,000 upon receipt of a pair of mice and is required to pay an additional $20,000 upon receipt of any additional pair of mice. OHSU is solely responsible for the prosecution, maintenance and enforcement (including all costs associated therewith) of this patent; however, the Company is required to pay 100% of expenses incurred by OHSU in the maintenance and prosecution of this patent. As of December 31, 2016, the Company has paid a total of approximately $118,000 in connection with the maintenance and prosecution of this patent. In addition, OHSU has the right to not file any patent application or to abandon any patent or patent application included in the patent rights, in which case it must provide the Company 60 days' prior written notice and, in response, the Company may elect at its sole cost to pursue these actions. The Company's rights to this patent extend through the expiration of the patent, which is expected to occur in 2024.

12. Stockholders' Equity

Common Stock and Common Stock Warrants

In December 2011, the Company completed a public offering of 5,646,173 units. Each unit consists of one tenth of a share of common stock and a warrant to purchase ten shares of common stock, at a price to the public of $1.45 per one tenth of a share of common stock and $14.49 per warrant to purchase each share of common stock, which together comprise the purchase price of $15.94 per unit. Net cash proceeds from the public offering were $86.9 million, after deducting underwriting discounts and commissions and offering expenses. The warrants issued in the transaction have an exercise price equal to $0.01 per share. Each warrant is exercisable

in whole or in part for a period of 10 years commencing on December 22, 2011. The initial warrants provided for the purchase of up to 5,646,173 shares. A total of 0, 57,197 and 1,729,452 shares were issued upon warrant exercises in 2016, 2015 and 2014, respectively.

In September 2015, the Company sold 2.0 million shares of its common stock and warrants to purchase 500,000 shares of its common stock in a private placement to an affiliate of The Baupost Group, L.L.C., at a purchase price of $30.00 per share of common stock and 0.25 of a warrant, raising net proceeds of $59.8 million. The warrants are exercisable for five years at $60.00 per share.

Warrants to purchase an aggregate of up to 22,500,000, 500,000 and 57,204 shares were outstanding as of December 31, 2016, 2015 and 2014, respectively.

Stock Options

During 2004, the Company adopted the 2004 Stock Plan, or the 2004 Plan, under which, as amended, 315,927 shares of common stock are reserved for issuance to employees, directors and consultants of the Company. The 2004 Plan provides for the grant of incentive stock options, non-statutory stock options and rights to purchase restricted stock to eligible recipients. Recipients of incentive stock options shall be eligible to purchase shares of the Company's common stock at an exercise price equal to no less than the estimated fair market value of such stock on the date of grant. The maximum term of options granted under the 2004 Plan is ten years. The options generally vest over four years, and some are immediately exercisable. At December 31, 2016, no stock options are outstanding under the 2004 Plan.

In February 2007, the Company's stockholders approved the 2007 Equity Incentive Award Plan, or the 2007 Plan, which became effective in April 2007, under which 352,500 shares of common stock were initially reserved for future issuance to employees, directors and consultants of the Company. Effective January 1, 2009, 2010 and 2011, the Company's Board of Directors increased the shares available for issuance under the 2007 Plan by 172,167, 200,000 and 200,000 shares, respectively, in accordance with an "evergreen" provision. The 2007 Plan provides for the issuance of stock options, stock appreciation rights, restricted stock units, performance stock units, and other stock-based awards. The 2007 Plan has an initial term of ten years. As of the effectiveness of the 2007 Plan, no additional shares will be granted under the 2004 Plan. The 2007 Plan was amended in October 2009 and February 2010 to provide for the reservation of 50,000 and 200,000 shares, respectively, of the Company's common stock to be used exclusively for the grant of awards to individuals not previously an employee or non-employee director of the Company (or following a bona fide period of non-employment with the Company), as an inducement material to the individual's entering into employment with the Company within the meaning of Rule 5635(c)(4) of the NASDAQ Listing Rules. In June 2011, the 2007 Plan was amended to, among other things, add an additional 1,000,000 shares to the number of shares of common stock authorized for issuance under the 2007 Plan, increase the number of shares to be added to the 2007 Plan automatically each January 1, starting with January 1, 2012, to the least of (i) 15% of the Company's outstanding common stock on the applicable January 1, (ii) 600,000 shares of common stock and (iii) a lesser number of shares of the Company's common stock determined by the Company's board of directors, and increase the limitation on the number of shares that may be granted pursuant to the exercise of incentive stock option to 4,000,000 shares. The 2007 Plan was amended and restated in July 2016 to, among other things, increase the shares available for issuance by 9.3 million shares and eliminate the "evergreen" provision. At December 31, 2016, options to purchase 6,227,224 shares have been granted and are outstanding under the 2007 Plan.

The following table summarizes stock option activity for the 2004 and 2007 Plans:

	Number of Options	Weighted Average Exercise Price
Outstanding at December 31, 2013	1,690,215	$ 31.00
Granted	319,451	62.20
Exercised	(111,155)	20.70
Forfeited/Cancelled	(102,614)	53.50
Outstanding at December 31, 2014	1,795,897	$ 35.90
Granted	501,447	46.80
Exercised	(138,987)	29.60
Forfeited/Cancelled	(171,398)	56.20
Outstanding at December 31, 2015	1,986,959	$ 37.40
Granted	5,234,327	8.58
Exercised	(2,290)	16.60
Forfeited/Cancelled	(991,784)	27.51
Outstanding at December 31, 2016	6,227,212	$ 14.75

The following table summarizes information about stock options outstanding under the 2007 Plan at December 31, 2016:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number of Options	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
$1.85 - $4.00	161,000	9.8	$ 3.02	—	$ —
$4.02 - $4.02	2,455,520	9.5	$ 4.02	44,375	$ 4.02
$4.30 - $7.20	391,025	9.3	$ 4.59	—	$ —
$15.00	1,735,225	9.5	$ 15.00	—	$ —
$16.60 - $81.80	1,484,442	6.3	$ 36.15	1,078,365	$ 36.55
$1.85 - $81.80	6,227,212	8.8	$ 14.75	1,122,740	$ 35.27

As of December 31, 2016, the aggregate intrinsic value of both options outstanding and exercisable was approximately $0. The aggregate intrinsic value of options exercised was approximately $5,000, $5.3 million and $3.6 million during the year ended December 31, 2016, 2015 and 2014, respectively. At December 31, 2016, the weighted average remaining contractual term for options exercisable was 5.6 years.

