TITAN PHARMACEUTICALS INC
Form 10-K
March 16, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

x **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 001-13341

TITAN PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3171940**

(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
400 Oyster Point Blvd., Suite 505, South San Francisco, California (Address of principal executive offices)	**94080 (Zip code)**

Registrant's telephone number, including area code: (650) 244-4990

Securities registered pursuant to Section 12(b) of the Act: Common Stock, $0.001 par value

Securities registered pursuant to Section 12(g) of the Act: Common Stock, $0.001 par value

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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 the filing requirements for the past 90 days. Yes x 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). x Yes ¨ No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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. x

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 x

Non-accelerated filer ¨ Smaller Reporting Company ¨

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based on the closing price on June 30, 2016 was $113.1 million.

As of March 10, 2017, 21,198,879 shares of common stock, $0.001 par value, of the registrant were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

NONE

PART I

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this Annual Report on Form 10-K or in the documents incorporated by reference herein may contain "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934 (the "Exchange Act"). Reference is made in particular to the description of our plans and objectives for future operations, assumptions underlying such plans and objectives and other forward-looking terminology such as "may," "expects," "believes," "anticipates," "intends," "projects," or similar terms, variations of such terms or the negative of such terms. Forward-looking statements are based on management's current expectations. Actual results could differ materially from those currently anticipated due to a number of factors, including but not limited to, uncertainties relating to the commercialization of Probuphine, financing and strategic agreements and relationships; difficulties or delays in the regulatory approval process; uncertainties relating to manufacturing, sales, marketing and distribution of our drug candidates that may be successfully developed and approved for commercialization; adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product development or commercialization; dependence on third party suppliers; the uncertainty of protection for our patents and other intellectual property or trade secrets; and competition.

We expressly disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based.

References herein to "we," "us," "Titan," and "our company" refer to Titan Pharmaceuticals, Inc. unless the context otherwise requires.

Probuphine ® and ProNeura™ are trademarks of our company. This Annual Report on Form 10-K also includes trade names and trademarks of companies other than Titan.

Item 1. Business

Overview

We are a pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura™, and focus

primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit.

Probuphine®, our first product candidate based on the ProNeura platform, was approved by the United States Food and Drug Administration, or FDA, on May 26, 2016 for the maintenance treatment of opioid dependence in patients who are stable on low to moderate doses of daily sublingual buprenorphine treatment. We have licensed development and commercialization rights of Probuphine for the U.S. and Canadian markets to Braeburn Pharmaceuticals, Inc. or Braeburn, and pursuant to the license agreement as amended to date, received $15 million shortly after FDA approval and we will receive royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties based on a tiered structure. The agreement also provides for up to an additional $165 million in sales milestones and $35 million in regulatory milestones on Probuphine. Additionally, in certain circumstances, the agreement entitles us to a low single digit royalty, up to an aggregate of $50 million, on net sales by Braeburn, if any, of other future competing products in the addiction market, e.g. a monthly depot injection.

Braeburn commenced U.S. commercialization activities through a medical affairs introduction in advance of the Probuphine product launch shortly after FDA approval focusing on the following two areas that are key to a successful launch for Probuphine:

(i) training of qualified health care providers on the use of Probuphine, the procedures for insertion and removal of the implant that are part of the Risk Evaluation and Mitigation Strategies, or REMS. approved by the FDA, and the selection of eligible patients

a. Over 2,500 health care providers from all 50 states and Puerto Rico have already been certified to provide Probuphine to their patients, and Braeburn has continued to conduct additional training programs as needed.

b. Shipment of Probuphine commenced in late June 2016 and the first patients were treated soon thereafter. Some of the initial patients have already begun to receive their second course of implants.

(ii) obtaining third party payor coverage for Probuphine and the insertion/removal procedures.

a. Probuphine is now covered by more than 70 insurance plans, including coverage under Medicare and Medicaid and Veterans Administration programs.

In January 2017, Braeburn announced that the Centers for Medicare & Medicaid Services (CMS) had granted a Healthcare Common Procedure Coding System (HCPCS) code, or permanent J-code, for Probuphine, as the first six-month buprenorphine implant for the maintenance treatment of opioid addiction. The new J-code (J0570) became effective January 1, 2017 and coincided with the activation of a new Braeburn field force. Braeburn continues to work to obtain additional codes to further facilitate reimbursement of Probuphine insertion and removal procedures. HCPCS codes are used by healthcare professionals to identify services and procedures for which they bill public or private health insurance programs. The codes included in the HCPCS set are maintained by CMS and universally accepted by all payors. As with any new form of medical treatment involving a procedure, it has been necessary to train the physician office staff and supply chain staff on new processes for approval and reimbursement for Probuphine and Braeburn has been focused on these activities to minimize delays in making the product available to patients. These activities necessitated a controlled product distribution process during the latter part of 2016, prior to receipt and effective date of the J-code, to ensure that the needs of the health care providers and the patients were being addressed in a timely manner.

Braeburn has continued to devote substantial resources to launch activities, including the establishment of a field sales force and medical support staff of more than 60 to support the health care providers throughout the entire process. In January 2017, Braeburn indicated that the field sales force was in place and it was commencing a full commercial launch in the U.S. focusing on more than 80 key treatment centers across the country to establish ‘sites of excellence’ for the long-term maintenance treatment with Probuphine.

In February 2016, Braeburn announced that it had sub-licensed the Canadian rights for development and commercialization of Probuphine to Knight Therapeutics, Inc. (TSX:GUD) and, based on available company

information, the product is currently indicated as being in the regulatory review stage.

We have also made some progress in the efforts to advance potential commercialization of Probuphine outside of the U.S. and Canada. During the year we interacted with several ex-U.S. companies that expressed interest in commercializing Probuphine in Europe and elsewhere. A few companies executed confidentiality agreements and commenced technical due-diligence to fully understand the product and its regulatory status outside the U.S. Completion of any ex-U.S. partnership with one or more of the interested parties will require regulatory clarity for product approval in Europe. Consequently, in December 2016, we sought scientific advice and met with the U.K. and German regulatory agencies, and based on feedback from these meetings we submitted an application to the European Medicines Agency, or EMA, seeking eligibility for Probuphine to follow the centralized review and approval process for its Marketing Authorization Application or MAA. In early March 2017, we received confirmation from the EMA that Probuphine is eligible for a centralized review and approval process and we estimate that an MAA could be filed in the fourth quarter of 2017. We have also been granted Small Manufacturing Entity, or SME, status in Europe, which provides for some monetary benefits during the application process and commercialization. We will continue to pursue partnerships for Probuphine in Europe and elsewhere during 2017.

We believe that our ProNeura long term drug delivery platform has the potential to be used in the treatment of other chronic conditions where maintaining stable, around the clock blood levels of a medication may benefit the patient and improve medical outcomes. We have two products in early development using the ProNeura platform, an implant designed to provide long-term delivery of ropinirole, a dopamine agonist approved as a daily dosed oral formulation for the treatment of Parkinson's disease, and an implant designed to provide long-term delivery of T3, a synthetic thyroid hormone approved as a daily dosed oral formulation for the treatment of hypothyroidism. In late January 2016, we received feedback from the FDA on our product development plans for the ropinirole implant which had been submitted as part of the briefing material to the FDA in December 2015 in support of a pre-Investigational New Drug ("IND") meeting request. The required non-clinical studies with the ropinirole implant in support of an IND application were completed in the third quarter and final reports were completed by December 2016. The IND was submitted to the FDA in January 2017, and in late February 2017, following its initial review of the IND, we received comments from the FDA requesting additional information. Specifically, in a telephone communication with Titan, the FDA indicated that it will require final release test data on the ropinirole implant and the applicator used to insert the implant before clearing the IND. Additionally, the FDA is requesting that we identify a participating Principal Investigator for the study. We expect to have final test data on the implant and the applicator within the next several weeks, and are in the process of qualifying the participating clinical sites. We expect to receive the FDA's written comments in late March. We are working quickly to provide the FDA with the additional information required, and are hopeful that we will be able to commence the clinical study toward the end of the second quarter.

Development of the T3 implant product continued during 2016 with non-clinical studies conducted to help optimize the formulation. We identified refinements to the formulation that will be necessary; however, due to shortage of the active pharmaceutical ingredient, or API, further investigation had to be temporarily suspended during the fourth quarter of 2016. In early 2017, we obtained the requisite supply of the API and have commenced work towards the optimization of the T3 implant. Once this work is completed, we will be in a position to request a pre-IND meeting with the FDA by mid-2017, resources permitting.

Our goal is to further expand our product pipeline, and we are currently evaluating other drugs and disease settings for opportunities to use the ProNeura platform in potential treatment applications where conventional treatment is limited by variability in blood drug levels and poor patient compliance.

We operate in only one business segment, the development of pharmaceutical products. We make available free of charge through our website, www.titanpharm.com, our periodic reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

ProNeura Continuous Drug Delivery Platform

Our ProNeura continuous drug delivery system consists of a small, solid rod made from a mixture of ethylene-vinyl acetate, or EVA, and a drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the inside part of the upper arm in a simple office procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released continuously through the process of dissolution. This results in a steady rate of release generally similar to intravenous administration. We believe that such long-term, almost linear release characteristics are desirable by avoiding peak and trough level dosing that may pose problems for many disease settings.

The ProNeura platform was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery, and, depending on the characteristics of the compound to be delivered, potentially can provide treatment on an outpatient basis over extended periods of up to 12 months. We believe that the benefits of this technology have been demonstrated by the clinical results to date with Probuphine, and the development and regulatory process have been affirmed by the FDA approval of this product in May 2016. We have commenced two product development programs, the first a ropinirole implant for the treatment of Parkinson’s disease and the second a T3 implant for the treatment of hypothyroidism. We have also been evaluating opportunities to develop this drug delivery platform for other potential treatment applications in which conventional treatment is limited by variability in blood drug levels and poor patient compliance and where existing therapeutic compounds have sufficient potency to be effective at low doses.

Our Product Pipeline

Probuphine

We developed Probuphine for the maintenance treatment of opioid dependence. Upon subdermal insertion in a patient, Probuphine is designed to release medication continuously and maintain a stable, around the clock blood level of the drug buprenorphine, an approved agent for the treatment of opioid dependence. Probuphine is expected to provide six months of medication following a single treatment and was approved by the FDA in May 2016 for the maintenance treatment of opioid dependence in clinically stable patients who are receiving treatment with an oral formulation of buprenorphine at a dose of 8mg/day or less.

We have licensed development and commercialization rights for the U.S. and Canada to Braeburn and pursuant to the license agreement, as amended to date, we received a $15 million milestone payment upon FDA approval of the Probuphine NDA and are entitled to receive royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. The agreement also provides for up to $165 million in sales milestones and up to $35 million in regulatory milestones for additional indications, and also entitles us to low single digit royalties on sales by Braeburn, if any, of other future competing products in the addiction market, such as the one month depot injection of buprenorphine that Braeburn licensed from Camurus AB for the U.S. and Canadian markets.

We have also made some progress in the efforts to advance potential commercialization of Probuphine outside of the U.S. and Canada. During the year we interacted with several ex-U.S. companies that expressed interest in commercializing Probuphine in Europe and elsewhere. A few companies executed confidentiality agreements and commenced technical due-diligence to fully understand the product and its regulatory status outside the U.S. Completion of any ex-U.S. partnership with one or more of the interested parties will require regulatory clarity for product approval in Europe. Consequently, in December 2016, we sought scientific advice and met with the U.K. regulatory agency, MHRA, and the German regulatory agency, BfArM, and based on feedback from these meetings we submitted an application to the EMA seeking eligibility for Probuphine to follow the centralized review and approval process for its MAA. In early March 2017, we received confirmation from the EMA that Probuphine is eligible for a centralized review and approval process, and we estimate that an MAA could be filed in the fourth quarter of 2017. We have also been granted Small Manufacturing Entity, or SME, status in Europe, which provides for some monetary benefits during the application process and commercialization. We will continue to pursue partnerships for Probuphine in Europe and elsewhere during 2017.

The goal of any therapy for an addictive disorder is to reduce the use of the addictive substance over time and to engage the patient in treatment long enough for therapeutic gains to be consolidated. In a clinical study, the effectiveness of a treatment for opioid dependence is primarily evaluated by testing a patient’s urine samples for the presence of illicit opioids over the treatment period along with self-reports by the patient of illicit opioid use. The FDA approval of Probuphine was based on the data from six Phase 3 clinical studies as listed below:

- One six month, double blind, double dummy study evaluating Probuphine in comparison to an orally dosed buprenorphine formulation in clinically stable patients receiving a daily dose of 8mg/day or less. The objective of the study was to show non-inferiority between the two treatment groups and the primary efficacy analysis was a non-inferiority comparison of the proportions of treatment responders in each group. A responder was defined as having at least four out of six months free of illicit opioids based on urine testing and subject self-report. The analyses conducted according to the pre-planned Statistical Analysis Plan indicated that the primary endpoint of non-inferiority and all secondary endpoints were met. The overall safety and tolerability profiles for each treatment group were also comparable. The implantation procedures were also generally well tolerated and comparable to observations from earlier studies with Probuphine.

- Two six-month, double-blind, placebo-controlled safety and efficacy trials; one of which included an open label, active control (Suboxone). In both studies, Probuphine demonstrated superiority to placebo implants, and in the

second study, established non-inferiority in comparison to Suboxone; In both placebo-controlled Phase 3 studies of Probuphine, the patients were new to buprenorphine treatment (no treatment during at least the prior 90 days) and inducted at a dose of 12-16mg/day of Suboxone over a short period. Every participant was required to provide urine samples three times a week and any missed sample was considered a positive result (i.e. urine testing positive for illicit opioid). In these studies, the primary effectiveness of the treatment with Probuphine (i.e. the primary endpoint) was established by comparing the negative urine results between the Probuphine and placebo arms using a statistical technique, specifically 'the cumulative distribution function of negative urines', which basically performs a comparative analysis on the relative proportions of negative urines between treatment groups over the time period of treatment. The patients in the Probuphine arm showed statistically significant difference in the negative urines as compared to the placebo arm in both studies demonstrating that the treatment with Probuphine was successful in reducing their usage of illicit opioids as compared to the treatment with placebo. These favorable results for Probuphine were also confirmed by a significant difference over the placebo arm in other secondary measures such as retention in treatment, withdrawal symptoms and craving for opioids, all of which are monitored by clinicians to see if a treatment is providing benefit to the patients. Results for the first double-blind, placebo-controlled safety and efficacy study have been published in the Journal of the American Medical Association (JAMA, October 2010) and results of the follow-on randomized three arm study with Probuphine, placebo and sublingual treatment have been published in the journal Addiction (Addiction, September 2013).

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- Two six-month, open-label re-treatment safety trials. Patients who completed the controlled studies were eligible for enrollment in six-month re-treatment studies, which provided data on up to one full year of treatment.

- A pharmacokinetic (relative bioavailability) safety study. The pharmacokinetic safety study has provided important data on the level of buprenorphine in the blood during the treatment period and gives a good profile of the safety of Probuphine.

Data from some or all of these studies has been presented at several scientific meetings, including the International Society of Addiction Medicine Annual Meeting, the American Society of Addiction Medicine Annual Meeting, the American College of Neuropharmacology Annual Meeting and the Annual Scientific Meeting of The College on Problems of Drug Dependence.

ProNeura-Ropinirole for Parkinson's Disease

Parkinson's disease, or PD, is a disease of the central nervous system characterized by the loss of dopaminergic neurons, which leads to increasing activity in the brain region that influences movement and motor function. According to the Parkinson's Disease Foundation, more than one million people in the U.S. suffer from PD, and this number is projected to double by 2030. Early stage PD patients are treated with daily doses of drugs designed to replace dopamine in the brain. However, these therapeutics typically lose their benefits after several years of chronic treatment, and trigger serious side effect. About one-third of the treated patients develop motor response fluctuations and/or drug-induced dyskinesias within only 3 to 5 years of treatment, and these symptoms are present in almost all patients after 10 to 12 years. Clinical and nonclinical research indicates that these motor side effects arise from the pulsatile dopaminergic stimulation resulting from current oral treatment. Continuous dopaminergic stimulation (CDS) by subcutaneous infusion has been shown to palliate these motor complications, as well as to delay or prevent the onset of dyskinesias. We believe our ProNeura drug delivery technology provides a clinically-validated platform to safely and conveniently provide CDS for several months from a single treatment. Further, the subdermal placement of these implants eliminates many of the device-related complications associated with existing treatment modalities.

We have previously conducted a non-clinical study in an MPTP Parkinsonian primate model and demonstrated that a sustained non-fluctuating plasma level of ropinirole could be delivered safely for several months following implantation and could control PD symptoms without triggering dyskenesias in severely lesioned primates. This data was presented in a poster at the 19th International Congress of Parkinson's Disease and Movement Disorders in San Diego in June 2015. In December 2015, we submitted briefing material to the FDA on the development plans for the ropinirole implant in support of a pre- IND meeting request, and in late January 2016 we received feedback from the FDA on our product development plans. During 2016, we completed the following steps to advance the ropinirole implant program:

- Optimized the implant formulation of ropinirole and developed a cGMP manufacturing process and produced the ropinirole implants for the non-clinical toxicology and other studies

- Implemented the non-clinical study plan to support an IND application and successfully completed all the studies and study reports by December

- Designed a proof of concept pharmacokinetic clinical study

- Prepared all sections of the IND for submission to the FDA

The IND was submitted to the FDA in January 2017, and in late February 2017, in a telephone communication with Titan, the FDA indicated that it will require final release test data on the ropinirole implant and the applicator used to insert the implant before clearing the IND. Additionally, the FDA is requesting that we identify a participating Principal Investigator for the study. We expect to receive final written comments on the IND by late March 2017.We expect to have final test data on the implant and the applicator within the next several weeks, and are in the process of qualifying the participating clinical sites. We are working quickly to provide the FDA with the additional information required, and are hopeful that we will be able to commence the clinical study toward the end of the second quarter of 2017.

ProNeura-Triiodothyronine (T3) for hypothyroidism

Hypothyroidism is a disorder that occurs when the thyroid gland does not make enough thyroid hormone to meet the body's needs.

Thyroid hormone regulates metabolism and affects nearly every organ in the body. It is a disease affecting about 15 million Americans, mostly women. Symptoms include chronic fatigue, weight gain and obesity, dry skin, impaired mental activity, and depression. The majority of patients are diagnosed with standard blood tests and receive treatment typically consisting of synthetic prohormone thyroxine (T4) given as a once-daily oral medication (Synthroid®, Levoxyl®, generics), which in turn is converted in the body to the active T3. Based upon symptoms and blood tests, it is estimated that as many as 15 percent of hypothyroid patients are not adequately treated with this therapy, resulting in a persistent deficiency in the primary active form of thyroid hormone, T3, and physicians typically add an oral T3 regimen to the treatment of these patients.

Once-daily synthetic T3 (Cytomel®) is an effective medication for hypothyroidism but can cause potential side effects such as headache, nervousness, irritability, sweating, and cardiac arrhythmias, which are caused by the peak-and-trough blood-level fluctuations of T3 associated with standard oral delivery. Continuous delivery of T3 by the oral or parenteral route is highly desirable, but has been difficult to achieve because of the unique solubility characteristics of the compound. Thus, an implantable T3 product utilizing the ProNeura platform that more closely replicates normal thyroid physiology and avoids the unwanted side effects associated with the current pulsatile-release oral formulation could benefit patients and serve a great, unmet medical need.

During 2016 we completed in-vivo non-clinical studies in small and large animal models evaluating implant formulations for drug release characteristics and the effectiveness of the implant. We identified further refinements that will be necessary; however, shortage of API led to a temporary suspension of activities during the fourth quarter.

