

TITAN PHARMACEUTICALS INC  
Form 10-K  
March 18, 2013

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-K**

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2012

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 000-27436

**TITAN PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or Other Jurisdiction of

94-3171940  
(I.R.S. Employer

Incorporation or Organization)

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: None

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).  Yes  No

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

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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller Reporting Company	<input type="checkbox"/>

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

The aggregate market value of the 64,592,330 shares of voting and non-voting common equity held by non-affiliates of the registrant based on the closing price on June 30, 2012 was \$45.2 million.

As of March 11, 2013, 81,811,489 shares of common stock, \$.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 and Section 21E of the Securities Exchange Act of 1934. 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, expects, projects, or similar terms, variations of such 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 financing and strategic agreements and relationships; difficulties or delays in the regulatory approval process; uncertainties relating to 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 biopharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs focus primarily on important pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. Such collaborations have helped to fund product development and have enabled us to retain significant economic interest in our products.

Our principal asset is Probuphine®, the first slow release implant formulation of buprenorphine, designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. The clinical and manufacturing development of Probuphine for the treatment of opioid dependence in adult patients is complete. The New Drug Application ( NDA ) seeking approval for treatment of opioid dependence has been accepted by the United States Food and Drug Administration ( FDA ) for a Priority Review. Priority Review designation is given to therapies that offer potential major advances in treatment, including improved safety, or provide a treatment where no adequate therapy exists. Based upon the Prescription Drug User Fee Act ( PDUFA ), the FDA has set a target date of April 30, 2013 for FDA action on the NDA. An FDA advisory committee review has been scheduled for March 21, 2013.

Probuphine is inserted subdermally in a patient's upper arm providing continuous medication, and has the potential to enhance patient compliance to treatment, and limit diversion for illicit use and accidental exposure to the daily dosed formulations. The outpatient treatment of opioid addiction with daily dosed sublingual buprenorphine formulations represents a \$1.3 billion market in the U.S., which continues to grow. A transdermal formulation of buprenorphine for the treatment of chronic pain entered the U.S. market in 2011 and Probuphine has the potential to be developed for treating chronic pain as well.

In December 2012, we entered into a license agreement with Braeburn Pharmaceuticals Sprl ( Braeburn ) that grants Braeburn exclusive commercialization rights to Probuphine® in the United States and Canada. We received a non-refundable up-front license fee of \$15.75 million and will receive a \$50 million milestone payment upon the approval of the NDA by the FDA. Additionally, we will be eligible to receive up to \$130 million upon achievement of specified sales milestones and up to \$35 million in regulatory milestones in the event of future NDA submissions and approvals for additional indications, including chronic pain. Titan will receive tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties. In addition to the potential milestone payments, Apple Tree Partners IV, Braeburn's parent company, has allocated in excess of \$75 million to launch, commercialize and continue the development of Probuphine.

Probuphine is the first product to utilize ProNeura, our novel, proprietary, continuous drug delivery technology. Our ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson's disease, where maintaining stable, around the clock blood levels of a drug can benefit the patient and improve medical outcomes.

Under a sublicense agreement with Novartis Pharma AG ( Novartis ), we are entitled to royalty revenue of 8-10% of net sales of Fanapt (iloperidone), an atypical antipsychotic compound being marketed in the U.S. by Novartis for the treatment of schizophrenia, based on a licensed U.S. patent that expires in October 2016 (excluding the potential of a six month pediatric extension). We have entered into several agreements with Deerfield Management ( Deerfield), a healthcare investment fund, which entitle Deerfield to most of the future royalty revenues related to Fanapt in exchange for cash and debt considerations, the proceeds from which we have been using to advance the development of Probuphine and for general corporate purposes. We have retained a portion of the royalty revenue from the net sales of Fanapt in excess of specified annual threshold levels; however, based on sales levels to date, it is unlikely that we will receive any revenue from Fanapt in the next several years, if ever.

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

## **Our Products**

### ***Probuphine***

We are developing Probuphine for the treatment of opioid dependence. Probuphine is the first product specifically designed for the long-term treatment of opioid dependence and it utilizes ProNeura, our novel, proprietary, long-term drug delivery technology. See Continuous Drug Delivery Technology (ProNeura) below. Probuphine is designed to maintain a stable, around the clock blood level of the drug buprenorphine, an approved agent for the treatment of opioid dependence. If approved, Probuphine is expected to provide six months of medication following a single treatment. Probuphine has been shown to be effective with an acceptable safety profile in the following Phase 3 clinical studies:

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;

Two six-month, open-label re-treatment safety trials; and

A pharmacokinetic (relative bioavailability) safety study.