Performance-vesting Stock Units

The Company granted an aggregate of 353,000 performance-vesting stock units, or PSUs, to certain employees in 2016, of which no shares vested during 2016. Approximately 89,000 were forfeited during 2016. These PSUs are subject to vesting in 20% installments over five years from the date of grant but will only be earned during such five-year period if pre-determined share price hurdles relating to the 20-trading day average of the closing price of the Company's common stock are attained. The expense associated with these awards is being recognized over the anticipated service period. At December 31, 2016, there were approximately 264,000 PSU's outstanding.

Employee Stock Purchase Plan

In June 2013, the Company's stockholders approved the Company's ESPP, which permits the Company's eligible employees to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 15% of the participant's cash compensation subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair market value of the stock at either the beginning of the applicable "Offering Period" or the Purchase Date. Each Offering Period is 24 months, with new Offering Periods commencing every six months on the dates of June 1 and December 1 of each year. Each Offering Period consists of four (4) six month purchase periods (each a "Purchase Period") during which payroll deductions of the participants are accumulated under the ESPP. The last business day of each Purchase Period is referred to as the "Purchase Date." Purchase Dates are every six months on the last business day of May and November.

The assumptions used for the years ended December 31, 2016, 2015 and 2014 and the resulting estimates of weighted-average fair value per share for stock purchased under the ESPP during 2016, 2015 and 2014 are as follows:

	Years Ended December 31,		
	2016	2015	2014
Expected term (in years)	0.49 – 2.00	0.49 – 2.00	0.49 – 2.00
Expected volatility	82.4 -106.6%	61.1 -74.6%	49.1 -72.9%
Risk-free interest rate	0.49 – 1.14%	0.02 – 0.91%	0.06 – 0.49%
Expected dividend yield	0.0%	0.0%	0.0%

At December 31, 2016, total unrecognized estimated stock-based compensation expense related to the ESPP was approximately $716,000, which is expected to be recognized over a weighted-average period of approximately 8 months. A total of 600,000 shares of the Company's common stock have been reserved for issuance under the ESPP plan. 59,978, 12,249 and 8,433 shares were issued under the ESPP during the years ended December 31, 2016, 2015 and 2014, respectively.

Common stock reserved for future issuance consists of the following at December 31, 2016:

Common stock warrants	22,500,000
Available for future issuance under ESPP	514,812
Stock options and PSU's issued and outstanding	6,491,452
Authorized for future option grants	6,389,096
	35,895,360

13. Income Taxes

The components of the pretax loss from operations for the years ended December 31, 2016 and 2015 are as follows (in thousands):

	2016	2015	2014
U.S. domestic	$ 2,189	$ (53,783)	$ (37,525)
Foreign	(26,580)	(13,528)	—
Pretax loss from operations	$ (24,391)	$ (67,311)	$ (37,525)

The provision for income taxes from continuing operations consists of the following (in thousands):

	2016	2015	2014
Current:			
Federal	$ (2)	$ 1,348	$ —
State	135	28	—
Foreign	—	—	—
Total current	133	1,376	—
Deferred:			
Federal	—	—	—
State	—	—	—
Foreign	—	—	—
Total deferred	—	—	—
Total income tax expense (benefit)	$ 133	$ 1,376	$ —

A reconciliation of income taxes to the amount computed by applying the statutory federal income tax rate to the net loss is summarized as follows:

	December 31,		
(In thousands)	2016	2015	2014
Income tax expense (benefit) at statutory rates	$ (8,537)	$ (23,559)	$ (13,133)
State income tax, net of federal benefit	1,276	(59)	(422)
Permanent items	683	553	2,157
Uncertain tax positions	971	5,943	843
Research and development credits	(2,429)	(1,877)	(2,041)
Mark to market - financial instruments	(2,555)	—	—
Stock-based compensation	6,252	548	751
Tax attribution limitation	(1,305)	(22,908)	—
Foreign rate differential	5,992	3,890	—
Change in rate	(2,347)	4,565	(2,624)
State net operating loss	1,203	(1,529)	—
Deferred intercompany profit	(1)	23,320	—
Change in valuation allowance	930	12,489	14,469
Income tax expense (benefit)	$ 133	$ 1,376	$ —

Significant components of the Company's deferred tax assets as of December 31, 2016 and 2015 are shown below. A valuation allowance has been recognized to offset the net deferred tax assets as realization of such deferred tax assets has not met the more likely than not threshold.

	December 31,	
(In thousands)	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$ 98,995	$ 72,064
Research and development credits	6,190	4,733
Capitalized research and development expenditures	2,733	1,460
Deferred revenue	—	26,761
Stock-based compensation	9,410	12,143
Other, net	9,163	3,531
Total deferred tax assets	126,491	120,692
Valuation allowance for deferred tax assets	(113,009)	(112,290)
Deferred tax assets, net of valuation allowance	13,482	8,402
Deferred tax liabilities:		
Convertible debt	(13,482)	(8,402)
Total deferred tax liabilities	(13,482)	(8,402)
	$ —	$ —

At December 31, 2016, federal, state and foreign net operating loss carryforwards are approximately $445.4 million, $417.4 million and $39.0 million, respectively, not considering the IRC Section 382 annual limitation discussed below. The federal loss carryforwards begin to expire in 2027, and the state loss carryforwards begin to expire in 2017, unless previously utilized. At December 31, 2016, federal and state research and development tax credit carryforwards are $21.8 million and $7.0 million, respectively. The federal research and development tax credit carryforwards begin to expire in 2024 unless previously utilized. The state research and development tax credits and foreign net operating losses carry forward indefinitely.