We obtained adequate supply of the API in early 2017 and have commenced work towards the optimization of the T3 implant. Once this work is completed we will be in a position to request a pre-IND meeting with the FDA by mid-2017, and, resources permitting, continue developing the product with completion of the non-clinical studies in support of the IND submission in the first half of 2018.

Fanapt® (iloperidone)

Fanapt (iloperidone) is an atypical antipsychotic approved in 2009 by the FDA for the treatment of schizophrenia and in 2014 was marketed by Novartis in the U.S. On December 31, 2014, Vanda Pharmaceuticals, Inc. (“Vanda”) acquired the rights to Fanapt for the U.S. and Canada from Novartis and is now marketing Fanapt in the U.S. Vanda already owned the development and commercialization rights to the oral and depot formulations of this product for the rest of the world, and by acquiring the U.S. and Canadian rights from Novartis, effectively replaced Novartis in the sublicense agreement with Titan. We transferred the right to royalty revenues related to Fanapt to a third party in exchange for cash and debt considerations, the proceeds of which we used to advance the development of Probuphine and for general corporate purposes. The U.S. patent expired in November 2016, and patent coverage on the compound has also expired in the significant markets outside of the U.S. We do not incur any ongoing expenses nor are we entitled to any royalties associated with this product.

License Agreements

In December 2012, we entered into a license agreement (the "Agreement") with Braeburn pursuant to which we granted Braeburn an exclusive right and license to commercialize Probuphine in the United States of America and its territories, including Puerto Rico, and Canada (the "Territory"). Under the Agreement, Braeburn made a non-refundable up-front license fee payment of $15.75 million and agreed to pay us tiered royalties on a percentage of net sales of Probuphine ranging from the mid-teens to the low twenties. Additionally, the Agreement provided for us to receive $45 million upon FDA approval of the NDA for Probuphine and at such time ownership of the NDA will transfer to Braeburn, as well as up to an additional $130 million upon the achievement of specified sales milestones and up to $35 million in regulatory milestones. We will retain all of the rights to Probuphine outside the Territory. Unless earlier terminated, the Agreement will expire on the later of (i) the 15th anniversary of the date of product launch in the Territory or (ii) the expiration of the last to expire patent in the Territory covered by the Agreement (the "Term"). Either party may terminate the Agreement prior to the expiration of the Term in the event of a material breach by the other party that remains uncured or in the event of the other party's bankruptcy. We may terminate the Agreement if, for reasons other than force majeure, regulatory, safety, manufacturing or product quality issues, Braeburn discontinues commercial sale of the product and fails to resume sales within 30 days following notice or in the event Braeburn or any of its affiliates or sublicensees commences any legal proceeding seeking to challenge or dispute the validity or ownership of the licensed patents. Braeburn may terminate the Agreement in the event that Braeburn, notwithstanding good faith efforts to do so, is unable to enter into an agreement for the supply of EVA or if such a supply agreement is terminated by Braeburn due to a material breach by the supplier or the supplier fails to provide EVA to Braeburn for a period of at least three months. Braeburn may also terminate the Agreement (i) on a country by country basis upon six months' notice following the occurrence of any "significant competition" in such country, as such term is defined in the Agreement; (ii) immediately upon notice if Braeburn determines in good faith that it is inadvisable to continue commercialization as a result of any actual or perceived safety issues.

In May 2013, we entered into an amendment to the Agreement (the "Amendment") primarily to modify certain of the termination provisions of the Agreement and to provide for us to share in legal and consulting expenses in excess of a specified amount prior to approval of the NDA.

In July 2013, we entered into a second amendment to the Agreement (the "Second Amendment") primarily to establish and provide the parameters for a committee comprised of representatives of Titan and Braeburn responsible for and with the authority to make all decisions regarding the development and implementation of a strategic plan to seek FDA approval of Probuphine®.

In November 2013, we entered into a stock purchase agreement pursuant to which Braeburn made a $5 million equity investment in our company and a third amendment to the Agreement (the "Third Amendment") primarily to modify the amount and timing of the approval and sales milestone payments payable under the Agreement. The Third Amendment, entitled us to a $15 million payment upon FDA approval of the NDA and to receive royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. The agreement also provides for up

to $165 million in sales milestones and $35 in regulatory milestones. In addition, we are entitled to receive royalties, up to an aggregate of $50 million, on a percentage of sales in the low single digit by Braeburn, if any, of other continuous delivery treatments for opioid dependence as defined in the Third Amendment and can elect to receive low single digit royalties on sales by Braeburn, if any, of other products in the addiction market in exchange for a similar reduction in our royalties on Probuphine.

In February 2016, Braeburn informed us that it has entered in a sublicense agreement with Knight Therapeutics, Inc. ("Knight"), a specialty pharmaceutical company, whereby Braeburn has granted to Knight the rights to commercialize Probuphine in Canada.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our product candidates, formulations, processes, methods and any other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, patent protection may not afford us with complete protection against competitors who seek to circumvent our patents.

We also depend upon the skills, knowledge, experience and know-how of our management and research and development personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how, which may not be patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

In June 2010, the United States Patent and Trademark Office ("USPTO") issued a patent covering methods of using Probuphine for the treatment of opiate addiction. Titan is the owner of this patent which claims a method for treating opiate addiction with a subcutaneously implanted device comprising buprenorphine and EVA, a biocompatible copolymer that releases buprenorphine continuously for extended periods of time. This patent will expire in April 2024. A U.S. continuation application is currently pending which includes claims related to Probuphine for the treatment of pain. Related patents covering use of Probuphine with the continuous delivery technology for the treatment of opiate addiction have also issued in Australia, Canada, India, Japan, Mexico and New Zealand. Further Probuphine applications are pending in Europe and Hong Kong. Patents covering certain dopamine agonist implants, including ropinirole implant, have already been issued or allowed in the United States, Europe, Japan, China, Australia, Canada, South Korea, Mexico, New Zealand, South Africa, Israel and Hong Kong, while prosecution of the patent application continues in India.

We have filed additional patent applications for a heterogeneous implant designed with some unique properties that may provide benefits to the structural integrity of the implants and potentially enhance drug delivery.

Future court decisions or changes in patent law might materially affect the patents or patent applications, including, but not limited to, their expiration dates.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in the development and commercialization of therapeutic agents designed for the treatment of the same diseases and disorders that we target. Many of our competitors have substantially greater financial and other resources, larger research and development staff and more experience in the regulatory approval process. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies.

With respect to Probuphine, there are no six-month implant formulations of buprenorphine on the market or in development, and the primary competition it will face will come from Indivior, PLC (formerly the pharmaceutical business of Reckitt Benckiser Group, PLC), which markets globally a sublingual buprenorphine product (tablet and film formulations) for the treatment of opioid dependence that currently holds the dominant market share of global sales. Probuphine may also face competition from two additional proprietary daily dose formulations that have been approved by the FDA in the past two years; the first is a sublingual tablet called Zubsolv marketed by Orexo and the second is a buccal patch called Bunavail marketed by Bio Delivery Sciences International. Also, during 2013 and 2014, several generic sublingual tablet formulations of buprenorphine similar to Suboxone and Subutex were approved by the FDA that are expected to compete in the opioid addiction treatment market. Other forms of buprenorphine are also in development by other companies, including intramuscular and intradermal one week and one month depot injections which, if approved, will also compete with our product. Braeburn has licensed rights to certain of such potential products and Titan is entitled to a low single digit royalty on net sales of competing products, if commercialized. The one-month depot formulations of buprenorphine are in late-stage clinical development for the treatment of opioid dependence, and are likely to be approved in 2018. Alkermes, Inc. also markets Vivitrol®, a one-month depot injection of naltrexone as a maintenance treatment for opioid dependent patients who have successfully achieved abstinence.

If successfully developed and approved for commercialization, our ProNeura ropinirole product for PD will face competition primarily from numerous daily dose dopamine agonist treatments currently in use that provide symptom relief from disease related immobility, as well as the complications associated with long-term levodopa therapy (e.g. dyskinesias, tolerance). Approved products in the U.S. in addition to Requip XL®, which is marketed by GlaxoSmithKline, include Apokyn® (US WorldMeds LLC), Parlodel® (Novartis Pharmaceuticals Inc.), Mirapex ER® (Boehringer Ingelheim Pharmaceuticals Inc.) and Neupro® (UCB Inc.). There is a strong need for products providing continuous, stable, long term delivery of dopamine and dopamine agonists and the FDA recently approved a product called Duodopa®, the first and only treatment delivered via catheters directly into the duodenum that is capable of providing 16 continuous hours of carbidopa and levodopa for treatment of motor fluctuations in advanced PD. Duodopa is marketed globally by Abbvie. Also, we are aware of products in mid-stage clinical development that are capable of short to medium-term subcutaneous and subdermal delivery of levodopa/carbidopa using pumps.

If successfully developed and approved for commercialization, our ProNeura T3 product for hypothyroidism will face competition primarily from the daily dose oral triiodothyronine (T3) liothyronine sodium tablet product; which is marketed by King Pharmaceuticals (Pfizer) as Cytomel®. Generic liothyronine sodium tablets are also available from Coastal Pharmaceuticals, Mylan, and Sigma Pharmaceuticals. We are also aware of products in nonclinical development that are being formulated for short to medium-term delivery of T3.

Manufacturing

The manufacturing of Probuphine has primarily been conducted at DPT Laboratories, Inc., or DPT, and we have expanded the manufacturing facility at this contract manufacturer to establish commercial scale capability to support

the market launch of Probuphine and ongoing demand. We have entered into a commercial manufacturing agreement with DPT that governs the terms of the production and supply of Probuphine. During 2016, we have continued to supply and support Braeburn while an agreement between Braeburn and DPT for the supply of Probuphine is being finalized. We will continue to manufacture Probuphine as needed for ex-US markets.

To date, we have obtained the supply of bupenorphine from Teva Pharmaceuticals, Inc., or Teva, under an arrangement similar to the one with DPT. We have entered into a commercial supply agreement with Teva; however, we anticipate that as the product is launched commercially, Braeburn will establish an agreement with Teva for the supply of buprenorphine and our requirements of buprenorphine will be only for the ex-US markets.

Sales and Marketing

We do not currently have and do not intend to establish any sales and marketing capability. As our licensee, Braeburn will have sole responsibility for sales and marketing of Probuphine within the United States and, through its sublicensee, Canada. We intend to seek comparable partnering arrangements for Probuphine outside the Territory, and our current plans are to make similar arrangements for the commercialization of any additional products we may successfully develop based on our ProNeura technology.

Government Regulation

Government authorities in the United States at the federal, state and local level and in other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug products. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific to each regulatory authority, submitted for review and approved by the regulatory authority.

U.S. drug development

In the United States, the FDA regulates drugs and devices under the Food, Drug and Cosmetics Act, or FDCA, and its implementing regulations. Drugs and devices are also subject to other federal, state and local statutes and regulations. Products composed of both a drug product and device product are combination products. If marketed individually, each component would be subject to different regulatory pathways and reviewed by different centers within the FDA. A combination product, however, is assigned to a center that will have primary jurisdiction over its regulation based on a determination of the combination product's primary mode of action, which is the single mode of action that provides the most important therapeutic action. In the case of some of our product candidates, we expect the primary mode of action to be attributable to the drug component of the product, which means that the FDA's Center for Drug Evaluation and Research would have primary jurisdiction over the premarket development, review and approval. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product seizures, total or partial suspension of production or distribution injunctions, fines, refusals of government contracts, restitution, disgorgement, or civil or criminal penalties. Additionally, a manufacturer may need to recall a product from the market. Any agency or judicial enforcement action could have a material adverse effect on us.

Our product candidates must be approved by the FDA through the New Drug Application, or NDA, process before they may be legally marketed in the United States. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- Completion of extensive nonclinical laboratory tests, animal studies and formulation studies in accordance with applicable regulations, including the FDA's Good Laboratory Practice, or GLP, regulations;
- Submission to the FDA of an IND application, which must become effective before human clinical trials may begin;
- Approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before each trial may be initiated;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, referred to as good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug for each proposed indication;
- Submission to the FDA of an NDA for a new drug;

- A determination by the FDA within 60 days of its receipt of an NDA to file the NDA for review;

- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;

- Potential FDA audit of the nonclinical study and/or clinical trial sites that generated the data in support of the NDA; and

- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug in the United States.

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

The data required to support an NDA is generated in two distinct development stages: nonclinical and clinical. For new chemical entities, the nonclinical development stage generally involves synthesizing the active component, developing the formulation and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which support subsequent clinical testing. These nonclinical tests include laboratory evaluation of product chemistry, formulation, stability and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations, including GLPs. The sponsor must submit the results of the nonclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans. Some nonclinical testing may continue even after the IND is submitted, but an IND must become effective before human clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for human trials. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials, including concerns that human research subjects will be exposed to unreasonable health risks, and places the IND on clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that could cause the trial to be suspended or terminated.

The clinical stage of development involves the administration of the drug candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completion. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

A sponsor who wishes to conduct a clinical trial outside the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. If a foreign clinical trial is not conducted under an IND, the sponsor may submit data from the clinical trial to the FDA in support of an NDA so long as the clinical trial is

conducted in compliance with GCP and FDA is able to validate the data through an onsite inspection if the agency deems it necessary.

Clinical trials

Clinical trials are generally conducted in three sequential phases that may overlap, known as Phase 1, Phase 2 and Phase 3 clinical trials.

- Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacologic action, side effect tolerability and safety of the drug.

- Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits and provide a preliminary evaluation of efficacy. At the same time, safety and further pharmacokinetic and pharmacodynamic information is collected, as well as identification of possible adverse effects and safety risks.

- Phase 3 clinical trials generally involve large numbers of patients at multiple sites (from several hundred to several thousand subjects) and are designed to provide the data necessary to demonstrate the effectiveness of the product for its intended use, its safety in use and to establish the overall benefit/risk relationship of the product and provide an adequate basis for physician labeling. Phase 3 clinical trials may include comparisons with placebo and/or comparator treatments.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA. Written IND safety reports must be submitted to the FDA and the investigators within 15 calendar days for serious and unexpected suspected adverse events, finding from other studies or animal or in vitro testing that suggests a significant risk for human subjects, and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. Additionally, a sponsor must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within 7 calendar days. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the trial.

Pursuant to the Cures Act, the manufacturer of an investigational drug for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational drug. This requirement applies on the later of 60 calendar days after the date of enactment of the Cures Act or the first initiation of a Phase 2 or Phase 3 trial of the investigational drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA review process

The results of the nonclinical studies and clinical trials, together with other detailed information, including extensive manufacturing information and information on the composition of the drug and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. FDA approval of an NDA must be obtained before a drug may be offered for sale in the United States.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy 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 product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

The FDA reviews all NDAs submitted before it accepts them for filing and may request additional information rather than accepting an NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under Prescription Drug User Fee Act, or PDUFA, for drugs that do not contain a new chemical entity the FDA has 10 months from the receipt date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the receipt date for a priority NDA. For drugs containing a new chemical entity, these 10 and six month review timeframes are from the filing date of an NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

After the NDA submission is accepted for filing, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with cGMP to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. In addition, before approving an NDA, the FDA may also audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

After the FDA evaluates an NDA, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter usually describes all of the specific deficiencies in the NDA identified by the FDA. The Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may resubmit the NDA addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing. Even if such data and information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data.

There is no assurance that the FDA will ultimately approve a drug product for marketing in the United States and we may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain

contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling, development of adequate controls and specifications, or a commitment to conduct post-marketing testing or clinical trials and surveillance to monitor the effects of approved products. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and efficacy and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. The FDA also may place other conditions on approvals including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. A REMS could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing. As a condition to the FDA's approval of Probuphine, Braeburn was required to put the Probuphine REMS in place.

505(b)(2) Approval process

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway to FDA approval for new or improved formulations or new uses of previously approved drug products. Specifically, Section 505(b)(2) was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments, and permits the filing of an NDA where at least one or more of the investigations relied upon by the applicant for approval were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. The applicant may rely upon the FDA's prior findings of safety and effectiveness for a previously approved product or on published scientific literature, in support of its application. The FDA may also require 505(b)(2) applicants to perform additional trials to support the changes from the previously approved drug and to further demonstrate the new drug's safety and effectiveness. The FDA may then approve the new product candidate for all or some of the labeled indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

Expedited development and review programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs that meet certain criteria. Specifically, new drugs are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. Any product submitted to the FDA for marketing, including under the Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or offers a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. Additionally, a drug may be eligible for designation as a breakthrough therapy if the drug is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinical development. Fast Track designation, priority review, and breakthrough designation do not change the standards for approval but may expedite the development or approval process.

Pediatric trials

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was signed into law on July 9, 2012, amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, that includes within 60 days of an end-of-Phase 2

meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information.

Post-marketing requirements

Following approval of a new product, a pharmaceutical company and the approved product are subject to continuing regulation by the FDA, including, among other things, monitoring and recordkeeping activities, reporting to the FDA of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements and complying with promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry-sponsored scientific and educational activities and requirements for promotional activities involving the internet. Any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or the PDMA, a part of the FDCA.

In the United States, once a product is approved, its manufacture is subject to comprehensive and continuing regulation by the FDA. The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMP. We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our products in accordance with cGMP regulations. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development. Changes in statutes, regulations, or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Orange book listing

Section 505 of the FDCA describes three types of marketing applications that may be submitted to the FDA to request marketing authorization for a new drug. A Section 505(b)(1) NDA is an application that contains full reports of investigations of safety and efficacy. A Section 505(b)(2) NDA is an application in which the applicant, in part, relies on investigations that were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. Section 505(j) establishes an abbreviated approval process for a generic version of approved drug products through the submission of an Abbreviated New Drug Application, or ANDA. An ANDA provides for marketing of a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use, among other things, to a previously approved product. Limited changes must be preapproved by the FDA via a suitability petition. ANDAs are termed "abbreviated" because they are generally not required to include nonclinical and clinical data to establish safety and efficacy. Instead, generic applicants must scientifically demonstrate that their product is bioequivalent to, or performs in the same manner as, the innovator drug through in vitro, in vivo, or other testing. The generic version must deliver the same amount of active ingredients into a subject's bloodstream in the same amount of time as the innovator drug and can often be substituted by pharmacists under prescriptions written for the reference listed drug.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents having claims that cover the applicant's product and method of use. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the Orange Book. These products may be cited by potential competitors in support of approval of an ANDA or 505(b)(2) NDA.

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make patent certifications to the FDA that (1) no patent information on the drug or method of use that is the subject of the application has been submitted to the FDA; (2) the patent has expired; (3) the date on which the patent has expired and approval will not be sought until after the patent expiration; or (4) the patent is invalid or will not be infringed upon by the manufacture, use, or sale of the drug product for which the application is submitted. The last certification is known as a paragraph IV certification. Generally, the ANDA or 505(b)(2) NDA cannot be approved until all listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a paragraph IV certification or if the applicant is not seeking approval of a patented method of use. If the applicant does not challenge the listed patents or does not indicate that it is not seeking approval of a patented method of use, the ANDA or 505(b)(2) NDA application will not be approved until all of the listed patents claiming the referenced product have 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 during which the FDA cannot grant effective approval of an ANDA based on the 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 applicant.