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. In both placebo-controlled Phase 3 studies of Probuphine, every participant was required to provide urine samples three times a week, essentially on alternate days. 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 (i.e. urine testing negative for illicit opioid) 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 clinically meaningful and a statistically significant difference in the negative urines as compared to the placebo arm in both studies, i.e. the Probuphine patients had statistically more negative results than the placebo arm, 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 clinically meaningful 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).

Patients who completed the controlled studies were eligible for enrollment in the six-month re-treatment studies, which provided data on up to one full year of treatment. 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 all of these studies was presented at several scientific meetings, including the International Society of Addiction Medicine Annual Meetings in November 2008 and September 2011, the American Society of Addiction Medicine Annual Meetings in May 2009 and 2012, American Society of Addiction Medicine Education Forum in October 2011, and the American College of Neuropharmacology in November 2009 and 2012.

These studies are part of a registration directed program intended to obtain marketing approval of Probuphine for the treatment of opioid dependence in the U.S. and in Europe. We met with the FDA in October 2011 for a pre-NDA meeting and reviewed the clinical development program as well as the chemistry, manufacturing and controls (CMC) aspects of the NDA. Based on this interaction we completed the requirements for an NDA and submitted it to the FDA in October 2012. The NDA seeking approval for the maintenance treatment of opioid dependence has been accepted by the FDA for a Priority Review. Priority Review designation is given to therapies that offer potential major advances in treatment, including improved safety, or provide a treatment where no adequate therapy exists. Based upon the PDUFA requirements, an FDA advisory committee review has been scheduled for March 21, 2013 and the FDA has set a target date of April 30, 2013 for FDA action on the NDA. If approved, Probuphine will be commercialized in the U.S. and Canada by Braeburn. We will seek appropriate commercial partners for Probuphine in other countries, particularly where therapy with daily dosed buprenorphine is already approved.

#### ***Continuous Drug Delivery Technology (ProNeura)***

Our continuous drug delivery system consists of a small, solid rod made from a mixture of ethylene-vinyl acetate (EVA) and a drug substance. The resulting product is a solid matrix that is placed subcutaneously, normally in 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 slowly, at continuous levels, through the process of dissolution. This results in a steady rate of release similar to intravenous administration. We believe that such long-term, linear release characteristics are desirable by avoiding peak and trough level dosing that may pose problems for many disease settings.

Our ProNeura technology was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery, and potentially can provide steady drug release on an outpatient basis over extended periods of up to 6-12 months. This technology has been validated with the successful development of Probuphine, and its potential commercialization in the near term is likely to further strengthen the appeal of this

continuous drug delivery system. We continue to seek opportunities to develop this drug delivery technology for other potential treatment applications in which conventional treatment is limited by variability in blood drug levels and poor patient compliance (e.g. treatment of Parkinson disease with dopamine agonists). During 2012, with the support of an SBIR grant, we completed a non-clinical study with long-term delivery of dopamine agonists which supports the potential to develop an implant delivering ropinirole for treating Parkinson's disease. Additional non clinical testing will be required to develop an optimal formulation and evaluating toxicity prior to any clinical testing. We are also evaluating other drugs and disease settings to establish product development programs during 2013.

#### ***Fanapt® (iloperidone)***

Fanapt (iloperidone) is an atypical antipsychotic approved by the FDA for the treatment of schizophrenia currently being marketed by Novartis in the U.S. Under a sublicense agreement with Novartis, we are entitled to a royalty of 8-10% of net sales, based on a U.S. patent that we licensed from Sanofi-Aventis. The U.S. patent expires in October 2016 (excluding a six-month pediatric extension). Vanda Pharmaceuticals, Inc. ( Vanda ) owns the development and commercialization rights to the oral and depot formulations of this product for the rest of the world. However, because patent coverage on the compound has now expired in the significant markets outside of the U.S. and no patent term extensions are possible since the product was not approved in these countries prior to patent expiration, we do not expect any royalties on any future sales in such markets.