The California net operating loss carry forwards are scheduled to expire as follows (in thousands):

Year	Amount
2017	$ 49,841
2018	3,841
2028 and beyond	336,492

Approximately $12.2 million of the net operating loss carryforwards relate to excess tax deductions for stock compensation, the income tax benefit of which will be recorded as additional paid-in-capital if and when realized.

Additionally, the utilization of the net operating loss and research and development tax credit carryforwards is subject to an annual limitation under Section 382 and 383 of the Internal Revenue Code of 1986, and similar state tax provisions due to ownership change limitations that have occurred previously or that could occur in the future. These ownership changes limit the amount of the net operating loss and research and development tax credit carryforwards and other deferred tax assets that can be utilized to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382 and 383, results from transactions increasing ownership of certain stockholders or public groups in the stock of the corporation by more than 50 percent points over a three-year period. The Company has completed an ownership change analysis in accordance with Section 382 from inception through December 31, 2016. As a result of the analysis, it was determined that the Company experienced several ownership changes during this period with the last one occurring in December 2014. The analysis to determine the limitation of NOLs and federal credits as a result of the ownership changes has not been finalized. Based on the preliminary analysis of the limitation of the net operating losses and federal credits, deferred tax assets for net operating losses of $189.4 million and $162.5 million for federal and state, respectively, and federal research and development credits of $12.0 million have been removed from the deferred tax asset schedule. A corresponding decrease to the valuation allowance has also been recorded. Due to the existence of the valuation allowance, future changes in the deferred tax assets related to these tax attributes will not impact the effective tax rate.

The following table summarizes the activity related to the Company's gross unrecognized tax benefits at the beginning and end of the years ended December 31, 2016, 2015 and 2014 (in thousands):

	December 31,		
	2016	2015	2014
Gross unrecognized tax benefits at the beginning of the year	$ 16,119	$ 7,309	$ 6,396
Increases related to current year tax positions	912	822	960
Increases related to prior year tax positions	196	7,988	—
Increases (decreases) related to prior year tax positions	—	—	(35)
Expiration of unrecognized tax benefits	—	—	(12)
Gross unrecognized tax benefits at the end of the year	$ 17,227	$ 16,119	$ 7,309

Due to the valuation allowance, none of the unrecognized tax benefits as of December 31, 2016, if recognized, would reduce the Company's annual effective tax rate. The Company does not expect a significant change in unrecognized tax benefits over the next 12 months.

The Company files income tax returns in the United States, Ireland and in various state jurisdictions with varying statutes of limitations. Due to net operating losses incurred, the Company's tax returns from inception to date are subject to examination by taxing authorities. The Company's policy is to recognize interest expense and penalties related to income tax matters as a component of income tax expense. As of December 31, 2016, the Company had no interest or penalties accrued for uncertain tax positions.

14. Litigation

In May 2013, the Company received a shareholder demand alleging that certain option grants to the President and Chief Executive Officer, Michael A. Narachi, the Chief Business Officer and acting-Chief Financial Officer, Joseph P. Hagan, and the Senior Vice President, General Counsel and Secretary, Heather D. Turner, in 2011 were granted in excess of the 1,500,000 share limit set forth in Section 3.3 of the Orexigen Therapeutics, Inc. 2007 Equity Incentive Award Plan, or Plan, as to the number of shares of the Company's common stock with respect to which one or more stock awards may be granted to any one eligible participant during any of the Company's fiscal years. The Company refers to this limit as the 162(m) Award Limit. The Company's board of directors established a demand review committee composed of independent directors to conduct an investigation with respect to the shareholder demand and to make recommendations to the board of directors. The demand review committee engaged independent counsel as part of its investigation and evaluated (1) the terms of the Plan, (2) the initial issuance procedures for the option grants to Mr. Narachi, Mr. Hagan and Ms. Turner during 2011, (3) the authority available to the compensation committee of the board of directors under its charter and the Plan, (4) the expectations of the award recipients and (5) the intent of the board of directors and the compensation committee regarding the availability of an exemption from the deductibility limitations of Section 162(m) of the Internal Revenue Code for such option grants. Following its investigation, the demand review committee determined that the 162(m) Award Limit first became effective as of June 2, 2011, and that, therefore, awards granted under the Plan prior to June 2, 2011, did not count toward the 162(m) Award Limit. The demand review committee determined that the awards granted to Mr. Hagan between June 2, 2011 and December 31, 2011 did not exceed the 162(m) Award Limit. The demand review committee further determined that the options granted to Mr. Narachi and Ms. Turner, including the portion of such awards in excess of the 162(m) Award Limit, were validly approved under the Plan, although the portion of those awards in excess of the 162(m) Award Limit does not qualify as performance-based compensation under Section 162(m). In September 2013, the compensation committee amended the Plan, with the approval of the Company's board of directors, to take the following actions: (1) to clarify that the 162(m) Award Limit only applies to awards or the portion thereof intended to qualify as performance-based compensation under Section 162(m); and (2) to confirm that the compensation committee has the authority to make awards in excess of the 162(m) Award Limit, which board action the Company refers to as the Plan Amendment. The Plan Amendment is deemed effective as of June 10, 2011, consistent with the authority of the compensation committee as administrator of the Plan as of that date. Any grants under the Plan in excess of the 162(m) Award Limit are not intended to qualify as performance-based compensation under Section 162(m).

On December 9, 2013, the same shareholder who made a demand on the board in May 2013 filed a derivative lawsuit purportedly on behalf of the Company against certain of the officers and current and former members of the board of directors in the United States District Court, for the Southern District of California, captioned *Turgeman v. Narachi, et al*. The lawsuit asserts claims for breach of fiduciary duty, waste and unjust enrichment based on, among other things, the alleged grant of stock options to certain officers in excess of the 162(m) Award Limit, repricing stock options allegedly in violation of the Company's equity incentive plan, the board of directors' conduct in responding to the May 2013 shareholder demand, and making allegedly false and misleading statements. The lawsuit seeks, among other things, declaratory relief, corporate governance reforms, rescission of certain stock option awards, rescission of the Plan Amendment, injunctive relief, damages, restitution, disgorgement and attorney's fees. On July 23, 2014, the Company and the individual defendants filed a motion to dismiss the *Turgeman* complaint. On March 9, 2015, the court granted the motion to dismiss with thirty days leave to amend. An amended complaint was filed on April 8, 2015. The amended complaint

asserts the same derivative claims as the original complaint and asserts a putative claim on behalf of plaintiff and the Company's shareholders for breach of contract for alleged violations of the 2007 Equity Incentive Plan. On May 8, 2015, the Company and the individual defendants filed a motion to dismiss the amended complaint. The court has not yet ruled on the motion.