U.S. marketing exclusivity

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example for new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving abbreviated new drug applications, or ANDAs, for drugs containing the active agent for the original indication or condition of use. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. Three-year and five-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Drug enforcement administration regulation

Because Probuphine is subject to the Controlled Substances Act, or CSA, Braeburn must comply with various requirements set forth by that legislation, as amended, its implementing regulations and as enforced by the DEA. The CSA imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls, prescription and order form requirements and restrictions on prescription refills for certain kinds of pharmaceutical products. A principal factor for determining the particular requirements of the CSA applicable to a product, if any, is its actual or potential abuse profile. A product may be listed as a Schedule I, II, III, IV or V controlled substance, with Schedule I presenting the highest perceived

risk of abuse and Schedule V presenting the least. The active ingredient in our product, buprenorphine, is a Schedule III controlled substance and under various restrictions, including, but not limited to, mandatory written prescriptions and a labeling statement informing patients that selling or giving away Probuphine is against the law. In addition, under the Drug Addiction Treatment Act, which amended the CSA, use of Probuphine in the treatment of opioid addiction is limited to physicians who meet certain qualifying requirements, and who have notified the Secretary of Health and Human Services, or HHS, of their intent to prescribe or dispense the product for the treatment of opioid addiction and have been assigned a unique identification number that must be included on every prescription. The HHS regulates the number of patients that physicians can treat with buprenorphine for opioid addiction and recently increased this number from a maximum of 100 patients to 275 patients for qualified physicians.

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

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA. Failure to maintain compliance with applicable DEA requirements can result in administrative, civil or criminal enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

Other regulatory matters

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services including the Office of the Inspector General, the United States Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local regulatory authorities. In the United States, sales, marketing and scientific/educational programs must also comply with state and federal fraud and abuse laws. These laws include the federal Anti-Kickback Statute, which makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it. Moreover, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Also, many states have similar fraud and abuse statutes or regulations that may be broader in scope and may apply regardless of payor, in addition to items and services reimbursed under Medicaid and other state programs. Additionally, to the extent that any of our product candidates, if approved, are sold in a foreign country, we may be subject to similar foreign laws.

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

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results. 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.

European Union drug development

In the European Union, our future products may also be subject to extensive regulatory requirements. As in the United States, medicinal products can only be marketed if a marketing authorization from the competent regulatory agencies has been obtained.

Similar to the United States, the various phases of nonclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the EU, the EU Member States have transposed and applied the provisions of the Directive differently. This has led to significant variations in the member state regimes. Under the current regime, before a clinical trial can be initiated it must be approved in each of the EU countries where the trial is to be conducted by two distinct bodies: the National Competent Authority, or NCA, and one or more Ethics Committees, or ECs. Under the current regime all suspected unexpected serious adverse reactions to the investigated drug that occur during the clinical trial have to be reported to the NCA and ECs of the Member State where they occurred.

The EU clinical trials legislation is currently undergoing a revision process mainly aimed at harmonizing and streamlining the clinical trials authorization process, simplifying adverse event reporting procedures, improving the supervision of clinical trials and increasing their transparency.

European Union drug review and approval

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

The Community MA is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the European Medicines Agency, or EMA, and 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 EU.

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. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another 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 Decentralized Procedure an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the other Member States (referred to as the Member States Concerned) for their approval. If the Member States Concerned raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the Member States Concerned).

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.

Rest of the world regulation

For other countries outside of the European Union and the United States, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases the clinical trials must be conducted in accordance with GCP requirements and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Reimbursement

Sales of Probuphine and any other product candidates we may successfully will depend, in part, on the extent to which such products are covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any products will be made on a payor by payor basis. As a result, the coverage determination process is often a time-consuming and costly process that will require our licensees to provide scientific and clinical support for the use of our product to each payor separately, with no assurance that coverage and adequate reimbursement will be

obtained.

Third-party payors are increasingly reducing reimbursements for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our ability to generate royalty revenue. If third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow our products to be sold on a profitable basis. Decreases in third-party reimbursement for our products or a decision by a third-party payor to not cover our products could reduce physician usage of the products and have a material adverse effect on our results of operations and financial condition.

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

Reimbursement for injectable and implantable medications that are administered by a healthcare provider generally require a J-Code for the drug itself. Braeburn submitted its application for a permanent J-Code for Probuphine in June 2016. On November 1, 2016, the U.S. Centers for Medicare & Medicaid Services, or CMS, released a final rule that assigned a specific J-Code for Probuphine beginning January 1, 2017. Separate reimbursement codes are required for the Probuphine insertion and removal procedures. Braeburn’s initial request for interim "G" fee codes to cover reimbursement for the insertion and removal procedures was declined. While there are codes that can be used in the interim, Braeburn is addressing several strategies to address the reimbursement for the multiple implant insertion and removal pertaining to Probuphine. The timeline for the creation of the various procedural reimbursement pathways will vary based on the required governmental process or market needs for accurately tracking and reimbursing for the delivery of Probuphine and related procedural services.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower.

Affordable Care Act and other reform initiatives

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

For example, in March 2010, the ACA, was enacted in the United States. The ACA includes measures that have significantly changed, and are expected to continue to significantly change, the way healthcare is financed by both governmental and private insurers. Many of the details regarding the implementation of the ACA are yet to be determined, and at this time, it remains unclear the full effect that the ACA would have on our business. There have been judicial and Congressional challenges to the ACA, and we expect such challenges and amendments to continue in the future. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted and there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

Employees

As of December 31, 2016, we had 14 full-time employees.

Item 1A. Risk Factors

We are dependent on the successful commercialization of Probuphine to fund our research and development programs and achieve value for our shareholders.

At December 31, 2016, we had cash and cash equivalents of approximately $14.0 million, which we believe is sufficient to fund our planned operations through the first quarter of 2018. Our ability to fund our research and development programs and achieve value for our shareholders depends in large part on the commercial success of Probuphine. Since the approval of Probuphine by the FDA in May 2016, Braeburn has been engaged in implant training, physician outreach, payment and reimbursement discussions and sales and marketing efforts associated with the launch of this new product. To date, however, the ramp up of sales of Probuphine has been slower than was generally anticipated and there can be no assurance that Braeburn will be successful in its commercialization efforts or that Probuphine will ever achieve substantial sales revenues. If we are unable to generate ample royalty revenue from Probuphine, we will be unable to fund our research and development programs without additional financing, which may not be available on acceptable terms, and our business will be materially harmed.

We are solely reliant on the efforts of Braeburn to commercialize Probuphine in the U.S.

Under an exclusive license covering the United States and Canada, Braeburn will be solely responsible for the marketing, manufacture and commercialization of Probuphine in the Territory and, accordingly, the timing and amount of any royalty revenues or sales milestones we receive from this product will be wholly dependent upon Braeburn's ability to successfully launch and commercialize this product. Braeburn is an early stage company and has not previously commercialized any product. Our ability to generate revenues in the Territory from any additional indications for Probuphine, including chronic pain, depends on Braeburn's ability to successfully develop, obtain regulatory approvals for and commercialize the product for additional indications. We do not have control over the amount and timing of resources that Braeburn will dedicate to these efforts. We will be similarly dependent on the development, regulatory and marketing efforts of third parties with respect to revenues, if any, from sales of Probuphine outside the Territory. To date, we have not entered into any collaborative arrangements or granted any rights with respect to Probuphine in the rest of the world.

We will also depend on our ability to develop new collaborative relationships with third parties and potentially to acquire or in-license additional products and technologies for the development of new product candidates.

Our dependence on third party collaborators and license agreements subjects us to a number of risks, including:

- our collaborators may not comply with applicable regulatory guidelines with respect to developing or commercializing our products, which could adversely impact sales or future development of our products;

- we and our collaborators could disagree as to future development plans and our collaborators may delay, fail to commence or stop future clinical trials or other development; and

- there may be disputes between us and our collaborators, including disagreements regarding the license agreements, that may result in the delay of or failure to achieve developmental, regulatory and commercial objectives that would result in milestone or royalty payments and/or the delay or termination of any future development or commercialization of our products.

In addition, collaborators may, to the extent permitted by our agreements, develop products that divert resources from our products, preclude us from entering into collaborations with their competitors or terminate their agreements with us prematurely. For example, Braeburn has obtained an exclusive license from Camurus for its long-acting bupenorphine injectables under development, which, if approved, could in the future divert resources from Probuphine. Moreover, disagreements could arise with our collaborators or strategic partners over rights to our intellectual property and our rights to share in any of the future revenues from products or technologies resulting from use of our technologies, or our activities in separate fields may conflict with other business plans of our collaborators.

Initiation of our ProNeura for PD clinical trial has been delayed and there can be no assurance that the IND will ultimately be cleared by the FDA.

Following its initial review of the IND for our ProNeura for PD program, the FDA informed us that it will require additional information, including data on the ropinirole implant and applicator, before clearing the IND that would enable the initiation of our clinical trial. We expect it will take several weeks to provide the FDA with the information it has requested and we do not know how long it may be before we can initiate the clinical study or if the FDA will ultimately clear the IND. If we are unable to pursue the ProNeura for PD program, our business and prospects will be adversely impacted.

Our ProNeura development programs are at very early stages and will require substantial additional resources that may not be available to us.

To date, we have conducted limited research and development activities based on our ProNeura delivery system beyond Probuphine. We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical studies and clinical trials, regulatory approvals and eventual commercialization of ProNeura for PD or hypothyroidism or any therapeutic based on our ProNeura platform technology. If we are unable to generate sufficient revenues from royalties from the sale of Probuphine or other payments under our license agreement with Braeburn, we will need to seek additional sources of financing, which may not be available on

favorable terms, if at all. If we do not succeed in raising the requisite financing on acceptable terms, we may be unable to initiate clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, forego sales and marketing efforts and forego attractive business opportunities.

To the extent we raise additional capital through the sale of equity securities, the issuance of those securities could result in dilution to our stockholders. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. In addition, we may be required to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

Our ProNeura programs for PD or hypothyroidism are at a very early stage and we may not be able to successfully develop these products or any other product based on our ProNeura drug delivery technology.

Our ability to successfully develop any future product candidates based on our ProNeura drug delivery technology is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including: delays in product development, clinical testing, or manufacturing; unplanned expenditures in product development, clinical testing, or manufacturing; failure to receive regulatory approvals; emergence of superior or equivalent products; inability to manufacture on its own, or through any others, product candidates on a commercial scale; and failure to achieve market acceptance.

Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercially successfully, our business, financial condition, and results of operations may be materially harmed.

Our development and commercialization strategy for ProNeura depends, in part, upon the FDA's prior findings regarding the safety and efficacy of the active drug incorporated into the implant based on data not developed by us, but upon which the FDA may rely in reviewing our NDA submissions.

The current strategy for our ProNeura development programs is based, in part, on the expectation that the products we develop will be eligible for approval through the regulatory pathway under Section 505(b)(2) of the FDCA. Section 505(b)(2) of the FDCA allows an NDA to rely in part on data in the public domain or the FDA's prior conclusions regarding the safety and effectiveness of an approved drug product, which could expedite our development programs by potentially decreasing the amount of clinical data that would need to be generated in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for product approval. If this were to occur, the time and financial resources required to obtain FDA approval for any additional

ProNeura products, and complications and risks associated with regulatory approval, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway may result in new competitive products reaching the market more quickly than those we have under development, which would adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee that this regulatory pathway will ultimately lead to accelerated product development or earlier approval. Moreover, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this result could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of any new ProNeura products.

Clinical trials required for new product candidates are expensive and time-consuming, and their outcome is uncertain.

In order to obtain FDA approval to market a new drug product based on our ProNeura drug delivery technology, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct "adequate and well controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example: inability to manufacture sufficient quantities of qualified materials under cGMP, for use in clinical trials; slower than expected rates of patient recruitment; failure to recruit a sufficient number of patients; modification of clinical trial protocols; changes in regulatory requirements for clinical trials; the lack of effectiveness during clinical trials; the emergence of unforeseen safety issues; delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

The results from early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in future clinical trials. Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates.

The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

If Probuphine or any other product candidate that we may successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors and the medical community, the revenues that it generates from their sales will be limited.

If Probuphine or any other product candidate we may in the future develop receives regulatory approval, it may not gain market acceptance among physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any approved products will depend on a

number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, operators of hospitals and clinics and patients of the product as a safe and effective product;
- the potential and perceived advantages of the product over alternative treatments;
- the safety of the product in broader patient groups, including its use outside of approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- the prevalence and severity of adverse events;
- the effectiveness of sales and marketing efforts; and
- unfavorable publicity relating to the product.

If any approved product candidate does not achieve an adequate level of acceptance by physicians, hospitals and clinics, healthcare payors and patients, we may not generate significant revenue from such products.

We must comply with extensive government regulations.

The research, development, manufacture labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of pharmaceutical products are subject to an extensive regulatory approval process by the FDA in the U.S. and comparable health authorities in foreign markets. The process of obtaining required regulatory approvals for drugs is lengthy, expensive and uncertain. Approval policies or regulations may change and the FDA and foreign authorities have substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Regulatory approval may entail limitations on the indicated usage of a drug, which may reduce the drug's market potential. Even if regulatory clearance is obtained, post-market evaluation of the products, if required, could result in restrictions on a product's marketing or withdrawal of the product from the market, as well as possible civil and criminal sanctions. Of the large number of drugs in development, only a small percentage successfully complete the regulatory approval process and are commercialized.

We face risks associated with third parties conducting preclinical studies and clinical trials of our products; as well as our dependence on third parties to manufacture any products that we may successfully develop.

We depend on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices. We also depend upon third party manufacturers for the production of any products we may successfully develop to comply with current Good Manufacturing Practices of the FDA, which are similarly outside our direct control. If third party laboratories and medical institutions conducting studies of our products fail to maintain both good laboratory and clinical practices, the studies could be delayed or have to be repeated. Similarly, if the manufacturers of any products we develop in the future fail to comply with current Good Manufacturing Practices of the FDA, we may be forced to cease manufacturing such product until we have found another third party to manufacture the product.

We face risks associated with product liability lawsuits that could be brought against us.

The testing, manufacturing, marketing and sale of human therapeutic products entail an inherent risk of product liability claims. We currently have a limited amount of product liability insurance, which may not be sufficient to cover claims that may be made against us in the event that the use or misuse of our product candidates causes, or merely appears to have caused, personal injury or death. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses. Adequate insurance coverage may not be available in the future on acceptable terms, if at all. If available, we may not be able to maintain any such insurance at sufficient levels of coverage and any such insurance may not provide adequate protection against potential liabilities. Whether or not a product liability insurance policy is obtained or maintained in the future, any claims against us, regardless of their merit, could severely harm our financial condition, strain our management and other resources or destroy the prospects for commercialization of the product which is the subject of any such claim.

We may be unable to protect our patents and proprietary rights.

Our future success will depend to a significant extent on our ability to:

- obtain and keep patent protection for our products and technologies on an international basis;
- enforce our patents to prevent others from using our inventions;

- maintain and prevent others from using our trade secrets; and

- operate and commercialize products without infringing on the patents or proprietary rights of others.

We cannot assure you that our patent rights will afford any competitive advantages, and these rights may be challenged or circumvented by third parties. Further, patents may not be issued on any of our pending patent applications in the U.S. or abroad. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before a potential product can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, reducing or eliminating any advantage of the patent. If we sue others for infringing our patents, a court may determine that such patents are invalid or unenforceable. Even if the validity of our patent rights is upheld by a court, a court may not prevent the alleged infringement of our patent rights on the grounds that such activity is not covered by our patent claims.

In addition, third parties may sue us for infringing their patents. In the event of a successful claim of infringement against us, we may be required to:

- pay substantial damages;

- stop using our technologies and methods;

- stop certain research and development efforts;

- develop non-infringing products or methods; and

- obtain one or more licenses from third parties.

If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in development, manufacture and commercialization of our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringe third party rights, will be costly, time consuming, and may distract management from other important tasks.

We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, we cannot assure you that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information, which may not be resolved in our favor.

We face intense competition.

Competition in the pharmaceutical and biotechnology industries is intense. We face, and will continue to face, competition from numerous companies that currently market, or are developing, products for the treatment of the diseases and disorders we have targeted. Many of these entities have significantly greater research and development capabilities, experience in obtaining regulatory approvals and manufacturing, marketing, financial and managerial resources than we have. We also compete with universities and other research institutions in the development of products, technologies and processes, as well as the recruitment of highly qualified personnel. Our competitors may succeed in developing technologies or products that are more effective than the ones we have under development or that render our proposed products or technologies noncompetitive or obsolete. In addition, our competitors may achieve product commercialization or patent protection earlier than we will.

If Braeburn is unable to achieve and maintain adequate levels of coverage and reimbursement for Probuphine on reasonable pricing terms, or we or our collaborators fail to do so for any of our other product candidates for which we may receive regulatory approval, their commercial success may be severely limited.

Successful sales of Probuphine or any other product we may successfully develop will depend on the availability of adequate coverage and reimbursement from third-party payors, as well as the ease of use and transparency of such

processes and systems once in place. Patients who are prescribed medicine for the treatment of their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their prescription drugs. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Third-party payors, whether governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products such as ours when more established or lower cost therapeutic alternatives are already available or subsequently become available. Decisions regarding the extent of coverage and amount of reimbursement to be provided for products and product candidates that we develop will be made on a plan-by-plan basis. As a result, the coverage determination process is often a time-consuming and costly process that may require us or our partners to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained.

Reimbursement for injectable and implantable drug products that require administration by a healthcare provider generally requires a drug code, and separate reimbursement codes are required for the injection, insertion and removal procedures, as applicable. Braeburn has obtained a drug code for Probuphine, but its application for a procedure code was recently denied. The lack of a drug code or procedure code that covers our product or describes the procedures performed using our products, or a change to an existing code that describes such procedures, may adversely affect reimbursement for our products and these procedures, including lower reimbursement rates, denials and delays in reimbursement if pre-authorization is required. Even if coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

In addition, the market for our products may depend on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Also, regional healthcare authorities and individual hospitals are increasingly using competitive bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

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

Health care reform measures and changes in policies, funding, staffing and leadership at the FDA and other agencies could hinder or prevent the commercial success of our products.

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

Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, or collectively ACA"), was signed into law,which includes measures to significantly change the way health care is financed by both governmental and private insurers.

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

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

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

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

Furthermore, regulatory authorities’ assessment of the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, changing policies and agency funding, staffing and leadership. We cannot be sure whether future changes to

the regulatory environment will be favorable or unfavorable to our business prospects.

We may not be able to retain our key management and scientific personnel, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.

As a company with a limited number of personnel, we are highly dependent on the services of our executive management and scientific staff, in particular Sunil Bhonsle, our President and Chief Executive Officer, Marc Rubin, our Executive Chairman and Katherine Beebe our Executive Vice President and Chief Development Officer. The loss of one or more of such individuals could substantially impair ongoing research and development programs and could hinder our ability to obtain corporate partners. Our success depends in large part upon our ability to attract and retain highly qualified personnel. We compete in our hiring efforts with other pharmaceutical and biotechnology companies, as well as universities and nonprofit research organizations, and we may not be successful in our efforts to attract and retain personnel.

Our net operating losses and research and development tax credits may not be available to reduce future federal and state income tax payments.

At December 31, 2016, we had federal net operating loss and tax credit carryforwards of $247.7 million and $8.7 million, respectively, and state net operating loss and tax credit carryforwards of $124.4 million and $8.5 million, respectively, available to offset future taxable income, if any. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change and we cannot assure you that our net operating loss and tax carryforwards will continue to be available.

Our stock price has been and will likely continue to be volatile.

Our stock price has experienced substantial fluctuations and could continue to fluctuate significantly due to a number of factors, including:

- variations in our anticipated or actual operating results or prospects;
- sales of substantial amounts of our common stock;
- announcements about us or about our competitors, including introductions of new products;
- litigation and other developments relating to our patents or other proprietary rights or those of our competitors;
- conditions in the pharmaceutical or biotechnology industries;
- governmental regulation and legislation; and
- change in securities analysts' estimates of our performance, or our failure to meet analysts' expectations.

We have never paid and do not intend to pay cash dividends. As a result, capital appreciation, if any, will be your sole source of gain.

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Provisions in our certificate of incorporation, our by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.