We have entered into several agreements with Deerfield, which entitle Deerfield to most of the future royalty revenues related to Fanapt in exchange for cash and debt considerations, the proceeds of which have been used to advance the development of Probuphine and for general corporate purposes. We have retained a portion of the royalty revenue from net sales of Fanapt in excess of specified annual threshold levels; however, based on sales levels to date, it is unlikely that we will receive any revenue from Fanapt in the next several years, if ever. We do not incur any ongoing expenses associated with this product.

#### **License Agreements**

In December 2012, we entered into a license 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 net sales of Probuphine ranging from the mid-teens to the low twenties. Additionally, we will receive \$50 million upon FDA approval of the NDA for Probuphine and at such time ownership of the NDA will transfer to Braeburn. We are also eligible to receive 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.

In January 1997, we acquired an exclusive worldwide license under U.S. and foreign patents and patent applications relating to the use of iloperidone for the treatment of psychiatric and psychotic disorders and analgesia from Sanofi-Aventis SA ( Sanofi-Aventis ) (formerly Hoechst Marion Roussel, Inc.). The Sanofi-Aventis agreement provides for the payment of royalties on future net sales and requires us to satisfy certain other terms and conditions, specifically continued diligent product development and commercialization efforts standard for these types of agreements, in order to retain our rights. In November 1997, we granted a worldwide sublicense, exclusive of Japan, to Novartis under which Novartis continued, at its expense, all further development of iloperidone. In April 2001, that sublicense was extended to include Japan. Under this agreement, Novartis agreed to pay Titan a royalty on future net sales of the product equal to 8% of annual worldwide net sales up to \$200 million and 10% of annual worldwide net sales above \$200 million, in addition to royalty payments owed by us to Sanofi-Aventis. In June 2004, Novartis granted Vanda the worldwide rights to develop and commercialize iloperidone. In October 2009, Vanda and Novartis amended and restated their sub-license agreement whereby Novartis acquired the U.S. and Canadian rights to commercialize Fanapt, the oral formulation of iloperidone approved in the U.S. Novartis also acquired the U.S. and Canadian development and

commercialization rights to the depot formulation previously under development by Vanda and retained the right of first negotiation to co-market Fanapt and the depot formulation in the rest of the world. All of our rights and economic interests in iloperidone, including royalties on sales, remained essentially unchanged under these agreements and, as previously stated, we have entered into several agreements with Deerfield, which entitle Deerfield to the future royalty revenues related to Fanapt in exchange for cash and debt considerations.

In October 1995, we acquired from the Massachusetts Institute of Technology ( MIT ) an exclusive worldwide license to certain U.S. and foreign patents relating to our continuous drug delivery system that provided for the payment of certain royalties and other payments with respect to based the licensed technology. Because the patent terms have expired, this license was terminated on July 31, 2012 and we have no continuing obligations to MIT with respect to our ProNeura technology.

In July 2005, we entered into an agreement with the University of Iowa Research Foundation. Under this agreement, we received an exclusive worldwide license to patent rights held by the University of Iowa Research Foundation covering the methods of treating biofilm formation, pseudomonas aeruginosa growth, human deficiency virus, and intracellular pathogens and pathogens causing chronic pulmonary infection using gallium maltolate. Under this agreement, we are required to pay a license issuance fee and certain minimum annual royalty payments. In addition, we are required to pay royalties based on net sales of products and processes incorporating the licensed technology. We will evaluate the utility of this license with respect to future product development programs and take action as appropriate.

### **Patents and Proprietary Rights**

Four patent applications have been filed which incorporate the use of specific compounds with the continuous delivery technology, including two applications related to Probuphine for the potential treatment of opioid addiction and chronic pain. In June 2010, the United States Patent and Trademark Office ( USPTO ) issued a patent covering Probuphine for the treatment of opiate addiction. Titan is the assignee 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. Patents have issued in Australia, India, Japan, Mexico and New Zealand. Further prosecution of these applications is currently proceeding at the USPTO and corresponding agencies in Europe, Canada, India and Hong Kong. Patents covering certain dopamine agonist implants have already been issued or allowed in Europe, Japan, Australia, Canada, South Korea, Mexico, New Zealand, South Africa, and Hong Kong, while prosecution of the patent application continues in the U.S., Israel, India and China.