On March 10, 2015, a purported class action lawsuit was filed against the Company and certain of the Company's officers in the United States District Court, for the Southern District of California, captioned *Colley v. Orexigen, et al*. The following day, two additional putative class action lawsuits were filed in the same court, captioned *Stefanko v. Orexigen, et al*., and *Yantz v. Orexigen, et al*., asserting substantially similar claims. On June 22, 2015, the court consolidated the lawsuits and appointed a lead plaintiff. On August 20, 2015, the lead plaintiff filed a consolidated complaint. The consolidated complaint purports to assert claims on behalf of a class of purchasers of the Company's stock between March 3, 2015 and May 12, 2015. It alleges that defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 by purportedly making false and misleading statements regarding the interim results and termination of the Light Study. The consolidated complaint seeks an unspecified amount of damages, attorneys' fees and equitable or injunctive relief. On October 5, 2015, defendants filed a motion to dismiss the consolidated complaint. On May 19, 2016, the District Court granted the motion to dismiss, dismissing portions of the consolidated complaint with prejudice and portions without prejudice. The Court granted lead plaintiff 30 days to file an amended complaint with respect to those portions not dismissed with prejudice. On June 16, 2016, lead plaintiff filed a notice of intent not to file an amended complaint but to proceed directly to an appeal of the Court's decision dismissing the consolidated complaint. As a result, the court entered judgment dismissing the consolidated complaint with prejudice on June 27, 2016. Lead plaintiff filed a Notice of Appeal with the Ninth Circuit Court of Appeals on July 26, 2016. Lead plaintiff filed their opening brief on December 2, 2016. Defendants filed their answering brief on February 2, 2017 and lead plaintiff filed a reply brief on February 16, 2017. No hearing date has been set. Although management believes that this appeal lacks merit and intends to defend against it vigorously, there are uncertainties inherent in any litigation and the Company cannot predict the outcome. As this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorney's fees.

On June 3, 2016, plaintiff Ben Wilkin, a shareholder who had previously made a shareholder demand to inspect certain books and records of the Company, filed a derivative lawsuit purportedly on behalf of the Company against certain of the Company's current and former officers and members of the board of directors in the Delaware Chancery Court, captioned *Wilkin v. Narachi, et al*. The lawsuit asserts claims for breach of fiduciary duty and waste of corporate assets based on essentially the same set of facts underlying the *Colley, Stefanko* and *Yantz* consolidated class action. The lawsuit seeks, among other things, damages, corporate governance reforms, injunctive relief, restitution, disgorgement and attorney's fees. Orexigen and the individual defendants filed a motion to dismiss on October 31, 2016, asserting that plaintiff failed to plead demand futility and otherwise failed to state a claim. Instead of opposing the motion to dismiss, on January 13, 2017, plaintiff filed an amended complaint pursuant to Chancery Rule 15(aaa). The amended complaint asserts nearly identical allegations and claims as the original complaint. Orexigen and the individual defendants' filed a motion to dismiss on March 27, 2017. Management believes that the claims lack merit and intends to defend against them vigorously.

As this time, the Company is unable to estimate possible losses or ranges of losses that may result from such legal proceedings described above, and it has not accrued any amounts in connection with such legal proceedings other than ongoing attorney's fees.

It is possible that additional securities class action litigation may be brought against the Company following stock price declines related to the release of information regarding Contrave or clinical trial results, including the Light Study or related to the matters alleged in the May 2013 shareholder demand and/or the Plan Amendment. Any adverse determination in such litigation could subject the Company to significant liabilities.

In April 2015, the Company and Takeda received a Paragraph IV certification notice letter regarding an abbreviated new drug application, or ANDA, submitted to the FDA by Actavis Laboratories FL, Inc., or Actavis, requesting approval to market, sell, and use a generic version of Contrave. In its notice letter, Actavis alleges that U.S. Patent Nos. 7,375,111; 7,462,626; 8,088,786; 8,318,788; 8,722,085; 8,815,889; and 8,916,195, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book, for Contrave, are invalid, unenforceable and/or will not be infringed by Actavis' manufacture, use or sale of the product described in its ANDA. In June 2015, the Company and Takeda filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Actavis and certain of its affiliates related to the ANDA previously filed by Actavis and described above. The lawsuit claims infringement of the seven patents that were the subject of Actavis' notice letter, as described above. In accordance with the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Act, as a result of having filed a patent infringement lawsuit within 45 days of receipt of Actavis' notice letter, FDA approval of the ANDA will be stayed until the earlier of (i) 30 months from the date of receipt of the notice letter or (ii) a District Court decision finding that the identified patents are invalid, unenforceable or not infringed. In July 2015, Actavis filed an answer, affirmative defenses and counterclaim to the Company's and Takeda's complaint, and the Company and Takeda filed an answer to Actavis' counterclaim in August 2015. Moreover, in July 2015, the court ordered a stipulation between the Company, Takeda and Actavis in which Orexigen and Takeda agreed to dismiss all defendants except Actavis without prejudice, and Actavis agreed that the related Actavis entities will be bound to judgments and orders of the court against Actavis and will be subject to discovery as if they were parties. In September

2015, the court entered a scheduling order, setting a claim construction hearing for May 2016 and a three-day bench trial to begin in June 2017. After reviewing Actavis' ANDA, the Company and Takeda subsequently dropped U.S. Patent Nos. 8,088,786, 8,318,788, 8,722,085 and 8,916,195 from the lawsuit. In April 2016, the Company and Takeda filed an amended complaint against Actavis asserting newly issued U.S. Patent No. 9,125,868. In June 2016, in response to the May 2016 claim construction hearing, the court adopted the Company's proposed constructions for the majority of the disputed claim terms. In August 2016, in connection with the end of the transition period associated with the separation agreement entered into between the Company and Takeda, Takeda transferred the responsibility for management of this patent infringement lawsuit to the Company. Although the Company plans to vigorously enforce Contrave intellectual property rights, there are uncertainties inherent in any litigation and we cannot predict the outcome.