Provisions of our certificate of incorporation, our by-laws and Delaware law may have the effect of deterring unsolicited takeovers or delaying or preventing a change in control of our company or changes in our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of stockholders to approve transactions that they may deem to be in their best interests. These provisions include:

- the inability of stockholders to call special meetings; and
- the ability of our board of directors, or our Board, to designate the terms of and issue new series of preferred stock without stockholder approval, which could include the right to approve an acquisition or other change in our control or could be used to institute a rights plan, also known as a poison pill, that would work to dilute the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board.

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

The existence of the forgoing provisions and anti-takeover measures could limit the price that investors might be willing to pay in the future for shares of our common stock. They could also deter potential acquirers of our company, thereby reducing the likelihood that you could receive a premium for your common stock in an acquisition.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties

Our executive offices are located in approximately 9,255 square feet of office space in South San Francisco, California that we occupy under a five-year operating lease expiring in June 2021. It is our intention to continue to be based in South San Francisco.

Item 3. Legal Proceedings

We are currently not a party to any material legal or administrative proceedings and are not aware of any pending or threatened legal or administrative proceedings against us.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

(a) Price Range of Securities

Our common stock has been listed on the NASDAQ Capital Market ("NASDAQ") under the symbol "TTNP" since October 2015. Previously, our common stock traded in the over-the-counter market and was quoted through the Over-The-Counter Bulletin Board ("OTCBB") under the symbol "TTNP" since June 2010. The following table sets forth, for the periods indicated, the high and low sale prices for our common stock as reported by the NASDAQ and OTCBB. Quotations on the OTCBB reflect inter-dealer prices, as adjusted for the reverse stock split, without retail mark-up, mark-down or commissions, and may not represent actual transactions. For current price information, stockholders are urged to consult publicly available sources.

	High	Low
Fiscal 2016		
Fourth Quarter	$6.10	$3.80
Third Quarter	$6.17	$4.80
Second Quarter	$7.41	$4.76
First Quarter	$4.91	$2.98
Fiscal 2015		
Fourth Quarter	$5.29	$3.77
Third Quarter	$4.59	$3.59
Second Quarter	$4.92	$3.76
First Quarter	$3.92	$2.54

(b) Approximate Number of Equity Security Holders

At March 10, 2017, there were 21,198,879 shares of our common stock outstanding held by 127 holders of record. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of common stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies.

(c) Dividends

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends to stockholders in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board and will be dependent upon our financial condition, results of operations, capital requirements, and such other factors as the Board deems relevant.

(d)

Equity Compensation Plan Information

The following table sets forth aggregate information regarding our equity compensation plans in effect as of December 31, 2016:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrant and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (c)
Equity compensation plans approved by security holders	1,249,343	$ 5.69	1,882,000
Equity compensation plans not approved by security holders(1)(2)(3)(4)	752,848	$ 5.65	—
Total	2,002,191	$ 5.67	1,882,000

(1) Includes 204,375 shares underlying options granted to employees and consultants who are not officers or directors of Titan under our 2001 Employee Non-Qualified Stock Option Plan.

(2) Includes 79,546 shares underlying non-qualified stock options exercisable at $13.20 per share granted to Dr. Rubin in October 2007 that vested over 48 months from the grant date.

(3) In May 2009, we granted 111,819 and 56,364 non-qualified stock options outside of our stock option plans to Dr. Rubin and Mr. Bhonsle, respectively, at an exercise price of $4.34 that vested over 48 months from the grant date.

(4) Includes 300,744 non-qualified stock options and restricted share awards granted to employees, directors and consultants under our 2014 Incentive Plan. For a description of the 2014 Plan, see note 12 to the financial statements.

Performance Graph

The information contained in the Performance Graph shall not be deemed to be "soliciting material" or "filed" with the SEC or subject to the liabilities of Section 18 of the Exchange Act, except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act or the Exchange Act.

The following graph compares the cumulative total stockholder return on our common stock with the cumulative total stockholder return of (i) the NYSE MKT Index, (ii) the NASDAQ Composite Index and (iii) the NASDAQ Biotechnology Index. The graph assumes $100 invested on December 31, 2011 and assumes dividends reinvested. Measurement points are at the last trading day of the fiscal years ended December 31, 2012, 2013, 2014, 2015 and 2016. The stock price performance on the following graph is not necessarily indicative of future stock price performance.

COMPARE CUMULATIVE TOTAL RETURN

AMONG TITAN PHARMACEUTICALS, INC., NYSE MKT INDEX, NASDAQ COMPOSITE INDEX AND

NASDAQ BIOTECHNOLOGY INDEX

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Item 6. Selected Financial Data.

The selected financial data presented below summarizes certain financial data which has been derived from and should be read in conjunction with our financial statements and notes thereto included in the section beginning on page F-1. See also “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	Years Ended December 31,				
	2016	2015	2014	2013	2012
	(in thousands, except per share data)				
Statement of Operations Data:					
Total revenue	$15,065	$1,671	$3,646	$10,481	$7,117
Operating expenses:					
Research and development	6,126	4,675	4,075	8,309	10,610
General and administrative	4,596	3,755	3,046	3,063	4,877
Other income (expense), net	792	(4,520)	1,072	10,602	(6,810)
Net income (loss) applicable to common stockholders	$5,135	$(11,279)	$(2,403)	$9,711	$(15,180)
Basic net income (loss) per common share	$0.25	$(0.56)	$(0.14)	$0.65	$(1.26)
Diluted net income (loss) per common share	$0.20	$(0.56)	$(0.20)	$0.53	$(1.26)
Shares used in computing:					
Basic net income (loss) per common share	20,744	20,053	17,057	14,927	12,093
Diluted net income (loss) per common share	21,459	20,053	17,060	15,029	12,093

	As of December 31,				
	2016	2015	2014	2013	2012
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$14,006	$7,857	$15,470	$11,798	$18,102
Working capital	12,973	7,391	12,921	5,974	2,042
Total assets	18,667	13,287	20,851	18,423	24,827
Total stockholders’ equity (deficit)	13,191	6,990	8,611	5,760	(23,128)

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Forward-Looking Statements

Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements" within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "in "believe," and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. Please see "Note Regarding Forward-Looking Statements" at the beginning of this Annual Report on Form 10-K.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes thereto and other financial information appearing elsewhere in this Annual Report on Form 10-K.

Overview

We are a pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura™, and focus primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit.

Probuphine®, our first product candidate based on the ProNeura platform, was approved by the FDA on May 26, 2016 for the maintenance treatment of opioid dependence in patients who are stable on low to moderate doses of daily sublingual buprenorphine treatment. We have licensed development and commercialization rights of Probuphine for the U.S. and Canadian markets to Braeburn and pursuant to the license agreement as amended to date, we received a $15 million milestone payment upon FDA approval of the Probuphine NDA, and are entitled to receive royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties based on a tiered structure. The agreement also provides for up to an additional $165 million in sales milestones and $35 million in regulatory milestones on Probuphine. Additionally, in certain circumstances the agreement entitles us to a low single digit royalty, up to an aggregate of $50 million, on net sales by Braeburn, if any, of other future competing products in the addiction market, e.g. a monthly depot injection.

Braeburn commenced commercialization activities in support of Probuphine product launch immediately following FDA approval starting with implementation at the end of May 2016 of the REMS directed training program for qualified health care providers. During the second half of 2016, Braeburn was engaged in training qualified health care providers in the implant insertion and removal procedures, physician outreach, payment and reimbursement discussions with third party payors and sales and marketing efforts associated with the launch including hiring personnel for a field sales force. In 2016, more than 2,500 health care providers from all 50 states and Puerto Rico were certified to provide Probuphine to their patients. However, as previously indicated, the adoption of the product by health care providers has been gradual resulting in limited sales.

In January 2017, Braeburn announced that the Centers for Medicare & Medicaid Services (CMS) had granted a Healthcare Common Procedure Coding System (HCPCS) code, or permanent J-code, for Probuphine, as the first six-month buprenorphine implant for the maintenance treatment of opioid addiction. The new J-code (J0570) became effective January 1, 2017 and coincided with the activation of a Braeburn field force. Braeburn continues to work to obtain additional codes to further facilitate reimbursement of Probuphine insertion and removal procedures.

We believe that our ProNeura long term drug delivery platform has the potential to be used in the treatment of other chronic conditions where maintaining stable, around the clock blood levels of a medication may benefit the patient and improve medical outcomes. We have two products in early development using the ProNeura platform, an implant designed to provide long-term delivery of ropinirole, a dopamine agonist approved as a daily dosed oral formulation for the treatment of Parkinson's disease, and an implant designed to provide long-term delivery of T3, a synthetic thyroid hormone approved as a daily dosed oral formulation for the treatment of hypothyroidism.

The non-clinical development work related to the ropinirole implant, including the toxicology studies, was completed in the fourth quarter of 2016 and the IND was submitted to the FDA in January 2017. In late February 2017, in a telephone conversation, we received comments from the FDA following its initial review of the IND requesting additional information related to final test results for the ropinirole implant and the applicator, as well as the name of the Principal Investigator. We have been asked to hold the initiation of the clinical study and we expect to receive the FDA's written comments by late March. We are working quickly to provide the FDA with the additional information required and are hopeful that we will be able to commence the clinical study toward the end of the second quarter, although there is no assurance that the FDA will clear the IND within that timeframe, if at all.

Development of the T3 implant product continued during 2016 with non-clinical studies designed to optimize the formulation. We identified refinements to the formulation that will be necessary; however, due to shortage of the API, further investigation had to be temporarily suspended during the fourth quarter of 2016. In early 2017, we obtained the requisite supply of the API and have commenced work towards the optimization of the T3 implant. Once this work is completed, we will be in a position to request a pre-IND meeting with the FDA by mid-2017, resources permitting.

Our goal is to further expand the product pipeline, and we are currently evaluating other drugs and disease settings for opportunities to use the ProNeura platform in potential treatment applications where conventional treatment is limited by variability in blood drug levels and poor patient compliance.

We operate in only one business segment, the development of pharmaceutical products.

Critical Accounting Policies and the Use of Estimates

The preparation of our financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. Actual results could differ materially from those estimates. We believe the following accounting policies for the years ended December 31, 2016 and 2015 to be applicable:

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses, and government grants. Consideration received for revenue arrangements with multiple components is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) a contractual agreement exists; (2) transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

- Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of our continuing research and development efforts.

- Royalties earned are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured.

- Government grants, which support our research efforts in specific projects, generally provide for reimbursement of approved costs as defined in the notices of grants. Grant revenue is recognized when associated project costs are incurred.

- Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collections are reasonably expected. Payments received related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

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Share-Based Payments

We recognize compensation expense for all share-based awards made to employees and directors. The fair value of share-based awards is estimated at the grant date based on the fair value of the award and is recognized as expense, net of estimated pre-vesting forfeitures, ratably over the vesting period of the award.

We use the Black-Scholes option pricing model to estimate the fair value method of our awards. Calculating stock-based compensation expense requires the input of highly subjective assumptions, including the expected term of the share-based awards, stock price volatility, and pre-vesting forfeitures. We estimate the expected term of stock options granted for the years ended December 31, 2016 and 2015 based on the historical experience of similar awards, giving consideration to the contractual terms of the share-based awards, vesting schedules and the expectations of future employee behavior. We estimate the volatility of our common stock at the date of grant based on the historical volatility of our common stock. The assumptions used in calculating the fair value of stock-based awards represent our best estimates, but these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and we use different assumptions, our stock-based compensation expense could be materially different in the future. In addition, we are required to estimate the expected pre-vesting forfeiture rate and only recognize expense for those shares expected to vest. We estimate the pre-vesting forfeiture rate based on historical experience. If our actual forfeiture rate is materially different from our estimate, our stock-based compensation expense could be significantly different from what we have recorded in the current period.

Income Taxes

We make certain estimates and judgments in determining income tax expense for financial statement purposes. These estimates and judgments occur in the calculation of certain tax assets and liabilities, which arise from differences in the timing of recognition of revenue and expense for tax and financial statement purposes.

As part of the process of preparing our financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our current tax exposure under the most recent tax laws and assessing temporary differences resulting from differing treatment of items for tax and accounting purposes.

We assess the likelihood that we will be able to recover our deferred tax assets. We consider all available evidence, both positive and negative, expectations and risks associated with estimates of future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for a valuation allowance. If it is not more likely than not that we will recover our deferred tax assets, we will increase our provision for taxes by recording a valuation

allowance against the deferred tax assets that we estimate will not ultimately be recoverable.

Clinical Trial Accruals

We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by CROs and clinical sites. These costs are recorded as a component of research and development expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. The actual clinical trial costs for the Probuphine studies conducted in the past three years have not differed materially from the estimated projection of expenses.

Warrants Issued in Connection with Equity Financing

We generally account for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that we may have to settle warrants in cash. For warrants issued with deemed possibility of cash settlement, we record the fair value of the issued warrants as a liability at each reporting period and record changes in the estimated fair value as a non-cash gain or loss in the Statements of Operations and Comprehensive Income (Loss).

Liquidity and Capital Resources

	2016	2015	2014
	(in thousands)		
As of December 31:			
Cash and cash equivalents	$14,006	$7,857	$15,470
Working capital	$12,973	$7,391	$12,921
Current ratio	3.7:1	2.5:1	2.9:1
Years Ended December 31:			
Cash provided by (used in) operating activities	$6,293	$(7,466)	$(5,865)
Cash used in investing activities	$(171)	$(133)	$(18)
Cash provided by (used in) financing activities	$27	$(14)	$9,555

We have funded our operations since inception primarily through the sale of our securities and the issuance of debt, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, the sale of royalty rights and government-sponsored research grants. At December 31, 2016, we had working capital of approximately $13.0 million compared to working capital of approximately $7.4 million at December 31, 2015.

Our operating activities provided approximately $6.3 million of cash during the year ended December 31, 2016. This consisted primarily of the net income for the period of approximately $5.1 million, approximately $0.4 million related to depreciation and amortization, non-cash charges of approximately $1.0 million related to share-based compensation expenses and approximately $0.6 million related to net changes in other operating assets and liabilities. This was offset in part by approximately $0.8 million related to non-cash gains resulting from changes in the fair value of warrants. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses.

Net cash used in investing activities of approximately $171,000 during the year ended December 31, 2016 was primarily related to purchases of equipment.

Our financing activities provided approximately $27,000 during the year ended December 31, 2016 which was primarily related to proceeds from the exercise of stock options.

In May 2016, the FDA approved our Probuphine NDA and pursuant to our license agreement with Braeburn, as amended to date, we received a $15 million milestone payment and subsequently transferred the NDA to Braeburn.

In September 2016, we entered into an agreement with Cantor Fitzgerald & Co. to enable us to sell up to $20 million of shares in an at-the-market offering (the “ATM”). To date, we have elected not to sell any shares pursuant to the ATM given our current financial position and the market price of our stock.

At December 31, 2016, we had cash and cash equivalents of approximately $14.0 million, which we believe is sufficient to fund our planned operations through the first quarter of 2018. We will require additional funds, either through payments from Braeburn under the license agreement or through other financing arrangements, to advance our current ProNeura development programs to later stage clinical studies and to complete the regulatory approval process necessary to commercialize any products we might develop.

The following table sets forth the aggregate contractual cash obligations as of December 31, 2016 (in thousands):

	Payments Due by Period				
Contractual obligations	Total	< 1 year	1-3 years	3-5 years	5 years+
Operating leases	$1,326	$ 277	$ 586	$ 463	$ —
Total contractual cash obligations	$1,326	$ 277	$ 586	$ 463	$ —

Results of Operations

Year Ended December 31, 2016 Compared to Year Ended December 31, 2015

License revenues were approximately $15.1 million and $1.7 million for the years ended December 31, 2016 and 2015, respectively. License revenues for the year ended December 31, 2016 reflect approximately $65,000 from the recognition of royalties earned on net sales of Probuphine and approximately $15.0 million from the recognition of the milestone payment earned upon FDA approval of our Probuphine NDA in May 2016. License revenues for the year ended December 31, 2015 reflect the amortization of the upfront license fee received from Braeburn in December 2012.

Research and development expenses for 2016 were approximately $6.1 million compared to approximately $4.7 million in 2015, an increase of approximately $1.4 million, or 30%. The increase in research and development costs was primarily associated with increases in external research and development expenses related to the support of our ProNeura product development programs, employee related expenses and other research and development expenses. These increases were partially offset by the reimbursement by our development partner, Braeburn, of approximately $1.1 million of expenses related to Probuphine. External research and development expenses include direct expenses such as CRO charges, investigator and review board fees, patient expense reimbursements, expenses for NDA preparation and contract manufacturing expenses. During 2016, external research and development expenses relating to our product development programs were approximately $3.5 million compared to approximately $1.5 million in 2015. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs. As a result of the risks and uncertainties inherently associated with pharmaceutical research and development activities described elsewhere in this document, we are unable to estimate the specific timing and future costs of our clinical development programs or the timing of material cash inflows, if any, from our product candidates. However, we anticipate that our research and development expenses will increase in connection with our current ProNeura development program and any other ProNeura technology based product development activities we may pursue.

General and administrative expenses for 2016 were approximately $4.6 million compared to approximately $3.8 million in 2015, an increase of approximately $0.8 million, or 21%. The increase in general and administrative expenses was primarily related to increases in non-cash stock-based compensation and employee-related costs of approximately $0.5 million, legal and professional fees of approximately $0.2 million and a contractual fee obligation in connection with payments received under the Probuphine license of approximately $0.2 million. This was partially offset by decreases of approximately $0.1 million in other administrative expenses.

Net other income for the year ended December 31, 2016 was approximately $0.8 million, compared to net other expense of approximately $4.5 million in 2015. Net other income in 2016 consisted primarily of $0.8 million related to non-cash gains on changes in the fair value of warrant liabilities. Net other expense in 2015 consisted primarily of $4.5 million related to non-cash losses on changes in the fair value of warrant liabilities.

Our net income applicable to common stockholders for the year ended December 31, 2016 was approximately $5.1 million, or approximately $0.25 per share, compared to our net loss applicable to common stockholders of approximately $11.3 million, or approximately $0.56 per share, for the comparable period in 2015.

Year Ended December 31, 2015 Compared to Year Ended December 31, 2014

License revenues of approximately $1.7 million and $3.6 million for the years ended December 31, 2015 and 2014, respectively, reflect the amortization of the upfront license fee received from Braeburn in December 2012.

Research and development expenses for 2015 were approximately $4.7 million compared to approximately $4.1 million in 2014, an increase of approximately $0.6 million, or 15%. The increase in research and development costs was primarily associated with increases in external research and development expenses related to the support of our Probuphine and ProNeura-ropinirole product development programs, employee related expenses and other research and development expenses. External research and development expenses include direct expenses such as CRO charges, investigator and review board fees, patient expense reimbursements, expenses for NDA preparation and contract manufacturing expenses. During 2015, external research and development expenses relating to our product development programs were approximately $1.5 million compared to approximately $0.9 million in 2014. Other research and development expenses include internal operating costs such as clinical research and development personnel-related expenses, clinical trials related travel expenses, and allocation of facility and corporate costs.

General and administrative expenses for 2015 were approximately $3.8 million compared to approximately $3.0 million in 2014, an increase of approximately $0.8 million, or 27%. The increase in general and administrative expenses was primarily related to increases in non-cash stock-based compensation and employee-related costs of approximately $0.4 million, legal and professional fees of approximately $0.2 million, board fees of approximately $0.1 million and travel related expenses of approximately $0.1 million.

Net other expense for the year ended December 31, 2015 was approximately $4.5 million, compared to net other income of approximately $1.1 million in 2014. Net other expense in 2015 consisted primarily of $4.5 million related to non-cash losses on changes in the fair value of warrant liabilities. Net other income in 2014 consisted primarily of $1.1 million related to non-cash gains on changes in the fair value of warrant liabilities.

Our net loss applicable to common stockholders for the year ended December 31, 2015 was approximately $11.3 million, or approximately $0.56 per share, compared to our net loss applicable to common stockholders of approximately $2.4 million, or approximately $0.14 per share, for the comparable period in 2014.

Off-Balance Sheet Arrangements

We have never entered into any off-balance sheet financing arrangements and we have never established any special purpose entities. We have not guaranteed any debt or commitments of other entities or entered into any options on non-financial assets.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

We held no marketable securities at December 31, 2016 and 2015.

Item 8. Financial Statements and Supplementary Data.

The response to this item is included in a separate section of this Report. See “Index to Financial Statements” on Page F-1.

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

None.

Item 9A. Controls and Procedures.

(a) *Evaluation of Disclosure Controls and Procedures* : Our principal executive and financial officers reviewed and evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)) as of the end of the period covered by this Annual Report on Form 10-K. Based on that evaluation, our principal executive and financial officers concluded that our disclosure controls and procedures are effective in timely providing them with material information relating to the Company, as required to be disclosed in the reports we file under the Exchange Act.

(b) *Management's Annual Report on Internal Control Over Financial Reporting*:

Internal control over financial reporting refers to the process designed by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our Board, 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 authorization of our management and directors; and

(3) Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisitions, use or disposition of our 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 overrides. Due to 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 financial reporting for the company.

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), known as COSO, to evaluate the effectiveness of the Company's internal control over financial reporting. Based on this assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2016.

Our independent registered public accounting firm, OUM & CO. LLP, that has audited the Company's financial statements contained in this Annual Report on Form 10-K, has issued an attestation report on the Company's internal control over financial reporting as of December 31, 2016. The attestation report appears on page F-3 of this Annual Report on Form 10-K.

(c) *Changes in Internal Control Over Financial Reporting* : There were no changes in our internal control over financial reporting (as defined in Rules 13(a)-15(f) and 15(d)-15(f) under the Securities Act) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors; Executive Officers and Corporate Governance

Set forth below are the name, age and position and a brief account of the business experience of each of our executive officers and directors:

Name	Age	Office	Director Since
Marc Rubin (1)	62	Executive Chairman of the Board	November 2007
Sunil Bhonsle	67	Chief Executive Officer, President and Director	February 2004
Joseph A. Akers (2)(3)	71	Director	November 2014
Rajinder Kumar	62	Director	January 2017
M. David MacFarlane (2)(3)	76	Director	May 2002
James R. McNab, Jr. (2)(4)	73	Director	November 2014
Scott A. Smith	54	Director	January 2017

(1) Member of Executive Committee

(2) Member of Audit Committee

(3) Member of Compensation Committee

(4) Member of Nominating Committee

Marc Rubin, M.D. served as our President and Chief Executive from October 2007 until December 2008 and was re-engaged as our Executive Chairman in May 2009. Until February 2007, Dr. Rubin served as Head of Global Research and Development for Bayer Schering Pharma, as well as a member of the Executive Committee of Bayer Healthcare and the Board of Management of Bayer Schering Pharma. Prior to the merger of Bayer Pharmaceuticals and Schering AG in June 2006, Dr. Rubin was a member of the Executive Board of Schering AG since joining the Company in October 2003, as well as Chairman of Schering Berlin Inc. and President of Berlex Pharmaceuticals, a division of Schering AG. From 1990 until August 2003, Dr. Rubin was employed by GlaxoSmithKline where he held positions of increasing responsibility in global clinical and commercial development overseeing programs in the United States, Europe, Asia and Latin America. From 2001 through 2003, he was Senior Vice President of Global Clinical Pharmacology & Discovery Medicine. Dr. Rubin holds an M.D. from Cornell University Medical College. Dr. Rubin currently serves on the board of directors of Curis Inc. and Galectin Therapeutics. Based on Dr. Rubin's position as our Executive Chairman, his extensive senior management experience and service on boards of directors in the biotechnology and pharmaceutical industries and his medical background, our Board believes that Dr. Rubin has

the appropriate set of skills to serve as a member of the Board.

Sunil Bhonsle served as our Executive Vice President and Chief Operating Officer from September 1995 until December 2008 and was re-engaged as our President in May 2009. Mr. Bhonsle was appointed as our Chief Executive Officer in November 2015. Mr. Bhonsle served in various positions, including Vice President and General Manager — Plasma Supply and Manager — Inventory and Technical Planning, at Bayer Corporation from July 1975 until April 1995. Mr. Bhonsle holds an M.B.A. from the University of California at Berkeley and a B.Tech. in chemical engineering from the Indian Institute of Technology. Based on Mr. Bhonsle's position as our principal executive officer and his substantial experience in the pharmaceutical industry, particularly in the areas of clinical development and manufacturing, our Board believes that Mr. Bhonsle has the appropriate set of skills to serve as a member of the Board.

Joseph A. Akers was employed in various capacities by Bayer Corporation, Bayer Healthcare and certain related entities, including as president of the Hematology/Cardiology Business Unit from 2004 to 2007, president and chief executive officer of Bayer Business and Corporate Services from July 2002 through 2003 and executive vice president and chief administrative and financial officer from 1999 to July 2002. Mr. Akers received a B.S. in marketing and an M.B.A. in finance from the University of California at Berkeley. Based on Mr. Akers' extensive management experience in the pharmaceutical industry, particularly in the areas of administration and finance, our Board believes that Mr. Akers has the appropriate set of skills to serve as a member of the Board.

Rajinder Kumar, Ph.D. has served as the Chairman and Chief Executive Officer of MeRaD Pharmaceutical Ltd. in Cambridge U.K. since May 2009. He has also served as President and Chief Medical Officer of Vitas Pharma in Hyderabad, India since he founded such company in 2010. For the decade prior to joining MeRaD, he served in various executive capacities with Dr. Reddy's Labs, Ranbaxy Laboratories Limited, Synaptic Pharmaceutical LLP and Glaxo SmithKline Beecham. Dr. Kumar is a member of scientific advisory boards in neuroscience, anti-infectives and metabolic disorders He received a B.S. in Human Biology from the University of London, a Masters in Ethology from the University of Birmingham, a MBChB in Medicine from the University of Dundee and an advanced diploma in Psychological Medicine from The Royal College of Surgeons and Physicians in Ireland. Based on Dr. Kumar's management experience in the pharmaceutical industry, our Board believes that Dr. Kumar has the appropriate set of skills to serve as a member of the Board.

M. David MacFarlane, Ph.D. served as Vice President and Responsible Head of Regulatory Affairs of Genentech, Inc. from 1989 until his retirement in August 1999. Prior to joining Genentech, Inc., he served in various positions with Glaxo Inc., last as Vice President of Regulatory Affairs. Based on Dr. MacFarlane's management experience in the pharmaceutical industry, particularly in the area of clinical and regulatory affairs, our Board believes that Dr. MacFarlane has the appropriate set of skills to serve as a member of the Board.

James R. McNab, Jr. has served since 1998 as chief executive officer and chairman of Palmetto Pharmaceuticals, Inc., a privately-held drug discovery company he founded. He has been a chairman of the board of directors of Curis, Inc. (Nasdaq:CRIS), an oncology focused biotechnology company, since May 2002. Since 2009, Mr. McNab has served as executive chairman of FirstString Research, Inc., a privately-held biopharmaceutical company, and as chief executive officer of JT Pharmaceuticals, Inc., a privately-held drug discovery company. Mr. McNab has co-founded several privately-held companies, including Sontra Medical Corporation, a drug delivery company, and Parker Medical Associates, a manufacturer and worldwide supplier of orthopedic and sports-related products. He received a B.A. in economics from Davidson College and an M.B.A. from the University of North Carolina at Chapel Hill. Based on Mr. McNab's extensive management experience in the pharmaceutical industry, our Board believes that Mr. McNab has the appropriate set of skills to serve as a member of the Board.

Scott A. Smith has served in various management capacities with Celgene Corporation since 2008, including as President, Inflammation and Immunology since August 2014. Effective April 2017, he will become President and Chief Operating Officer. From 2003 to 2008, he served in various executive capacities with Biovail Pharmaceuticals, Inc. and prior thereto spent 16 years Pharmacia & Upjohn Company. Mr. Smith holds a BSc in Chemistry and Biology and an HBSc in Pharmacology and Toxicology from the University of Western Ontario and a Masters in International Management from the American Graduate School of International Management in Arizona. Based on Mr. Smith's extensive management experience in the pharmaceutical industry, our Board believes that Mr. Smith has the appropriate set of skills to serve as a member of the Board.

As indicated above, each of our directors has extensive management and operational experience in one or more facets of the pharmaceutical industry, including research, product development, clinical and regulatory affairs,

manufacturing and sales and marketing, providing our company with the leadership needed by a biotechnology company in all stages of its development.

Directors serve until the next annual meeting or until their successors are elected and qualified. Officers serve at the discretion of the Board, subject to rights, if any, under contracts of employment. See “Item 6. Executive Compensation—Employment Agreements.”

Board Leadership Structure

Currently, our principal executive officer and chairman of the Board positions are held separately by Sunil Bhonsle and Marc Rubin, respectively.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act, requires our executive officers, directors and persons who beneficially own more than 10% of a registered class of our equity securities to file with the Securities and Exchange Commission initial reports of ownership and reports of changes in ownership of our common stock and other equity securities. Such executive officers, directors, and greater than 10% beneficial owners are required by SEC regulation to furnish us with copies of all Section 16(a) forms filed by such reporting persons.

Based solely on our review of such forms furnished to us and written representations from certain reporting persons, we believe that all filing requirements applicable to our executive officers, directors and greater than 10% beneficial owners were complied with during 2016.

Code of Ethics

We adopted a Code of Business Conduct and Ethics (the "Code") in February 2013 that applies to all directors, officers and employees. The Code was filed as an exhibit to our Annual Report on Form 10-K for the year ended December 31, 2012 and is available on our website at *www.titanpharm.com.* A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 400 Oyster Point Blvd, Suite 505, South San Francisco, California 94080.

Changes in Director Nomination Process for Stockholders

None.

Item 11. Executive Compensation

Overview

During 2016, the compensation packages of Dr. Rubin, our Executive Chairman, and Sunil Bhonsle, our Chief Executive Officer and President continued to reflect our current level of operations and resources. The key objectives for 2016 were to support the review by the FDA of the Probuphine NDA, and if approved, support Braeburn in the commercial launch of the product. This compensation discussion describes the material elements of compensation awarded to, earned by, or paid to each of our executive officers who served as named executive officers during the year ended December 31, 2016. This compensation discussion focuses on the information contained in the following tables and related footnotes and narrative for primarily the last completed fiscal year; however, we also describe compensation actions taken before or after the last completed fiscal year to the extent it enhances the understanding of our executive compensation disclosure.

Compensation Program Objectives and Philosophy

Our Compensation Committee currently oversees the design and administration of our executive compensation program. It reviews and approves all elements of compensation for each of our named executive officers taking into consideration recommendations from our principal executive officer (for compensation other than his own), as well as competitive market guidance. We define our competitive markets for executive talent to be the pharmaceutical and biotechnology industries in northern California. To date, we have utilized the Radford Biotechnology Surveys, a third party market specific compensation survey, and, when applicable, other independent third-party compensation consultants to benchmark our executive compensation.

The principal elements of our executive compensation program have historically been base salary, annual cash incentives, long-term equity incentives in the form of stock options or restricted stock awards, other benefits and perquisites, post-termination severance and acceleration of stock option vesting for certain named executive officers upon termination and/or a change in control. Our other benefits and perquisites have consisted of life, health and disability insurance benefits, and a qualified 401(k) savings plan. Our philosophy has been to position the aggregate of these elements at a level that is competitive within the industry and commensurate with our size and performance recognizing operational needs and limited financial resources during this period.

Base Salaries

During 2016, the base salary of our named executives was reflective of the availability of resources and level of continuing operations. Dr. Rubin received an annual salary of $295,000 and Mr. Bhonsle received an annual salary of $395,000.

As we continue to evaluate the strategic alternatives for us going forward and our related human resource requirements, our Compensation Committee will continue to review appropriate base salaries for our executive officers. In making its determination, the Compensation Committee will consider the time commitment necessary and the roles our executives will play in implementing our plans.

Long-term Equity Incentives

We provide the opportunity for our named executive officers and other executives to earn a long-term equity incentive award. Long-term incentive awards provide employees with the incentive to stay with us for longer periods of time, which in turn, provides us with greater stability. Equity awards also are less costly to us in the short term than cash compensation. We review long-term equity incentives for our named executive officers and other executives annually.

Historically, for our named executive officers, our stock option grants were of a size and term determined and approved by the Compensation Committee in consideration of the range of grants in the Radford Survey, generally falling within the 50-75% range outlined in the survey. We have traditionally used stock options as our form of equity compensation because stock options provide a relatively straightforward incentive for our executives, result in less immediate dilution of existing stockholders' interests and, prior to our adoption of FAS 123(R), resulted in less compensation expense for us relative to other types of equity awards. All grants of stock options to our employees are granted with exercise prices equal to or greater than the fair market value of our common stock on the respective grant dates. For a discussion of the determination of the fair market value of these grants, see "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and the Use of Estimates."

We do not time stock option grants to executives in coordination with the release of material non-public information. Our stock option grants have a 10-year contractual exercise term. In general, the option grants are also subject to the following post-termination and change in control provisions:

Event	Award Vesting	Exercise Term
• Termination by us for Reason Other than Cause, Disability or Death	• Forfeit Unvested Options	• Earlier of: (1) 90 days or (2) Remaining Option Period
• Termination for Disability, Death or Retirement	• Forfeit Unvested Options	• Earlier of: (1) 2 years or (2) Remaining Option Period
• Termination for Cause	• Forfeit Vested and Unvested Options	• Expire
• Other Termination	• Forfeit Unvested Options	• Earlier of: (1) 90 days or (2) Remaining Option Period
• Change in Control	• Accelerated*	• *

* The Compensation Committee may provide that, in the event of a change in control, any outstanding awards that are unexercisable or otherwise unvested will become fully vested and immediately exercisable. If there is a termination of employment, the applicable termination provisions regarding exercise term will apply.

In February 2016, Dr. Rubin and Mr. Bhonsle were granted options to purchase 79,100 shares and 89,100 shares of common stock, respectively, which vest monthly over 24 months from the grant date.

Compensation Committee Interlocks and Insider Participation

Members of our Compensation Committee of the board of directors are Joseph Akers and M. David MacFarlane. No member of our Compensation Committee was, or has been at any time in the last 10 years, an officer or employee of Titan or any of our former subsidiaries.

No member of the Compensation Committee has a relationship that would constitute an interlocking relationship with executive officers or directors of the Company or another entity.

SUMMARY COMPENSATION TABLE

The following table shows information concerning the annual compensation for services provided to us by our Chief Executive Officer, our Chief Financial Officer and our other executive officers for the periods set forth.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Options Awards ($) (1)	Stock Awards ($) (1)	All Other Compensation ($)	Total Compensation ($)
Marc Rubin, M.D.	2016	$295,000	$73,000	$245,311	$—	$ —	$ 613,311
Executive Chairman	2015	210,000	—	473,719	—	—	683,719
	2014	210,000	—	—	66,000	—	276,000
Sunil Bhonsle	2016	395,000	96,000	276,323	—	—	767,323
Chief Executive Officer, President and Principal Financial Officer	2015	300,000	—	496,767	—	—	796,767
	2014	300,000	—	—	66,000	—	366,000

(1) Amounts shown represent the grant date fair value computed in accordance with FASB ASC 718. The assumptions used by us with respect to the valuation of option grants and stock awards are set forth in "Titan Pharmaceuticals, Inc. Financial Statements—Notes to Financial Statements—Note 12—Stock Plans."

GRANTS OF PLAN-BASED AWARDS

The following table shows information concerning grants of plan based awards to named executive officers during the year ended December 31, 2016**.**

Name	Grant Date	Approval Date(1)	Number of Shares of Common Stock Underlying Awards (#)		Exercise or Base Price of Option Awards ($/Sh)	Grant Date Fair Value of Stock and Option Awards($)(2)
Marc Rubin, M.D.	2/02/2016	2/01/2016	79,100	(3)	$ —	$ 245,311
Sunil Bhonsle	2/02/2016	2/01/2016	89,100	(3)	$ —	$ 276,323

(1) All grants were approved by the Compensation Committee on the dates indicated.

(2) Valuation assumptions are found under "Titan Pharmaceuticals, Inc. Financial Statements—Notes to Financial Statements—Note 12—Stock Plans."

(3) These option grants vest monthly over 24 months from the grant date.

Employee Benefits Plans

The principal purpose of our stock incentive plans is to attract, motivate, reward and retain selected employees, consultants and directors through the granting of stock-based compensation awards. The stock option plans provides for a variety of awards, including non-qualified stock options, incentive stock options (within the meaning of Section 422 of the Code), stock appreciation rights, restricted stock awards, performance-based awards and other stock-based awards.

2001 Stock Option Plan

In August 2001, we adopted the 2001 Employee Non-Qualified Stock Option Plan, or the 2001 NQ Plan, pursuant to which 318,182 shares of common stock were authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan. The 2001 NQ Plan expired by its terms in August 2011. On December 31, 2016, options to purchase an aggregate of 204,375 shares of our common stock were outstanding under the 2001 NQ Plan.

2002 Stock Incentive Plan

In July 2002, we adopted the 2002 Stock Incentive Plan, or the 2002 Plan. Under the 2002 Plan, as amended, a total of approximately 1.3 million shares of our common stock were authorized for issuance to employees, officers, directors, consultants, and advisers. The 2002 Plan expired by its terms in July 2012. On December 31, 2016, options to purchase an aggregate of 631,343 shares of our common stock were outstanding under the 2002 Plan.

2014 Incentive Plan

In February 2014, our Board adopted the 2014 Incentive Plan, or the 2014 Plan, pursuant to which 454,546 shares of our common stock were authorized for issuance to employees, directors, officers, consultants and advisors. On December 31, 2016, options to purchase 300,744 shares of our common stock were outstanding under the 2014 Plan.

2015 Omnibus Equity Incentive Plan

In August 2015, our stockholders approved the 2015 Omnibus Equity Incentive Plan, or the 2015 Plan. The 2015 Plan, as amended in August 2016, authorized a total of 2.5 million shares of our common stock for issuance to employees, directors, officers, consultants and advisors. On December 31, 2016, options to purchase 618,000 shares of our common stock were outstanding under the 2015 Plan.

OUTSTANDING EQUITY AWARDS AT FISCAL YEAR-END

The following table summarizes the number of securities underlying outstanding plan awards for each named executive officer as of December 31, 2016.

	Option Awards				
Name	Number of Securities Underlying Unexercised Awards (#) Exercisable	Number of Securities Underlying Unexercised Awards (#) Unexercisable		Exercise Price ($)	Expiration Date
Marc Rubin, M.D.	79,546	—		$ 13.20	10/01/2017
	1,364	—		8.36	5/30/2018
	18,182	—		4.34	5/17/2019
	2,729	—		4.34	5/17/2019
	51,818	—		4.34	5/17/2019
	111,819	—		4.34	5/17/2019
	27,273	—		7.70	4/15/2021
	45,455	—		6.32	1/3/2022
	36,364	—		3.30	3/16/2025
	45,450	45,450	(1)	5.10	12/14/2025
	32,958	46,142	(1)	5.10	02/02/2026
Sunil Bhonsle	13,939	—		17.21	1/3/2017
	909	—		8.36	5/30/2018
	18,182	—		4.34	5/17/2019
	1,819	—		4.34	5/17/2019
	70,910	—		4.34	5/17/2019
	56,364	—		4.34	5/17/2019
	36,364	—		7.70	4/15/2021
	54,546	—		6.32	1/3/2022
	43,637	—		3.30	3/16/2025
	45,450	45,450	(1)	5.10	12/14/2025
	37,125	51,975	(1)	5.10	2/02/2026

(1) These option grants vest monthly over 24 months from the grant date.