15. Employee Benefit Plan

The Company has a defined contribution 401(k) retirement plan which allows employees to contribute up to 100% of their annual compensation up to the maximum annual amount prescribed by the Internal Revenue Service. The Company may elect to make a discretionary contribution or match a discretionary percentage of employee contributions. During the years ended December 31, 2016, 2015 and 2014, the Company's matching contributions to the plan were approximately $421,000, $277,000 and $275,000, respectively.

16. Subsequent Event

In February 2017, the Company entered into an indenture, dated as of February 23, 2017 (the "Indenture"), between the Company and U.S. Bank National Association, as trustee, governing the Company's new 2.75% Convertible Exchange Senior Notes due 2020 (the "New Notes"). Approximately $49.6 million in aggregate principal amount of the Company's 2.75% Convertible Senior Notes due 2020, or the Old Notes, were exchanged for an equal principal amount of New Notes.

The New Notes will be the Company's senior, unsecured obligations and will rank senior in right of payment to any of the Company's indebtedness that is expressly subordinated in right of payment to the New Notes; equal in right of payment to any of the Company's unsecured indebtedness that is not so subordinated, including the Old Notes; effectively junior in right of payment to any of the Company's secured indebtedness (including the Company's existing 0% Convertible Senior Secured Notes due 2020, or the Secured Notes) to the extent of the value of the assets securing such indebtedness; and will be structurally junior to all indebtedness and other liabilities (including trade payables) of the Company's subsidiaries.

The New Notes bear interest at a fixed rate of 2.75% per year, payable semiannually in arrears on June 1 and December 1 of each year, beginning June 1, 2017. Interest on the New Notes accrues from December 1, 2016. The New Notes will mature on December 1, 2020, unless earlier repurchased, redeemed or converted.

The New Notes are convertible at any time prior to the close of business on the business day immediately preceding the maturity date, at the option of the holders, into (i) shares of the Company's common stock, or the Common Stock, plus (ii) a cash payment equal to $150 for each $1,000 principal amount of New Notes converted (the "Additional Conversion Payment"), subject to certain adjustments. For conversions prior to September 1, 2018 and the Company's election to exercise its Mandatory Conversion Right (as hereinafter defined), the Company will make an interest make-whole payment to a converting holder for each $1,000 principal amount of New Notes being converted, or the Interest Make-Whole Payment. The Company may pay any Interest Make-Whole Payment either in cash or in shares of Common Stock, at the Company's election. If the Company elects to pay any Interest Make-Whole Payment in cash it will pay cash in an amount equal to the Interest Make-Whole Payment. If Company elects, or is deemed to have elected, to pay any Interest Make-Whole Payment by delivering shares of Common Stock, the number of shares of Common Stock a converting holder of New Notes will receive for each $1,000 principal amount of New Notes will be the number of shares equal to the amount of the Interest Make-Whole Payment to be paid to such holder, divided by the product of (x) 98% and (y) the simple average of the daily volume-weighted average price of the Common Stock for the five trading days ending on and including the trading day immediately preceding the conversion date. Subject to compliance with certain conditions, the Company has the right, or the Mandatory Conversion Right, to, at its option, mandatorily convert all of the New Notes if the daily volume-weighted average price of the Common Stock is equal to or greater than 60.0% of the applicable conversion price of the New Notes for at least 20 Daily VWAP Trading Days (as defined in the indenture governing the New Notes) (whether or not consecutive) during any 30 consecutive Daily VWAP Trading Day period (including the last trading day of such period).

The conversion rate is initially approximately 66.6667 shares of Common Stock per $1,000 principal amount of New Notes (equivalent to an initial conversion price of $15.00 per share of Common Stock), and will be subject to adjustment upon the occurrence of certain events.

The Company may redeem for cash all or any portion of the New Notes, at its option, on or after December 1, 2019 at a r
unpaid interest to, but excluding, the redemption date. Upon a fundamental change (as defined in the indenture governing the New Notes), subject to certain exceptions, the holders of the New Notes may require that the Company repurchase some or all of their New Notes for cash at a repurchase price equal to 100% of the principal amount of the New Notes being repurchased, plus any accrued and unpaid interest to, but excluding, the fundamental change repurchase date.

The events of default, which may result in the acceleration of the maturity of the New Notes, include, among other things:

- the Company's failure to pay any interest on the New Notes when due and such failure continues for a period of 30 days past the applicable due date;
- the Company's failure to pay principal amount of the New Notes when due and payable at maturity, upon declaration of acceleration, upon any fundamental change purchase date, upon any redemption date or otherwise;
- the Company's failure to deliver the consideration due upon the conversion of any New Notes (including the Additional Conversion Payment and the Interest Make-Whole Payment, if applicable) and such failure continues for five business days;
- the Company's failure to give a fundamental change notice when due and such failure continues for a period of five days;
- the Company's failure to comply with the Company's obligations set forth in the indenture governing the New Notes relating to certain consolidations, mergers and sales of assets;
- the Company's failure to perform or observe any of the Company's other covenants or warranties in the indenture governing the New Notes or in the New Notes for 60 days after written notice to the Company from the trustee or to the Company and the trustee from the holders of at least 25% of the aggregate principal amount of then outstanding New Notes has been received by the Company;
- default by the Company or any of the Company's significant subsidiaries with respect to any mortgage, agreement or other instrument under which there may be outstanding, or by which there may be secured or evidenced, any indebtedness for money borrowed in excess of $10.0 million in the aggregate of the Company and/or any of the Company's subsidiaries, whether such indebtedness now exists or shall hereafter be created (i) resulting in such indebtedness becoming or being declared due and payable or (ii) constituting a failure to pay the principal or interest of any such debt when due and payable at its stated maturity, upon required repurchase, upon declaration or otherwise, and such acceleration shall not have been rescinded or annulled or such failure to pay cured within 30 days after written notice has been received by the Company or such subsidiary from the trustee or by the trustee, the Company and such subsidiary by the holders of at least 25% in principal amount of the New Notes then outstanding;
- a final judgment for the payment of $10.0 million or more (excluding any amounts covered by insurance) rendered against the Company or any of the Company's significant subsidiaries, which judgment is not discharged or stayed within 60 days after (i) the date on which the right to appeal thereof has expired if no such appeal has commenced, or (ii) the date on which all rights to appeal have been extinguished; and
- certain events of bankruptcy, insolvency and reorganization of the Company or any of the Company's significant subsidiaries.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Securities and Exchange Commission Rule 13a-15(b), we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Internal control over financial reporting refers to the process designed by, or under the supervision of, our Chief Executive Officer and Chief Financial Officer, and effected by our board of directors, management and other personnel, 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, and 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 our assets; (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 our receipts and expenditures are being made only in accordance with authorizations of our management and directors; 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.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations. Internal control over financial reporting is a process that involves human diligence and compliance and is subject to lapses in judgment and breakdowns resulting from human failures. Internal control over financial reporting also can be circumvented by collusion or improper management override. Because of such limitations, there is a risk that material misstatements may not be prevented or detected on a timely basis by internal control over financial reporting. However, these inherent limitations are known features of the financial reporting process. Therefore, it is possible to design into the process safeguards to reduce, though not eliminate, this risk.

Management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Under the supervision and with the participation of our management, including our chief executive officer and chief financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting. Management has used the framework set forth in the report entitled "Internal Control—Integrated Framework" published by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework) to evaluate the effectiveness of our internal control over financial reporting. Based on its evaluation, management has concluded that our internal control over financial reporting was effective as of December 31, 2016, the end of our most recent fiscal year.

During the fourth quarter of 2016, we implemented additional controls and procedures to formally monitor all changes to our business and consider the impact to our financial statements, including proper recording and disclosure of the impact of those events as well as documenting the related significant estimates and judgments made by management. These new controls were implemented to remediate a material weakness identified in the third quarter of 2016.

Item 9B. Other Information.

None.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2017 annual meeting of stockholders, or the Definitive Proxy Statement, pursuant to Regulation 14A of the Securities Exchange Act of 1934, as amended, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the Definitive Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

Information regarding Directors, Executive Officers and Corporate Governance is hereby incorporated by reference to our Definitive Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2016.

We have adopted a Code of Business Conduct and Ethics that applies to our officers, directors and employees which is available on our internet website at www.orexigen.com. The Code of Business Conduct and Ethics contains general guidelines for conducting the business of our company consistent with the highest standards of business ethics, and is intended to qualify as a "code of ethics" within the meaning of Section 406 of the Sarbanes-Oxley Act of 2002 and Item 406 of Regulation S-K. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our code of ethics that is granted to one of these specified officers, the name of such person who is granted the waiver and the date of the waiver on our website in the future.

Item 11. Executive Compensation.

Information regarding Executive Compensation is hereby incorporated by reference to our Definitive Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2016.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information regarding Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters is hereby incorporated by reference to our Definitive Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2016.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information regarding Certain Relationships and Related Transactions, and Director Independence is hereby incorporated by reference to our Definitive Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2016.

Item 14. Principal Accounting Fees and Services.

Information regarding the Principal Accounting Fees and Services is hereby incorporated by reference to our Definitive Proxy Statement, which will be filed with the SEC within 120 days after December 31, 2016.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) Documents filed as part of this report:

1. The following financial statements of Orexigen Therapeutics, Inc. are filed as part of this report under Item 8 – Financial Statements and Supplementary Data:

2. List of financial statement schedules. All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

3. List of Exhibits required by Item 601 of Regulation S-K. See paragraph (b) below.

(b) The following exhibits are filed as part of this report:

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	Amended and Restated Certificate of Incorporation of Orexigen Therapeutics, Inc.	S-1/A	333-139496	3.2	02/16/2007	
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Orexigen Therapeutics, Inc.	S-8	333-175071	3.2	06/22/2011	
3.3	Amended and Restated Bylaws of Orexigen Therapeutics, Inc.	S-1/A	333-139496	3.4	02/16/2007	
3.4	Amendment to Amended and Restated Bylaws of Orexigen Therapeutics, Inc.	8-K	001-33415	3.1	07/03/2014	
3.5	Certificate of Designations, Preferences and Rights of Series Z Non-Convertible Non-Voting Preferred Stock	8-K	001-33415	3.1	03/15/2016	
3.6	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Orexigen Therapeutics, Inc.	8-K	001-33415	3.1	07/11/2016	
4.1	Form of Common Stock Certificate	S-1/A	333-139496	4.1	04/09/2007	
4.1	Form of Warrant to Purchase Common Stock	8-K	001-33415	4.1	12/15/2011	
4.2	Indenture dated as of December 6, 2013, by and between Orexigen Therapeutics, Inc. and Wilmington Trust, National Association, as trustee	8-K	001-33415	4.1	12/09/2013	
4.3	Form of Warrant to Purchase Common Stock	8-K	001-33415	10.1	09/10/2015	
4.4	Investor Rights Agreement, dated as of March 15, 2016, by and among Orexigen Therapeutics, Inc., Baupost, and the other investors party thereto	8-K	001-33415	10.2	03/15/2016	
4.5	Securities Purchase Agreement, dated as of March 15, 2016, by and among Orexigen Therapeutics, Inc. and each purchaser party thereto	8-K	001-33415	10.1	03/15/2016	
4.6	Indenture, dated as of March 21, 2016, by and between Orexigen Therapeutics, Inc. and U.S. Bank National Association, as trustee and collateral agent, including the Form of 0% Convertible Senior Secured Note due 2020	8-K	001-33415	4.1	03/25/2016	
4.7	Form of Warrant to Purchase Common Stock	8-K	001-33415	10.4	03/15/2016	
4.8	Supplemental Indenture, dated December 19, 2016, among Orexigen Therapeutics, Inc., U.S. Bank National Association, as trustee and collateral agent, and certain holders of 0% Convertible Senior Secured Notes due 2020	8-K	001-33415	4.1	12/20/2016	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
4.9	Supplemental Indenture, dated February 16, 2017, among Orexigen Therapeutics, Inc., U.S. Bank National Association, as trustee and collateral agent, and certain holders of 0% Convertible Senior Secured Notes due 2020	8-K	001-33415	4.2	02/17/17	
4.10	Indenture, dated as of February 23, 2017, by and between Orexigen Therapeutics, Inc. and U.S. Bank National Association, as trustee.	8-K	001-33415	4.1	02/24/2017	
10.1	Form of Director and Executive Officer Indemnification Agreement	S-1/A	333-139496	10.1	02/16/2007	
10.2*	Form of Executive Officer Employment Agreement	8-K	001-33415	10.2	01/28/2010	
10.3*	2004 Stock Plan and forms of option agreements thereunder	S-1	333-139496	10.3	12/19/2006	
10.4*	Amended and Restated 2007 Equity Incentive Award Plan and forms of stock option grant notice and stock option agreement thereunder	10-Q	001-33415	10.5	08/05/2016	
10.5*	2013 Employee Stock Purchase Plan	S-8	333-189120	10.1	06/06/2013	
10.6†	License Agreement dated June 27, 2003, by and between Orexigen Therapeutics, Inc. and Oregon Health & Science University	S-1	333-139496	10.7	12/19/2006	
10.7†	Amendment to License Agreement dated November 1, 2003 by and between the Registrant and Oregon Health & Science University	S-1	333-139496	10.8	12/19/2006	
10.8†	Letter Agreement Amendment to License Agreement dated December 6, 2006, by and between Orexigen Therapeutics, Inc. and Oregon Health & Science University.	S-1	333-139496	10.9	12/19/2006	
10.9	Amendment No. 3 to License Agreement dated December 7, 2007 by and between the Orexigen Therapeutics, Inc. and Oregon Health & Science University	8-K	001-33415	10.1	12/14/2007	
10.10	Amended and Restated Master Agreement for Pharmaceutical Development Services dated March 12, 2010 by and between Orexigen Therapeutics, Inc. and Patheon Pharmaceuticals, Inc.	10-K/A	001-33415	10.17	01/26/2015	
10.11	Manufacturing Services Agreement dated March 12, 2010 by and among Orexigen Therapeutics, Inc., Patheon Pharmaceuticals, Inc. and Patheon Inc.	10-K/A	001-33415	10.18	01/26/2015	
10.12†	Amendment No. 1 to Manufacturing Services Agreement dated November 1, 2013 by and between Orexigen Therapeutics, Inc., Patheon Pharmaceuticals, Inc. and Patheon Inc.	10-k/A	001-33415	10.36	01/26/2015	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.13	Amendment No. 2 to Manufacturing Services Agreement dated September 11, 2014 by and between Orexigen Therapeutics, Inc., Patheon Pharmaceuticals, Inc. and Patheon Inc.	10-K	001-33415	10.33	02/27/2015	
10.14	Office Lease dated December 11, 2007 by and between Orexigen Therapeutics, Inc. and Mullrock 3 Torrey Pines, LLC	8-K	001-33415	10.2	12/14/2007	
10.15	First Amendment to Lease dated September 23, 2008 by and between Orexigen Therapeutics, Inc. and Mullrock 3 Torrey Pines, LLC	10-Q	001-33415	10.1	11/07/2008	
10.16	Partial Lease Termination Agreement dated February 22, 2012 by and between Orexigen Therapeutics, Inc. and Mullrock 3 Torrey Pines, LLC	10-Q	001-33415	10.2	05/10/2012	
10.17	Second Amendment to Lease dated February 15, 2013 by and between Orexigen Therapeutics, Inc. and Mullrock 3 Torrey Pines, LLC	10-Q	001-33415	10.1	05/09/2013	
10.18	Third Amendment to Lease dated August 17, 2015 by and between Orexigen Therapeutics, Inc. and Mullrock 3 Torrey Pines, LLC	10-Q	001-33415	10.4	11/09/2015	
10.19*	Key Executive Employee Retention Plan	8-K	001-33415	10.1	03/07/2011	
10.20*	Form of Acknowledgment Orexigen Therapeutics, Inc. Recoupment Policy	8-K	001-33415	10.1	04/25/2014	
10.21*	Form of Second Amended and Restated Employment Agreement by and between Orexigen Therapeutics, Inc. and Michael A. Narachi	8-K	001-33415	10.1	06/14/2011	
10.22*	Amendment No. 1 to Second Amended and Restated Employment Agreement dated February 15, 2013 by and between Orexigen Therapeutics, Inc. and Michael A. Narachi	10-Q	001-33415	10.3	08/07/2013	
10.23	Securities Purchase Agreement, dated September 10, 2015, by and between Orexigen Therapeutics, Inc. and Baupost Group Securities, LLC (including the Form of Warrant attached thereto as Exhibit B)	8-K	001-33415	10.1	09/10/2015	
10.24	Securities Purchase Agreement, dated as of March 15, 2016, by and among Orexigen Therapeutics, Inc. and each purchaser party thereto	8-K	001-33415	10.1	03/15/2016	
10.25*	Form of Performance Stock Unit Award Agreement	10-Q	001-33415	10.10	05/05/2016	