There were no option exercises by our named executive officers during 2016.

Pension Benefits

We do not sponsor any qualified or non-qualified defined benefit plans.

Nonqualified Deferred Compensation

We do not maintain any non-qualified defined contribution or deferred compensation plans. The Compensation Committee, which is comprised solely of "outside directors" as defined for purposes of Section 162(m) of the Code, may elect to provide our officers and other employees with non-qualified defined contribution or deferred compensation benefits if the Compensation Committee determines that doing so is in our best interests. We sponsor a tax qualified defined contribution 401(k) plan in which Dr. Rubin and Mr. Bhonsle participated.

Employment Agreements

In September 2016, we entered into new employment agreements with Dr. Rubin and Mr. Bhonsle providing for base annual salaries of $295,000 and 395,000, respectively. The employment agreements contain the following terms:

- Bonuses. The executive may, at the sole discretion of the board of directors or the compensation committee, be considered for an annual bonus of up to 50% of his then base salary, payable in cash or awards under the Company's equity incentive plan.

- Term; Termination. The Employment Agreements have a two-year term but may be terminated by the Company for any reason at any time. In the event of termination by the Company without cause or by the executive for good reason not in connection with a change of control, as those terms are defined in such agreements, the executive is entitled to (i) severance for the greater of 12 months or the balance of the term, (ii) a pro rata portion of any annual bonus, (iii) 12 months of COBRA payments, and (iv) the immediate accelerated vesting of any unvested restricted shares and stock options. In the event such a termination is within 30 days prior to or six months following a change of control, the executive is entitled to an additional six months of COBRA payments.

- Restrictive Covenants. The Employment Agreements contain one-year post-termination noncompetition and non-solicitation provisions.

- Clawback. The Employment Agreements contain a two-year post-termination clawback of benefits provision in the event of a restatement of financial results upon which such benefits were based.

DIRECTOR COMPENSATION

Summary of Director Compensation

The following table summarizes compensation that our directors earned during 2016 for services as members of our Board.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Options Awards ($)(1)	Non-Equity Incentive Plan Compensation ($)	Nonqualified Deferred Compensation Earnings ($)	All Other Compensation ($)	Total ($)
Joseph A. Akers (2)	$ 57,500	$ —	$ —	$ —	$ —	$ —	$ 57,500
Victor J. Bauer, Ph.D. (3)(8)	32,083	—	—	—	—	—	32,083
Eurelio M. Cavalier (4)	57,500	—	—	—	—	—	57,500
M. David MacFarlane, Ph.D. (5)	52,083	—	—	—	—	—	52,083
James R. McNab, Jr. (6)	54,583	—	—	—	—	—	54,583
Ley S. Smith (7)(8)	32,083	—	—	—	—	—	32,083

(1) Valuation assumptions are found under “Titan Pharmaceuticals, Inc. Financial Statements—Notes to Financial Statements—Note 12—Stock Plans.”
(2) The aggregate number of option awards held at December 31, 2016 was 16,819.
(3) The aggregate number of option awards held at December 31, 2016 was 57,279.
(4) The aggregate number of option awards held at December 31, 2016 was 48,192. Mr. Cavalier retired from the Board effective February 28, 2017.
(5) The aggregate number of option awards held at December 31, 2016 was 42,736.
(6) The aggregate number of option awards held at December 31, 2016 was 16,819.
(7) The aggregate number of option awards held at December 31, 2016 was 48,192.
(8) Dr. Bauer and Mr. Smith resigned from their board positions effective August 1, 2016.

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

The following table sets forth as of March 10, 2017, the number of shares of our common stock beneficially owned by (i) each person who is known by us to be the beneficial owner of more than five percent of our common stock; (ii) each director and director nominee; (iii) each of the named executive officers in the Summary Compensation Table; and (iv) all directors and executive officers as a group. As of March 10, 2017, we had 21,198,879 shares of common stock issued and outstanding.

Beneficial ownership is determined in accordance with the rules of the Securities and Exchange Commission (the "SEC") and generally includes voting or investment power with respect to securities. Unless otherwise indicated, the stockholders listed in the table have sole voting and investment power with respect to the shares indicated.

Name and Address of Beneficial Owner [1]	**Shares Beneficially Owned** [2]		Percent of Shares Beneficially Owned	
Joseph A. Akers	39,819	(3)	*	
Sunil Bhonsle	595,950	(4)	2.8	%
Rajinder Kumar, Ph.D.	1,667	(5)	*	
M. David MacFarlane, Ph.D.	75,011	(6)	*	
James R. McNab, Jr.	126,819	(7)	*	
Marc Rubin, M.D.	664,923	(8)	3.1	
Scott A. Smith	1,667	(9)	*	
Robert E. Mead	1,355,220	(10)	6.4	%
All executive officers and directors as a group (7) persons	1,505,855		6.8	%

*Less than one percent.

(1) Unless otherwise indicated, the address of such individual is c/o Titan Pharmaceuticals, Inc., 400 Oyster Point Boulevard, Suite 505, South San Francisco, California 94080.

(2) In computing the number of shares beneficially owned by a person and the percentage ownership of a person, shares of our common stock subject to options held by that person that are currently exercisable or exercisable within 60 days of March 24, 2015 are deemed outstanding. Such shares, however, are not deemed outstanding for purposes of computing the percentage ownership of each other person. Except as indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.

(3) Includes 26,819 shares issuable upon exercise of outstanding options.

(4) Includes (i) 405,688 shares issuable upon exercise of outstanding options and (ii) 54,684 shares held in a family trust for which he serves as trustee.

(5) Includes 1,667 shares issuable upon exercise of outstanding options.

(6) Includes 52,736 shares issuable upon exercise of outstanding options.

(7) IncludesJ6,819 shares issuable upon exercise of outstanding options.

(8) Includes 508,606 shares issuable upon exercise of outstanding options.

(9) Includes 1,667 shares issuable upon exercise of outstanding options.

(10) Derived from a Schedule 13G filed by Mr. Mead. The address of Mr. Mead’s principal business office is 3653 Maplewood Ave., Dallas, TX 75205.

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

Certain Relationships and Related Transactions.

None.

Independence of Directors

The following members of our Board meet the independence requirements and standards currently established by the NYSE MKT: Joseph A. Akers, Rajinder Kumar, M. David MacFarlane, James R. McNab, Jr. and Scott A. Smith.

Board Committees

Our Board has established the following three standing committees: audit committee; compensation committee; and nominating and governance committee, or nominating committee.

The audit committee was formed in compliance with Section 3(a)(58)(A) of the Exchange Act and consists of Joseph A. Akers, M. David MacFarlane and James R. McNab, Jr., each of whom meets the independence requirements and standards currently established by the NYSE MKT and the SEC. In addition, the Board has determined that Messrs. Akers and Smith are “audit committee financial experts” and “independent” as defined under the relevant rules of the SEC and the NYSE MKT. The audit committee assists the Board by overseeing the performance of the independent auditors and the quality and integrity of Titan’s internal accounting, auditing and financial reporting practices. The audit committee is responsible for retaining (subject to stockholder ratification) and, as necessary, terminating, the independent auditors, annually reviews the qualifications, performance and independence of the independent auditors and the audit plan, fees and audit results, and pre-approves audit and non-audit services to be performed by the auditors and related fees. During the fiscal year ended December 31, 2016, the audit committee met four times.

The compensation committee makes recommendations to the Board concerning salaries and incentive compensation for our officers, including our Principal Executive Officer, and employees and administers our stock option plans. The compensation committee consists of Joseph A. Akers and M. David MacFarlane, each of whom meets the independence requirements and standards currently established by the NYSE MKT. The compensation committee met one time as a separate committee, and took action by written consent two times during the fiscal year ended December

31, 2016.

The purpose of the nominating committee is to assist the Board in identifying qualified individuals to become Board members, in determining the composition of the Board and in monitoring the process to assess Board effectiveness. The nominating committee consists of and James R. McNab, Jr., who meets the independence requirements and standards currently established by the NYSE MKT. The nominating committee did not meet as a separate committee, but took action by written consent one time during the fiscal year ended December 31, 2016.

The charters for the audit, compensation and nominating committees, which have been adopted by our Board, contain detailed descriptions of the committees' duties and responsibilities and are available in the Investor Relations section of our website at *www.titanpharm.com.*

Role of the Board in Risk Oversight

Our audit committee is primarily responsible for overseeing our risk management processes on behalf of the full Board. The audit committee receives reports from management at least quarterly regarding our assessment of risks. In addition, the audit committee reports regularly to the full Board, which also considers our risk profile. The audit committee and the full Board focus on the most significant risks we face and our general risk management strategies. While the Board oversees our risk management, management is responsible for day-to-day risk management processes. Our Board expects management to consider risk and risk management in each business decision, to proactively develop and monitor risk management strategies and processes for day-to-day activities and to effectively implement risk management strategies adopted by the audit committee and the Board. We believe this division of responsibilities is the most effective approach for addressing the risks we face and that our Board leadership structure, which also emphasizes the independence of the Board in its oversight of its business and affairs, supports this approach.

Board Meetings

Our business and affairs are managed under the direction of our Board, which is currently composed of eight members. The primary responsibilities of the Board are to provide oversight, strategic guidance, counseling and direction to our management. During the fiscal year ended December 31, 2016, the Board met six times and took action by written consent one time and no director attended fewer than 75% of the meetings of the Board and Board committees of which the director was a member.

Item 14. Principal Accounting Fees and Services.

Aggregate fees billed by OUM & Co. LLP, an independent registered public accounting firm, during the fiscal years ended December 31, 2016 and 2015 were as follows:

	2016	2015
Audit Fees	$164,688	$149,091
Audit-Related Fees	41,037	—
Tax Fees	26,000	32,425
All Other Fees	—	—
Total	$231,725	$181,516

Audit Fees —This category includes aggregate fees billed by our independent auditors for the audit of our annual financial statements, audit of management's assessment and effectiveness of internal controls over financial reporting, review of financial statements included in our quarterly reports on Form 10-Q and services that are normally provided by the auditor in connection with statutory and regulatory filings for those fiscal years.

Audit-Related Fees —This category consists of services by our independent auditors that, including accounting consultations on transaction related matters, are reasonably related to the performance of the audit or review of our financial statements and are not reported above under Audit Fees.

Tax Fees —This category consists of professional services rendered for tax compliance and preparation of our corporate tax returns and other tax advice.

All Other Fees —During the years ended December 31, 2016 and 2015, OUM & Co. LLP did not incur any fees for other professional services.

The audit committee reviewed and approved all audit and non-audit services provided by OUM & Co. LLP and concluded that these services were compatible with maintaining its independence. The audit committee approved the provision of all non-audit services by OUM & Co. LLP. Of the total number of hours expended during OUM & Co. LLP's engagement to audit our financial statements for the year ended December 31, 2016, none of the hours were attributed to work performed by persons other than permanent, full-time employees of OUM & Co. LLP.

Pre-Approval Policies and Procedures

In accordance with the SEC's auditor independence rules, the audit committee has established the following policies and procedures by which it approves in advance any audit or permissible non-audit services to be provided to us by our independent auditor.

Prior to the engagement of the independent auditors for any fiscal year's audit, management submits to the audit committee for approval lists of recurring audit, audit-related, tax and other services expected to be provided by the independent auditors during that fiscal year. The audit committee adopts pre-approval schedules describing the recurring services that it has pre-approved, and is informed on a timely basis, and in any event by the next scheduled meeting, of any such services rendered by the independent auditor and the related fees.

The fees for any services listed in a pre-approval schedule are budgeted, and the audit committee requires the independent auditor and management to report actual fees versus the budget periodically throughout the year. The audit committee will require additional pre-approval if circumstances arise where it becomes necessary to engage the independent auditor for additional services above the amount of fees originally pre-approved. Any audit or non-audit service not listed in a pre-approval schedule must be separately pre-approved by the audit committee on a case-by-case basis.

Every request to adopt or amend a pre-approval schedule or to provide services that are not listed in a pre-approval schedule must include a statement by the independent auditors as to whether, in their view, the request is consistent with the SEC's rules on auditor independence.

The audit committee will not grant approval for:

- any services prohibited by applicable law or by any rule or regulation of the SEC or other regulatory body applicable to us;
- provision by the independent auditors to us of strategic consulting services of the type typically provided by management consulting firms; or
- the retention of the independent auditors in connection with a transaction initially recommended by the independent auditors, the tax treatment of which may not be clear under the Internal Revenue Code and related regulations and which it is reasonable to conclude will be subject to audit procedures during an audit of our financial statements.

Tax services proposed to be provided by the auditor to any director, officer or employee of Titan who is in an accounting role or financial reporting oversight role must be approved by the audit committee on a case-by-case basis where such services are to be paid for by us, and the audit committee will be informed of any services to be provided to such individuals that are not to be paid for by us.

In determining whether to grant pre-approval of any non-audit services in the “all other” category, the audit committee will consider all relevant facts and circumstances, including the following four basic guidelines:

- whether the service creates a mutual or conflicting interest between the auditor and us;
- whether the service places the auditor in the position of auditing his or her own work;
- whether the service results in the auditor acting as management or an employee of our company; and
- whether the service places the auditor in a position of being an advocate for our company.

PART IV

Item 15. Exhibits and Financial Statements Schedules.

(a) 1. Financial Statements

An index to Financial Statements appears on page F-1.

2. Schedules

All financial statement schedules are omitted because they are not applicable, not required under the instructions or all the information required is set forth in the financial statements or notes thereto.

TITAN PHARMACEUTICALS, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of

Titan Pharmaceuticals, Inc.

We have audited the accompanying balance sheets of Titan Pharmaceuticals, Inc. as of December 31, 2016 and 2015, the related statements of operations and comprehensive income (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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Titan Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) and our report dated March 16, 2017 expressed an unqualified opinion thereon.

/s/ OUM & CO. LLP

San Francisco, California

March 16, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of

Titan Pharmaceuticals, Inc.

We have audited Titan Pharmaceuticals, Inc.'s internal control over financial reporting as of December 31, 2016, based on criteria established in Internal Control – Integrated Framework (2013*)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). Titan Pharmaceuticals, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying *Management's Annual Report on Internal Control Over Financial Reporting* included in Item 9A of this Form 10-K. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

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

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

In our opinion, Titan Pharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2016, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets of Titan Pharmaceuticals, Inc. as of December 31, 2016 and 2015, the related statements of operations and comprehensive income (loss), stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2016, and our report dated March 16, 2017 expressed an unqualified opinion thereon.

/s/ OUM & CO. LLP

San Francisco, California

March 16, 2017

TITAN PHARMACEUTICALS, INC.

BALANCE SHEETS

	December 31,	
	2016	2015
	(in thousands, except share and per share data)	
Assets		
Current assets:		
Cash and cash equivalents	$14,006	$7,857
Receivables	3,587	4,213
Prepaid expenses and other current assets	237	174
Total current assets	17,830	12,244
Property and equipment, net	837	1,043
Total Assets	$18,667	$13,287
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$3,015	$4,158
Accrued clinical trials expenses	1,387	341
Other accrued liabilities	455	354
Total current liabilities	4,857	4,853
Warrant liability	619	1,444
Total Liabilities	5,476	6,297
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.001 par value per share; 5,000,000 shares authorized, none issued and outstanding at December 31, 2016 and 2015.	—	—
Common stock, at amounts paid-in, $0.001 par value per share; 125,000,000 shares authorized, 21,198,879 and 20,059,820 shares issued and outstanding at December 31, 2016 and 2015, respectively.	297,855	297,828
Additional paid-in capital	24,300	23,261
Accumulated deficit	(308,964)	(314,099)
Total stockholders' equity	13,191	6,990
Total Liabilities and Stockholders' Equity	$18,667	$13,287

See accompanying notes to financial statements.

TITAN PHARMACEUTICALS, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

	Years ended December 31,		
	2016	2015	2014
	(in thousands, except per share amount)		
Revenue:			
License revenue	$15,065	$1,671	$3,646
Total revenue	15,065	1,671	3,646
Operating expenses:			
Research and development	6,126	4,675	4,075
General and administrative	4,596	3,755	3,046
Total operating expenses	10,722	8,430	7,121
Income (loss) from operations	4,343	(6,759)	(3,475)
Other income (expense):			
Interest income, net	37	—	—
Other income (expense), net	(70)	(8)	(11)
Non-cash gain (loss) on changes in the fair value of warrants	825	(4,512)	1,083
Other income (expense), net	792	(4,520)	1,072
Net income (loss) and comprehensive income (loss) applicable to common stockholders	$5,135	$(11,279)	$(2,403)
Basic net income (loss) per common share	$0.25	$(0.56)	$(0.14)
Diluted net income (loss) per common share	$0.20	$(0.56)	$(0.20)
Weighted average shares used in computing basic net income (loss) per common share	20,744	20,053	17,057
Weighted average shares used in computing diluted net income (loss) per common share	21,459	20,053	17,060

See accompanying notes to financial statements.

TITAN PHARMACEUTICALS, INC

STATEMENTS OF STOCKHOLDERS' EQUITY

(in thousands)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balances at December 31, 2013	16,143	$284,485	$ 21,692	$ (300,417)	$ —	$ 5,760
Net loss				(2,403)		(2,403)
Issuance of common stock, net of issuance costs	3,819	4,747				4,747
Issuance of common stock upon vesting of restricted stock awards, net	38	(36)				(36)
Stock-based compensation			543			543
Balances at December 31, 2014	20,000	289,196	22,235	(302,820)	—	8,611
Net loss				(11,279)		(11,279)
Reclassification of warrants from liabilities to stockholders' equity		8,646				8,646
Issuance of common stock upon vesting of restricted stock awards, net	60	(14)				(14)
Stock-based compensation			1,026			1,026
Balances at December 31, 2015	20,060	297,828	23,261	(314,099)	—	6,990
Net income				5,135		5,135
Issuance of common stock upon exercise of warrants, net	1,131					—
Issuance of common stock upon exercise of options, net	8	27				27
Stock-based compensation			1,039			1,039
Balances at December 31, 2016	21,199	$297,855	$ 24,300	$ (308,964)	$ —	$ 13,191

See accompanying notes to financial statements.

TITAN PHARMACEUTICALS, INC.

STATEMENTS OF CASH FLOWS

	Years ended December 31,		
	2016	2015	2014
	(in thousands)		
Cash flows from operating activities:			
Net income (loss)	$5,135	$(11,279)	$(2,403)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	377	358	353
Non-cash (gain) loss on changes in fair value of warrants	(825)	4,512	(1,083)
Stock-based compensation	1,039	1,026	543
Changes in operating assets and liabilities:			
Receivables	626	(245)	850
Prepaid expenses and other assets	(63)	(29)	59
Accounts payable	(1,143)	(250)	(710)
Other accrued liabilities	1,147	112	172
Deferred contract revenue	—	(1,671)	(3,646)
Net cash provided by (used in) operating activities	6,293	(7,466)	(5,865)
Cash flows from investing activities:			
Purchases of furniture and equipment	(171)	(133)	(18)
Net cash used in investing activities	(171)	(133)	(18)
Cash flows from financing activities:			
Proceeds from issuance of common stock from the exercise of stock options	27	—	—
Proceeds from issuance of common stock and warrants, net of issuance costs	—	—	9,591
Issuance of common stock from the vesting of restricted shares	—	(14)	(36)
Net cash provided by (used in) financing activities	27	(14)	9,555
Net increase (decrease) in cash	6,149	(7,613)	3,672
Cash and cash equivalents at beginning of period	7,857	15,470	11,798
Cash and cash equivalents at end of period	$14,006	$7,857	$15,470
Supplemental disclosure of cash flow information			
Fair value of warrants at the time of reclassification to equity	$—	$8,646	$—

See accompanying notes to financial statements.

TITAN PHARMACEUTICALS, INC.

NOTES TO FINANCIAL STATEMENTS

1. Organization and Summary of Significant Accounting Policies

The Company

We are a pharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs utilize our proprietary long-term drug delivery platform, ProNeura™, and focus primarily on innovative treatments for select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. We operate in only one business segment, the development of pharmaceutical products. All share and per share amounts give retroactive effect to a 1 for 5.5 reverse stock split effected in September 2015. See Note 11 “Stockholders’ Equity – Reverse Stock Split.”

The accompanying financial statements have been prepared assuming we will continue as a going concern.

In May 2016, the U.S. Food and Drug Administration (“FDA”) approved our Probuphine New Drug Application (“NDA”) and pursuant to our license agreement with Braeburn Pharmaceuticals, Inc. (“Braeburn”), as amended to date, we received a $15 million milestone payment and subsequently transferred the NDA to Braeburn.

At December 31, 2016, we had cash of approximately $14.0 million, which we believe is sufficient to fund our planned operations through the first quarter of 2018. We will require additional funds, either through payments from Braeburn under the license agreement or through other financing arrangements, to advance our current ProNeura development programs to later stage clinical studies and to complete the regulatory approval process necessary to commercialize any products we might develop.

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 amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

Going concern assessment

With the implementation of FASB's new standard on going concern, Accounting Standard Update, or ASU No. 2014-15, beginning with year ended December 31, 2016 and all annual and interim periods thereafter, we will assess going concern uncertainty in our financial statements to determine if we have sufficient cash on hand and working capital, including available borrowings on loans, to operate for a period of at least one year from the date the financial statements are issued or available to be issued, which is referred to as the “look-forward period” as defined by ASU No. 2014-15. As part of this assessment, based on conditions that are known and reasonably knowable to us, we will consider various scenarios, forecasts, projections, estimates and will make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and its ability to delay or curtail expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period in accordance with ASU No. 2014-15.

Stock-Based Compensation

We recognize compensation expense using a fair-value based method, for all stock-based payments including stock options and restricted stock awards and stock issued under an employee stock purchase plan. These standards require companies to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model. See Note 12 “Stock Plans,” for a discussion of our stock-based compensation plans. Our non-cash stock-based compensation expense related to employees and non-employee members of our Board totaled approximately $1.0 million, $1.0 million and $0.5 million for the years ended December 31, 2016, 2015 and 2014, respectively.

Warrants Issued in Connection with Equity Financing

We generally account for warrants issued in connection with equity financings as a component of equity, unless there is a deemed possibility that we may have to settle the warrants in cash. For warrants issued with deemed possibility of cash settlement, we record the fair value of the issued warrants as a liability at each reporting period and record changes in the estimated fair value as a non-cash gain or loss in the Statements of Operations and Comprehensive Income (Loss).

Cash, Cash Equivalents and Marketable Securities

Our investment policy emphasizes liquidity and preservation of principal over other portfolio considerations. We select investments that maximize interest income to the extent possible given these two constraints. We satisfy liquidity requirements by investing excess cash in securities with different maturities to match projected cash needs and limit concentration of credit risk by diversifying our investments among a variety of high credit-quality issuers and limit the amount of credit exposure to any one issuer. The estimated fair values have been determined using available market information. We do not use derivative financial instruments in our investment portfolio.

All investments with original maturities of three months or less are considered to be cash equivalents. Marketable securities, consisting primarily of high-grade debt securities, U.S. government and corporate notes and bonds, and commercial paper, are classified as available-for-sale at time of purchase and carried at fair value. If the fair value of a security is below its amortized cost and we plan to sell the security before recovering its cost, the impairment is considered to be other-than-temporary. Other-than-temporary declines in fair value of our marketable securities are charged against interest income. We had money market funds of approximately $13.7 million and $7.6 million as of December 31, 2016 and 2015, respectively, included in our cash and cash equivalents. We did not hold any marketable securities as of December 31, 2016 and 2015.

Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from three to five years. Leasehold improvements are amortized over the shorter of the lease term or the estimated useful life of the assets.

Revenue Recognition

We generate revenue principally from collaborative research and development arrangements, technology licenses, and government grants. Consideration received for revenue arrangements with multiple components is allocated among the separate units of accounting based on their respective selling prices. The selling price for each unit is based on vendor-specific objective evidence, or VSOE, if available, third party evidence if VSOE is not available, or estimated selling price if neither VSOE nor third party evidence is available. The applicable revenue recognition criteria are then applied to each of the units.

Revenue is recognized when the four basic criteria of revenue recognition are met: (1) a contractual agreement exists; (2) transfer of technology has been completed or services have been rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

- Technology license agreements typically consist of non-refundable upfront license fees, annual minimum access fees or royalty payments. Non-refundable upfront license fees and annual minimum payments received with separable stand-alone values are recognized when the technology is transferred or accessed, provided that the technology transferred or accessed is not dependent on the outcome of our continuing research and development efforts.

- Royalties earned are based on third-party sales of licensed products and are recorded in accordance with contract terms when third-party results are reliably measurable and collectability is reasonably assured. We no longer recognize royalty income related to the Fanapt royalty payments received from Novartis (see Note 8, “Royalty Liability” for further discussion).

- Government grants, which support our research efforts in specific projects, generally provide for reimbursement of approved costs as defined in the notices of grants. Grant revenue is recognized when associated project costs are incurred.

- Collaborative arrangements typically consist of non-refundable and/or exclusive technology access fees, cost reimbursements for specific research and development spending, and various milestone and future product royalty payments. If the delivered technology does not have stand-alone value, the amount of revenue allocable to the delivered technology is deferred. Non-refundable upfront fees with stand-alone value that are not dependent on future performance under these agreements are recognized as revenue when received, and are deferred if we have continuing performance obligations and have no evidence of fair value of those obligations. Cost reimbursements for research and development spending are recognized when the related costs are incurred and when collections are reasonably expected. Payments received related to substantive, performance-based “at-risk” milestones are recognized as revenue upon achievement of the clinical success or regulatory event specified in the underlying contracts, which represent the culmination of the earnings process. Amounts received in advance are recorded as deferred revenue until the technology is transferred, costs are incurred, or a milestone is reached.

Research and Development Costs and Related Accrual

Research and development expenses include internal and external costs. Internal costs include salaries and employment related expenses, facility costs, administrative expenses and allocations of corporate costs. External expenses consist of costs associated with outsourced clinical research organization activities, sponsored research studies, product registration, patent application and prosecution, and investigator sponsored trials. We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by CROs and clinical sites. These costs are recorded as a component of research and development expenses. Under our agreements, progress payments are typically made to investigators, clinical sites and CROs. We analyze the progress of the clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of accrued liabilities. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. Actual results could differ from those estimates under different assumptions. Revisions are charged to expense in the period in which the facts that give rise to the revision become known.

Net Income (Loss) Per Share

Basic net income (loss) per share excludes the effect of dilution and is computed by dividing net income (loss) by the weighted-average number of shares outstanding for the period. Diluted net income (loss) per share reflects the potential dilution that could occur if securities or other contracts to issue shares were exercised into shares. In calculating diluted net income (loss) per share, the numerator is adjusted for the change in the fair value of the warrant liability (only if dilutive) and the denominator is increased to include the number of potentially dilutive common shares assumed to be outstanding during the period using the treasury stock method.

The following table sets forth the reconciliation of the numerator and denominator used in the computation of basic and diluted net income (loss) per common share for the years ended December 31, 2016, 2015 and 2014:

	Years ended December 31,		
(in thousands, except per share amounts)	2016	2015	2014
Numerator:			
Net income (loss) used for basic earnings per share	$5,135	$(11,279)	$(2,403)
Less change in fair value of warrant liability	825	—	1,083
Net income (loss) used for diluted earnings per share	$4,310	$(11,279)	$(3,486)
Denominator:			
Basic weighted-average outstanding common shares	20,744	20,053	17,057
Effect of dilutive potential common shares resulting from options	141	—	3
Effect of dilutive potential common shares resulting from warrants	574	—	—
Weighted-average shares outstanding—diluted	21,459	20,053	17,060
Net income (loss) per common share:			
Basic	$0.25	$(0.56)	$(0.14)
Diluted	$0.20	$(0.56)	$(0.20)

The table below presents common shares underlying stock options and warrants that are excluded from the calculation of the weighted average number of shares of common stock outstanding used for the calculation of diluted net income (loss) per common share. These are excluded from the calculation due to their anti-dilutive effect for the years ended December 31, 2016, 2015 and 2014:

	Years ended December 31,		
(in thousands)	2016	2015	2014
Weighted-average anti-dilutive common shares resulting from options and awards	1,286	1,346	1,254
Weighted-average anti-dilutive common shares resulting from warrants	—	231	425
	1,286	1,577	1,679

Comprehensive Income (Loss)

Comprehensive income and loss for the periods presented is comprised solely of our net income and loss. Comprehensive income for the year ended December 31, 2016 was $5.1 million. Comprehensive loss for the years ended December 31, 2015 and 2014 was $ 11.3 million and $2.4 million, respectively.

Recent Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments,*

addressing eight specific cash flow issues in an effort to reduce diversity in practice. The amended guidance is effective for fiscal years beginning after December 31, 2017, and for interim periods within those years. Early adoption is permitted. We do not expect the amended guidance to have a material impact on its statements of cash flows.

In June 2014, the FASB issued ASU No. 2014-12, *Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period* ("ASU 2014-12"). The standard provides guidance that a performance target that affects vesting of a share-based payment and that could be achieved after the requisite service condition is a performance condition. ASU 2014-12 is effective for annual reporting periods beginning after December 15, 2015. The adoption of this ASU did not have a significant impact on our financial statements.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"), which supersedes nearly all existing revenue recognition guidance under U.S. GAAP. The core principle of ASU 2014-09 is to recognize revenues when promised goods or services are transferred to customers in an amount that reflects the consideration to which an entity expects to be entitled for those goods or services. ASU 2014-09 defines a five step process to achieve this core principle and, in doing so, more judgment and estimates may be required within the revenue recognition process than are required under existing U.S. GAAP.

The standard is effective for annual periods beginning after December 15, 2017, and interim periods therein, using either of the following transition methods: (i) a full retrospective approach reflecting the application of the standard in each prior reporting period with the option to elect certain practical expedients, or (ii) a retrospective approach with the cumulative effect of initially adopting ASU 2014-09 recognized at the date of adoption (which includes additional footnote disclosures). We are currently evaluating the impact of our pending adoption of ASU 2014-09 on our financial statements and have not yet determined the method by which we will adopt the standard.

Subsequent Events

We have evaluated events that have occurred subsequent to December 31, 2016 and through the date that the financial statements are issued.

Fair Value Measurements

We measure the fair value of financial assets and liabilities based on authoritative guidance which defines fair value, establishes a framework consisting of three levels for measuring fair value, and requires disclosures about fair value measurements. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. There are three levels of inputs that may be used to measure fair value:

Level 1 – quoted prices in active markets for identical assets or liabilities;

Level 2 – quoted prices for similar assets and liabilities in active markets or inputs that are observable;

Level 3 – inputs that are unobservable (for example cash flow modeling inputs based on assumptions).

Financial instruments, including receivables, accounts payable and accrued liabilities are carried at cost, which we believe approximates fair value due to the short-term nature of these instruments. The $13.7 million and $7.6 million fair values of money market funds as of December 31, 2016 and 2015 included in our cash and cash equivalents, are classified as Level 1 and were derived from quoted market prices as active markets for these instruments exists. Our warrant liabilities are classified within level 3 of the fair value hierarchy because the value is calculated using significant judgment based on our own assumptions in the valuation of these liabilities.

As a result of the fair value adjustment of the warrant liabilities, during the year ended December 31, 2016 we recorded a non-cash gain on decreases in the fair value of $825,000 and during the year ended December 31, 2015 we recorded a non-cash loss on increases in the fair value of $4,512,000 in our Statements of Operations and Comprehensive Income (Loss). See Note 9, “Warrant Liability” for further discussion on the calculation of the fair value of the warrant liability.

The following table rolls forward the fair value of the Company's warrant liability, the fair value of which is determined by Level 3 inputs for the years ended December 31, 2016 and 2015 (in thousands):

	December 31,	
	2016	2015
Fair value, beginning of period	$1,444	$5,578
Reclassification of Class A and Underwriter warrants to equity	—	(8,646)
Change in fair value	(825)	4,512
Fair value, end of period	$619	$1,444

2. Property and Equipment

Property and equipment consisted of the following at December 31, 2016 and 2015 (in thousands):

	2016	2015
Furniture and office equipment	$388	$388
Leasehold improvements	408	408
Laboratory equipment	2,548	2,466
Computer equipment	1,135	1,046
	4,479	4,308
Less accumulated depreciation and amortization	(3,642)	(3,265)
Property and equipment, net	$837	$1,043

Depreciation and amortization expense was $377,000, $358,000 and $353,000 for the years ended December 31, 2016, 2015 and 2014, respectively.

3. Research and License Agreements

We have entered into various agreements with research institutions, universities, clinical research organizations and other entities for the performance of research and development activities and for the acquisition of licenses related to those activities. Expenses under these agreements totaled approximately $3,000 in the years ended December 31, 2015 and 2014.

We have no annual payment requirements to maintain our current licenses after 2015. Certain licenses provide for the payment of royalties by us on future product sales, if any. In addition, in order to maintain these licenses and other rights during product development, we must comply with various conditions including the payment of patent-related costs.

4. Agreement with Sanofi-Aventis SA

In 1997, we entered into an exclusive license agreement with Sanofi-Aventis. The agreement gave us a worldwide license to the patent rights and know-how related to the antipsychotic agent iloperidone, including the ability to

develop, use, sublicense, manufacture and sell products and processes claimed in the patent rights. The license agreement provided that we pay royalties based on net sales. The underlying patent rights expired in November 2016.

5. Iloperidone Sublicense

In November 1997, we granted Novartis a worldwide sublicense to iloperidone (Fanapt®) in exchange for tiered royalties on net sales ranging from 8% to 10% and assumption of responsibility for all clinical development, registration, manufacturing and marketing of the product. Novartis had the right to commercialize Fanapt in the United States and Canada. In June 2004, Novartis transferred all rights to commercialize Fanapt in the United States and Canada to Vanda Pharmaceuticals, Inc. and in December 2014 assigned the agreement to Vanda. Our rights under the agreements have not changed. Pursuant to agreements entered into during 2011, we sold substantially all of our future royalties on the sales of Fanapt ® to a third party and, accordingly, we no longer recognize revenue related to Fanapt. See Note 8, “Royalty Liability” for further discussion of our royalty liabilities.

6. Braeburn License

In December 2012, we entered into the Agreement with Braeburn granting Braeburn exclusive commercialization rights to Probuphine in the United States and its territories, including Puerto Rico, and Canada. As part of the Agreement, we received a non-refundable up-front license fee of $15.75 million (approximately $15.0 million, net of expenses), and would have received $45.0 million upon approval by the FDA of the NDA as well as up to an additional $130.0 million upon achievement of specified sales milestones and up to $35.0 million in regulatory milestones for additional indications, including chronic pain. We would have received tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties.

On May 28, 2013, we entered into the Amendment to the Agreement primarily to modify certain of the termination provisions of the Agreement. The Amendment gives Braeburn the right to terminate the Agreement in the event that (A) after May 28, 2013, based on written or oral communications from or with the FDA, Braeburn reasonably determines either that the FDA will require significant development to be performed before approval of the Probuphine™ NDA can be given, such as, but not limited to, one or more additional controlled clinical studies with a clinical efficacy endpoint, or substantial post-approval commitments that may materially impact the product's financial returns or that the FDA will require one or more changes in the proposed label, which change(s) Braeburn reasonably determines will materially reduce the authorized prescribed patient base, or (B) the NDA has not been approved by the FDA on or before June 30, 2014. The Amendment also provides that we will share in legal and consulting expenses in excess of a specified amount prior to approval of the NDA.

On July 2, 2013, we entered into the Second Amendment to the Agreement primarily to establish and provide the parameters for a committee comprised of representatives of Titan and Braeburn responsible for and with the authority to make all decisions regarding the development and implementation of a strategic plan to seek approval from the FDA of Probuphine® for subdermal use in the maintenance treatment of adult patients with opioid dependence, including development of the strategy for all written and oral communications with the FDA. The Second Amendment also makes Braeburn the primary contact for FDA communications regarding the Probuphine NDA.

On November 12, 2013, we entered into the stock purchase agreement pursuant to which Braeburn made a $5 million equity investment in our company and the Third Amendment primarily to modify the amount and timing of the approval and sales milestone payments payable under the Agreement. Under the Third Amendment, we are entitled to receive a $15 million payment upon FDA approval of the NDA and royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. The agreement also provides for up to $165 million in sales milestones and $35 million in regulatory milestones. In addition, we are entitled to receive a low single digit royalty, up to an aggregate of $50 million, on sales by Braeburn, if any, of other continuous delivery treatments for opioid dependence as defined in the Third Amendment and can elect to receive a low single digit royalty on sales by Braeburn, if any, of other products in the addiction market in exchange for a similar reduction in our royalties on Probuphine.

We have evaluated the revenue components of the agreement, which includes multiple elements, to determine whether the components of the arrangement represent separate units of accounting. We have determined that the non-refundable, up-front license fee of $15.75 million (approximately $15.0 million, net of expenses) and our costs up to the PDUFA date to be one deliverable which will be accounted for as a single unit of accounting. This amount was recognized on a straight-line basis over the estimated period during which we expected to meet the contract deliverables. Based on our understanding of subsequent steps to be performed following the PDUFA date related to the completion of the transition of production and supply services to Braeburn, we estimated the revenue recognition period from the up-front payment to be approximately 12 months from the date of the Agreement. Accordingly, we recognized revenue for the up-front payment ratably from December 14, 2012, the date of the Agreement, through March 31, 2013 at an amount equal to approximately $1.25 million per month. Following the receipt of the CRL in April 2013, we estimated the revenue recognition period for the up-front payment would be approximately 18 months from the date of the Agreement. Accordingly, we recognized the remaining revenue from the up-front payment ratably

from April 1, 2013 through September 30, 2013 at an amount equal to approximately $733,000 per month. Following our meeting with the FDA in November 2013 and subsequent discussions in which an agreement in principle with respect to a path forward was reached with the FDA, we estimated the revenue recognition period for the up-front payment to be approximately 30 months from the date of the Agreement. Accordingly, we recognized the remaining revenue from the up-front payment ratably from September 30, 2013 at an amount equal to approximately $304,000 per month. As of December 31, 2016, we have recognized approximately $15.0 million in license revenue related to the up-front payment. Internal and external research and development costs related to this product will be expensed in the period incurred.

Under the Agreement, we received a $15.0 million milestone payment from Braeburn following the achievement of FDA approval of the product NDA. As such, upon receipt of FDA approval our obligation was fulfilled and we recognized the $15.0 million regulatory milestone payment from Braeburn in accordance with the milestone method of revenue recognition. We will be reimbursed by Braeburn for any development services and activities performed by us at Braeburn's request.