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.26	Separation Agreement dated as of March 15, 2016 by and between Orexigen Therapeutics, Inc. and Takeda Pharmaceutical Company Limited	10-Q	001-33415	10.9	05/05/2016	
10.27	Security Agreement, dated as of March 21, 2016, by and among Orexigen Therapeutics, Inc., the guarantors party thereto from time to time, and U.S. Bank National Association, as collateral agent.	8-K	001-33415	10.1	03/25/2016	
10.28*	Amendment No. 2 to Second Amended and Restated Employment Agreement dated February 4, 2016 by and between the Registrant and Michael A. Narachi	10-Q	001-33415	10.1	05/05/2016	
10.29*	Amendment No. 2 to Amended and Restated Employment Agreement dated February 5, 2016 by and between the Registrant and Preston Klassen, M.D.	10-Q	001-33415	10.2	05/05/2016	
10.30*	Employment Agreement dated March 30, 2015 by and between the Registrant and Thomas Cannell, D.V.M.	10-Q	001-33415	10.3	05/05/2016	
10.31*	Amendment No. 1 to Employment Agreement dated February 2, 2016 by and between the Registrant and Thomas Cannell	10-Q	001-33415	10.4	05/05/2016	
10.32*	Employment Agreement dated December 1, 2015 by and between the Registrant and Thomas Lynch	10-Q	001-33415	10.5	05/05/2016	
10.33*	Amendment No. 1 to Employment Agreement dated February 2, 2016 by and between the Registrant and Thomas Lynch	10-Q	001-33415	10.6	05/05/2016	
10.34*	Employment Agreement dated February 3, 2015 by and between Orexigen Therapeutics, Inc. and Jason Keyes	10-Q	001-33415	10.1	08/05/2016	
10.35*	Amendment No. 1 to Employment Agreement dated February 2, 2016 by and between Orexigen Therapeutics, Inc. and Jason Keyes	10-Q	001-33415	10.2	08/05/2016	
10.36*	Amendment No. 2 to Employment Agreement dated June 16, 2016 by and between Orexigen Therapeutics, Inc. and Thomas Cannell D.V.M.	10-Q	001-33415	10.3	08/05/2016	
10.37*	Amendment No. 2 to Employment Agreement dated June 16, 2016 by and between Orexigen Therapeutics, Inc. and Jason Keyes	10-Q	001-33415	10.4	08/05/2016	
21.1	Subsidiaries of Orexigen Therapeutics, Inc.	10-K	001-33415	21.1	02/26/2016	
23.1	Consent of Independent Registered Public Accounting Firm					X

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act of 1934, as amended					X
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rule 13a-14 and Rule 15d-14 of the Securities Exchange Act of 1934, as amended					X
32.1#	Certification of Chief Executive officer and Principal Financial and Accounting Officer pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					X
101	The following financial statements and footnotes from the Orexigen Therapeutics, Inc. Annual Report on Form 10-K for the year ended December 31, 2016 formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets; (ii) Consolidated Statements of Operations; (iii) Consolidated Statements of Comprehensive Loss; (iv) Consolidated Statements of Stockholders' Equity; (v) Consolidated Statements of Cash Flows; and (vi) the Notes to Condensed Consolidated Financial Statements.					X

† Confidential treatment has been granted for a portion of this exhibit.

* Indicates management contract or compensatory plan or arrangement.

The certifications attached as Exhibit 32.1 accompany this Annual Report on Form 10-K pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

OREXIGEN THERAPEUTICS, INC.

By: /s/ Michael A. Narachi
Michael A Narachi
President and Chief Executive Officer

Dated: March 29, 2017

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/Michael A. Narachi Michael A. Narachi	President and Chief Executive Officer Director (Principal Executive Officer)	March 29, 2017
/s/ Jason Keyes Jason Keyes	SVP, Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2017
/s/Patrick Mahaffy Patrick Mahaffy	Chairman of the Board of Directors	March 29, 2017
/s/Louis C. Bock Louis C. Bock	Director	March 29, 2017
/s/Brian H. Dovey Brian H. Dovey	Director	March 29, 2017
/s/ David J. Endicott David J. Endicott	Director	March 29, 2017
/s/Peter K. Honig Peter K. Honig, M.D.	Director	March 29, 2017
/s/Deborah A. Jorn Deborah A. Jorn	Director	March 29, 2017
/s/Lota S. Zoth Lota S. Zoth	Director	March 29, 2017

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statements (Form S-3 Nos. 333-207961 and 333-210224) of Orexigen Therapeutics, Inc. and

(2) Registration Statements (Form S-8 Nos. 333-142405, 333-165442, 333-175071, 333-189120, 333-194951, 333-202763, and 333-214771) pertaining to the Orexigen Therapeutics, Inc. Amended and Restated 2007 Equity Incentive Award Plan, 2004 Stock Plan and the Orexigen Therapeutics, Inc. 2013 Employee Stock Purchase Plan;

of our report dated March 29, 2017, with respect to the consolidated financial statements of Orexigen Therapeutics, Inc. included in this Annual Report (Form 10-K) of Orexigen Therapeutics, Inc. for the year ended December 31, 2016.

/S/ Ernst & Young LLP

San Diego, California
March 29, 2017

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael A. Narachi, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

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

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

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

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

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

Date: March 29, 2017

/s/ Michael A. Narachi
Michael A. Narachi
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jason A. Keyes, certify that:

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

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

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

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

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

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;

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

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

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

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

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

Date: March 29, 2017

/s/ Jason A. Keyes
Jason A. Keyes
SVP, Chief Financial Officer

Exhibit 32.1

Certifications
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
(Subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code)

In connection with the Annual Report of Orexigen Therapeutics, Inc., a Delaware corporation (the "Company"), on Form 10-K for the period ended December 31, 2016, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael A. Narachi, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 29, 2017

/s/ Michael A. Narachi
Michael A. Narachi
President and Chief Executive Officer
(principal executive officer of the registrant)

In connection with the Report, I, Jason A. Keyes, SVP, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: March 29, 2017

/s/ Jason A. Keyes
Jason A. Keyes
SVP, Chief Financial Officer
(principal financial and accounting officer of the registrant)

The foregoing certifications are being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.