The Agreement also provides for a development committee. The duties of the development committee are to periodically report to each other, exchange information, and confer with and review the clinical development of the product and matters pertaining to regulatory approval. The development committee has no authority to approve or direct either party to take action, approve or withhold approval for any plan, budget, timeline or strategies, amend, modify or waive compliance with the Agreement, create new obligations or alter, increase or expand, or waive compliance with the Agreement, create new obligations not specified in the Agreement, or alter, increase or expand, or waive compliance by a party with obligations under the Agreement. The development committee can be disbanded upon mutual agreement of the parties and shall automatically disband six years after the NDA transfer date. Based on the above, we have determined that participation in the development committee is perfunctory and inconsequential, and is not considered a separate deliverable in the Agreement.

7. Commitments and Contingencies

Lease Commitments

We lease our facilities under an operating lease that expires in June 2021. Rent expense was $257,000, $211,000, and $209,000 for years ended December 31, 2016, 2015, and 2014, respectively.

The following is a schedule of future minimum lease payments at December 31, 2016 (in thousands):

2017	$277
2018	287
2019	299
2020	308
2021 and thereafter	155
	$1,326

Legal Proceedings

There are no ongoing legal proceedings against our company.

8. Royalty Liability

On March 28, 2013, we amended the agreements with Deerfield terminating our option to repurchase the royalty rights. As a result, we recognized a gain on the extinguishment of the royalty liability of approximately $9.0 million, which was recorded in other income, because we are no longer required to account for it as a liability. Additionally, we will no longer recognize royalty income related to the Fanapt royalty payments received from Novartis.

9. Warrant Liability

On March 15, 2011, in connection with the facility agreement, we issued Deerfield six-year warrants to purchase 1,090,910 shares of our common stock at an initial exercise price of $8.64 per share. As a result of our April 2012 sale of equity, and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants was adjusted to $6.88 per share. The Deerfield Warrants contain a provision where the warrant holder has the option to receive cash, equal to the Black-Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480, *Distinguishing Liabilities from Equity* requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Binomial Lattice ("Lattice") valuation model, and the changes in the fair value are recorded in the Statements of Operations and Comprehensive Income (Loss). The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity.

On February 6, 2013, the facility agreement was amended to provide that the exercise price of the Deerfield Warrants could be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised all of the Deerfield Warrants resulting in a $7.5 million reduction in the amount owed to Deerfield.

On April 9, 2012, in connection with subscription agreements with certain institutional investors for the purchase and sale of 1,185,034 shares of our common stock, we issued (i) six-year warrants ("Series A Warrants") to purchase 1,185,034 shares of common stock at an exercise price of $6.32 per share and (ii) six-month warrants to purchase 1,185,034 shares of common stock at an exercise price of $4.67 per share which expired in October 2012. As a result of our public offering in October 2014 and anti-dilution provisions contained in the outstanding Series A Warrants, the exercise price of such warrants was reduced from $6.32 to $4.89 per share. The Series A Warrants contain a provision where the warrant holder has the option to receive cash, equal to the Black Scholes fair value of the remaining unexercised portion of the warrant, as cash settlement in the event that there is a fundamental transaction (contractually defined to include various merger, acquisition or stock transfer activities). Due to this provision, ASC 480, *Distinguishing Liabilities from Equity* requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded

in the Statements of Operations and Comprehensive Income (Loss). The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity.

During the year ended December 31, 2013, Series A Warrants to purchase 201,639 shares of common stock were exercised resulting in gross proceeds of approximately $1,275,000. The remaining Series A Warrants to purchase 983,395 shares of common stock will expire in April 2018.

The key assumptions used to value the Series A Warrants were as follows:

Assumption	December 31, 2016	
Expected price volatility	62	%
Expected term (in years)	1.27	
Risk-free interest rate	0.94	%
Dividend yield	0.00	%
Weighted-average fair value of warrants	$ 0.63	

In October 2014, we completed an underwritten public offering (the "2014 Offering") of units consisting of one share of common stock and 0.75 of a warrant ("Class A Warrant"). The Class A Warrants entitle the holders thereof to purchase an aggregate of 2,863,643 shares of our common stock at an initial exercise price of $3.30 per share of common stock.

We agreed to hold a stockholders meeting no later than August 31, 2015 in order to seek stockholder approval for an amendment to our certificate of incorporation to either (i) increase the number of shares of common stock we are authorized to issue or (ii) effect a reverse split of the common stock, in either case in an amount sufficient to permit the exercise in full of the Class A Warrants in accordance with their terms. Failure to effect an increase in our authorized shares of common stock or effect a reverse split of our common stock prior to October 9, 2015 would have required us to pay liquidated damages in the aggregate amount of $2,500,000. In September 2015, we effected a 1-for-5.5 reverse split of our common stock (the "Reverse Split"), which was within the range approved by our stockholders at the annual meeting held on August 24, 2015.

We also agreed to issue to the underwriter warrants to purchase 114,546 shares of common stock (the "Underwriter Warrants"). The Underwriter Warrants have an exercise price per share of $3.30 and may be exercised on a cashless basis. The Underwriter Warrants are not redeemable by us. The Underwriter Warrants are substantially the same form as the Class A Warrants included in the units except that they do not include certain liquidated damages rights contained in the Class A Warrants and will expire on the fifth anniversary of the date of effectiveness of the registration statement.

At the time these warrants were issued, we did not have adequate authorized and unissued common shares to be able to satisfy the exercise of these warrants. ASC 480, *Distinguishing Liabilities from Equity* requires that these warrants be classified as liabilities. The fair values of these warrants have been determined using the Lattice valuation model, and the changes in the fair value are recorded in the Statements of Operations and Comprehensive Income (Loss). The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity. On September 29, 2015, we effected the Reverse Split, which permits the exercise in full of the Class A Warrants in accordance with their terms and, accordingly, the associated warrant liability was reclassified to stockholders' equity.

10. Guarantees and Indemnifications

As permitted under Delaware law and in accordance with our Bylaws, we indemnify our officers and directors for certain events or occurrences while the officer or director is or was serving at our request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum amount of potential future indemnification is unlimited; however, we have a director and officer insurance policy that limits our exposure and may enable us to recover a portion of any future amounts paid. We believe the fair value of these indemnification

agreements is minimal. Accordingly, we have not recorded any liabilities for these agreements as of December 31, 2016.

In the normal course of business, we have commitments to make certain milestone payments to various clinical research organizations in connection with our clinical trial activities. Payments are contingent upon the achievement of specific milestones or events as defined in the agreements, and we have made appropriate accruals in our financial statements for those milestones that were achieved as of December 31, 2016. We also provide indemnifications of varying scope to our CROs and investigators against claims made by third parties arising from the use of our products and processes in clinical trials. Historically, costs related to these indemnification provisions were immaterial. We also maintain various liability insurance policies that limit our exposure. We are unable to estimate the maximum potential impact of these indemnification provisions on our future results of operations.

11. Stockholders' Equity (Deficit)

Reverse Stock Split

On September 29, 2015, pursuant to prior stockholder authorization, our Board effected the Reverse Split of the outstanding shares of our common stock at a ratio of one (1) share for every five and one-half (5.5) shares outstanding, so that every five and one-half (5.5) outstanding shares of common stock before the Reverse Split represents one (1) share of common stock after the Reverse Split. Pursuant to their respective terms, the number of shares underlying our outstanding options and warrants was reduced by the Reverse Split ratio.

All share and per share amounts in the accompanying financial statements have been restated for all periods presented to give retroactive effect to the Reverse Split. The shares of common stock retained a par value of $0.001 per share.

Common Stock

In May and June 2016, 1,072,307 shares of common stock were issued upon the cashless net exercise of 2,016,075 Class A Warrants in accordance with their terms. There were 847,569 Class A Warrants outstanding at December 31, 2016.

In May and June 2016, 58,569 shares of common stock were issued upon the cashless net exercise of 114,546 Underwriter Warrants in accordance with their terms. There were no remaining Underwriter Warrants outstanding at December 31, 2016.

In October 2014, we completed the 2014 Offering. Net proceeds were approximately $9.6 million after deducting underwriting discounts, commissions and other related expenses. As a result of the 2014 Offering, and pursuant to the terms of the existing Series A Warrants, the exercise price of the Series A Warrants (See Note 9, "Warrant Liability" for further discussion) was adjusted to $4.89 per share.

As of December 31, 2016, warrants to purchase shares of common stock consisted of the following (in thousands, except per share price):

Date Issued	Expiration Date	Exercise Price	Outstanding at December 31, 2016
04/13/2012	04/13/2018	$ 4.89	983
10/08/2014	10/08/2020	$ 3.30	848
			1,831

Shares Reserved for Future Issuance

As of December 31, 2016, shares of common stock reserved by us for future issuance consisted of the following (in thousands):

Stock options outstanding	2,002
Shares issuable upon the exercise of warrants	1,831
	3,833

12. Stock Plans

In August 2015, our stockholders approved the 2015 Omnibus Equity Incentive Plan, or the 2015 Plan. The 2015 Plan, as amended in August 2016, authorized a total of 2,500,000 shares of our common stock for issuance to employees, directors, officers, consultants and advisors. On December 31, 2016, options to purchase 618,000 shares of our common stock were outstanding under the 2015 Plan.

In February 2014, our Board adopted the 2014 Incentive Plan, or the 2014 Plan, pursuant to which 454,546 shares of our common stock were authorized for issuance to employees, directors, officers, consultants and advisors. On December 31, 2016, options to purchase 300,744 shares of our common stock were outstanding under the 2014 Plan. Upon receipt of stockholder approval of the 2015 Plan, the 2014 Plan was terminated.

In May 2009, we granted 111,819 and 56,364 non-qualified stock options outside of our stock option plans to Dr. Rubin and Mr. Bhonsle, respectively, at an exercise price of $4.34 that vested over 48 months from the grant date.

In October 2007, we granted 79,546 non-qualified stock options outside of our stock option plans to Dr. Rubin, at an exercise price of $13.20 per share that vested over 48 months from the grant date.

In July 2002, we adopted the 2002 Stock Incentive Plan ("2002 Plan"). The 2002 Plan, as amended in 2005, authorized a total of approximately 1.3 million shares of our common stock for issuance to employees, officers, directors, consultants, and advisers. The exercise prices of options granted under the 2002 Plan were 100% of the fair market value of our common stock on the date of grant. The 2002 Plan expired by its terms in July 2012. On December 31, 2016, options to purchase an aggregate of 631,343 shares of our common stock were outstanding under the 2002 Plan.

In August 2001, we adopted the 2001 Employee Non-Qualified Stock Option Plan ("2001 NQ Plan") pursuant to which 318,182 shares of common stock were authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan. The exercise prices of options granted under the 2001 NQ Plan were 100% of the fair market value of our common stock on the date of grant. The 2001 Stock Option Plan expired by its terms in August 2011. On December 31, 2016, options to purchase an aggregate of 204,375 shares of our common stock were outstanding under the 2001 NQ Plan.

Activity under our stock plans, as well as non-plan activity, is summarized below (shares in thousands):

	Shares or Awards Available For Grant	Number of Options and Awards Outstanding	Weighted Average Exercise Price
Balance at December 31, 2013	—	1,223	$ 7.21
Increase in shares reserved	455	—	—
Options granted	(60)	60	$ 3.47
Options cancelled and forfeited	—	(5)	$ 9.13
Options expired	—	(75)	$ 11.66
Awards granted	(113)	113	$ —
Awards issued	—	(47)	$ —
Balance at December 31, 2014	282	1,269	$ 6.40
Increase in shares reserved	1,364	—	—
Options granted	(700)	700	$ 4.46
Options expired	—	(20)	$ 13.27
Awards issued	—	(66)	$ —

Termination of option plan	(32)	—	$ —
Balance at December 31, 2015	914	1,883	$ 5.83
Increase in shares reserved	1,136	—	—
Options granted	(168)	168	$ 5.10
Options exercised	—	(8)	$ 3.37
Options expired	—	(41)	$ 10.85
Balance at December 31, 2016	1,882	2,002	$ 5.67

Options to purchase approximately 1.7 million and 1.4 million shares were exercisable at December 31, 2016 and 2015, respectively. The options outstanding at December 31, 2016 have been segregated into five ranges for additional disclosure as follows (options in thousands):

Range of Exercise Prices	Options Outstanding Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Options Exercisable Number Exercisable	Weighted Average Exercise Price
$2.47 - $4.06	306	7.88	$ 3.34	306	$ 3.34
$4.07 - $4.72	411	2.37	$ 4.34	411	$ 4.34
$4.73 - $5.41	618	8.99	$ 5.10	325	$ 5.10
$5.42 - $6.54	303	4.97	$ 6.31	303	$ 6.31
$6.55 - $17.21	364	2.55	$ 9.60	364	$ 9.60
$2.47 - $17.21	2,002	5.68	$ 5.67	1,709	$ 5.77

We use the Black-Scholes-Merton option-pricing model with the following assumptions to estimate the stock-based compensation expense for the years ended December 31, 2016, 2015 and 2014:

	Years Ended December 31,		
	2016	2015	2014
Weighted-average risk-free interest rate	1.53 %	1.88 %	2.04 %
Expected dividend payments	—	—	—
Expected holding period (years)(1)	6.53	6.48	6.46
Weighted-average volatility factor(2)	0.92	1.16	1.65
Estimated forfeiture rates for options granted	29 %	30 %	31 %

(1) Expected holding period is based on historical experience of similar awards, giving consideration to the contractual terms of the stock-based awards, vesting schedules and the expectations of future employee behavior.

(2) Weighted average volatility is based on the historical volatility of our common stock.

(3) Estimated forfeiture rates are based on historical data.

During the year ended December 31, 2016, options to purchase 168,000 shares were granted to employees, directors and consultants. Based upon the above methodology, the weighted-average fair value of options and awards granted during the years ended December 31, 2016, 2015 and 2014 was $3.10, $3.67 and $3.52, respectively.

The following table summarizes the stock-based compensation expense and impact on our basic and diluted loss per share for the years ended December 31, 2016, 2015 and 2014:

	Years Ended December 31,		
(in thousands, except per share amounts)	2016	2015	2014
Research and development	$ 386	$ 341	$ 245
General and administrative	653	685	298
Total stock-based compensation expenses	$ 1,039	$ 1,026	$ 543
Increase in basic net income (loss) per share	$ (0.05)	$ (0.05)	$ (0.03)
Increase in diluted net income (loss) per share	$ (0.05)	$ (0.05)	$ (0.03)

No tax benefit was recognized related to stock-based compensation expense since we have incurred operating losses and we have established a full valuation allowance to offset all the potential tax benefits associated with our deferred tax assets.

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

(in thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2016	1,883	$ 5.83		
Granted	168	5.10		
Exercised	(8)	3.37		
Expired	(41)	10.85		
Outstanding at December 31, 2016	2,002	$ 5.67	5.68	$ 203
Exercisable at December 31, 2016	1,709	$ 5.77	5.12	$ 203

As of December 31, 2016, there was approximately $704,000 of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 0.88 years.

There were no outstanding stock awards at December 31, 2016.

13. Income Taxes

As of December 31, 2016, we had net operating loss carryforwards for federal income tax purposes of approximately $247.7 million that expire at various dates through 2035, and federal research and development tax credits of approximately $8.7 million that expire at various dates through 2035. We also had net operating loss carryforwards for California income tax purposes of approximately $124.4 million that expire at various dates through 2035 and state research and development tax credits of approximately $8.5 million which do not expire. Approximately $12.4 million of federal and state net operating loss carryforwards represent stock option deductions arising from activity under our stock option plans, the benefit of which will increase additional paid in capital when realized.

Current federal and California tax laws include substantial restrictions on the utilization of net operating losses and tax credits in the event of an ownership change of a corporation. We have performed a change in ownership analysis through December 31, 2016 and all of our net operating loss and tax credit carryforwards are available to offset future taxable income, if any.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes and operating loss and credit carryforwards. Significant components of our deferred tax assets are as follows (in thousands):

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$87,267	$91,365
Research credit carryforwards	14,322	13,884
Other, net	2,637	3,417
Deferred revenue	—	—
Total deferred tax assets	104,226	108,666
Valuation allowance	(104,226)	(108,666)
Net deferred tax assets	$—	$—

Realization of deferred tax assets is dependent upon future earnings, if any, the timing and amount of which are uncertain. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance. The valuation allowance decreased by $4.4 million during 2016, increased by $2.7 million during 2015 and increased by $0.5 million during 2014.

Under ASC 718, the deferred tax asset for net operating losses as of December 31, 2016 excludes deductions for excess tax benefits related to stock based compensation.

The provision for income taxes consists of state minimum taxes due. The effective tax rate of our provision (benefit) for income taxes differs from the federal statutory rate as follows (in thousands):

	Year Ending December 31,		
	2016	2015	2014
Computed at 34%	$1,758	$(3,840)	$(839)
State taxes	(187)	(268)	592
Book gains (losses) not currently benefited	(4,439)	2,740	454
Other	659	(20)	235
Revaluation of warrant liability	(280)	1,534	(346)
Research and development credits	(252)	(146)	(97)
Net operating loss carryforward expirations	2,741	—	—
Total	$—	$—	$(1)

We had no unrecognized tax benefits or any amounts accrued for interest and penalties for the three year period ended December 31, 2016. Our policy is to recognize interest and penalties related to income taxes as a component of income tax expense.

We file tax returns in the U.S. federal jurisdiction and some state jurisdictions. We are subject to the U.S. federal and state income tax examination by tax authorities for such years 1998 through 2016, due to net operating losses that are being carried forward for tax purposes.

14. Quarterly Financial Data (Unaudited)

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(in thousands, except per share amount)			
2016				
Total revenue	$—	$ 15,004	$ 26	$ 35
Net income (loss)	$(1,846)	$ 11,928	$ (2,620)	$ (2,327)
Basic net income (loss) per share	$(0.09)	$ 0.58	$ (0.12)	$ (0.11)
Diluted net income (loss) per share	$(0.09)	$ 0.55	$ (0.12)	$ (0.15)
2015				
Total revenue	$911	$ 760	$ —	$ —
Net income (loss)	$(4,897)	$ (2,281)	$ (1,807)	$ (2,294)

Basic net income (loss) per share	$(0.24)	$ (0.11)	$ (0.09)	$ (0.11)
Diluted net income (loss) per share	$(0.24)	$ (0.11)	$ (0.09)	$ (0.11)

(b) Exhibits

No.	Description
3.1(1)	Amended and Restated Certificate of Incorporation of the Registrant, as amended [7]
3.1(2)	Certificate of Amendment to the Restated Certificate of Incorporation dated September 24, 2015 [18]
3.2	By-laws of the Registrant [1]
3.3	Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc. [10]
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10.21	Employment Agreement between the Company and Sunil Bhonsle dated September 29, 2016 [21]
10.22	Employment Agreement between the Company and Marc Rubin dated September 29, 2016 [21]
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101.SCH	XBRL Taxonomy Extension Schema Document
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101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
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SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 16, 2017 TITAN PHARMACEUTICALS, INC.

By: /S/ SUNIL BHONSLE
Name: **Sunil Bhonsle**
Title: **President and Chief Executive Officer**

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

Signature	**Title**	**Date**
/s/ Marc Rubin, M.D. Marc Rubin, M.D.	Executive Chairman	March 16, 2017
/s/ Sunil Bhonsle Sunil Bhonsle	President, Chief Executive Officer and Director (principal executive officer and principal financial officer)	March 16, 2017
/s/ Joseph A. Akers Joseph A. Akers	Director	March 13, 2017
/s/ Rajinder Kumar, Ph.D. Rajinder Kumar, Ph.D.	Director	March 10, 2017
/s/ M. David MacFarlane, Ph.D. M. David MacFarlane, Ph.D.	Director	March 16, 2017
/s/ James R. McNab, Jr. James R. McNab, Jr.	Director	March 16, 2017
/s/ Scott A. Smith Scott A. Smith	Director	March 9, 2017
/s/ Brian E. Crowley Brian E. Crowley	Vice President, Finance (principal accounting officer)	March 16, 2017

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