We hold a license from Sanofi-Aventis under certain issued U.S. patents and certain issued foreign patents relating to iloperidone and its methods of use in the treatment of psychiatric disorders, psychotic disorders and analgesia. The term of the U.S. patent that covers certain aspects of our iloperidone product expires in October 2016, excluding a six month extension possible if an approval of pediatric indication is obtained. Limited foreign patent protection remains in Lichtenstein, Georgia, Korea and the Philippines, although no royalty payments are expected from these patents.

We are the licensee from the University of Iowa Research Foundation ( UIRF ) of two issued U.S. patents (expiring in 2016) relating to methods of use of gallium compounds to inhibit the growth of P. aeruginosa, and the treatment of infections by pathogens causing chronic pulmonary infection. We are also the licensee from UIRF of certain rights to patent applications covering the use of gallium complexes in preventing and also treating bacterial biofilm-based infections, for which patents have issued in Australia, Japan, Mexico, New Zealand, and South Africa, and prosecution in the U.S., Canada, Europe, China, Hong Kong, and India continues.



## **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. For risks we face with respect to competition, see **Risk Factors** We face intense competition.

With respect to Probuphine, Reckitt Benckiser Group, PLC ( **Reckitt** ) markets globally a sublingual buprenorphine product (tablet and film formulations) for the treatment of opioid dependence. This product (Subutex<sup>®</sup>, Suboxone<sup>®</sup>) which is administered daily, will compete with our six-month implantable product for treating opioid dependence. Reckitt recently announced the discontinuation of the sublingual tablet formulation of Suboxone in favor of the sublingual film formulation which they will continue to market aggressively. In addition, in February 2013, two generic sublingual tablet formulations of Suboxone were approved by the FDA which are expected to compete with Suboxone. Other forms of buprenorphine are also in development by other companies, including intramuscular injections, buccal delivery and intranasally delivered buprenorphine, which also might compete with our product. In 2010, Alkermes, Inc. received FDA approval to market Vivitrol<sup>®</sup>, a one month depot injection of naltrexone as a maintenance treatment for opioid dependent patients who have successfully achieved abstinence. We are aware of one month depot formulations of buprenorphine in early clinical development for the treatment of opioid dependence, but we are not aware of any six-month formulations being developed other than Probuphine.

## **Manufacturing**

The manufacturing of Probuphine has primarily been conducted at DPT Laboratories, Inc., and we have expanded the manufacturing facility at this contract manufacturer to establish commercial scale capability to support the potential market launch of Probuphine, and ongoing demand following potential approval by the FDA.

## **Government Regulation**

### ***FDA Approval Process***

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

Pharmaceutical product development in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of either a notice of claimed investigational exemption or an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

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

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial.

Once the submission is accepted for filing, the FDA begins an in-depth review. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. 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. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one, or more, clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practice, or GMP—a quality system regulating manufacturing—is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and

may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

#### ***The Hatch-Waxman Act***

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

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. The ANDA application also will not be approved until any non-patent exclusivity listed in the Orange Book for the referenced product has expired. Federal law provides a period of five years following approval of a drug containing no previously approved active ingredients during which ANDAs for generic versions of those drugs cannot be submitted, unless the submission contains a Paragraph IV challenge to a listed patent - in which case the submission may be made four years following the original product approval. Federal law provides for a period of three years of exclusivity 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.

#### ***Section 505(b)(2) New Drug Applications***

Most drug products obtain FDA marketing approval pursuant to an NDA or an ANDA. A third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, enables the applicant to rely, in part, on the FDA's previous approval of a similar product, or published literature, in support of its application. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of

reference. If the 505(b)(2) applicant can establish that reliance on the FDA's previous approval is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all, or some, of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

#### ***Advertising and Promotion***

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet.

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

#### ***Adverse Event Reporting and GMP Compliance***

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, risk minimization action plans, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

#### ***Pediatric Information***

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity—patent or non-patent—for a drug if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

### ***Physician Drug Samples***

As part of the sales and marketing process, pharmaceutical companies frequently provide samples of approved drugs to physicians. The Prescription Drug Marketing Act, or the PDMA, imposes requirements and limitations upon the provision of drug samples to physicians, as well as prohibits states from licensing distributors of prescription drugs unless the state licensing program meets certain federal guidelines that include minimum standards for storage, handling, and record keeping. In addition, the PDMA sets forth civil and criminal penalties for violations.

### ***Controlled Substances***

Manufacturers of controlled substances, including buprenorphine, are also subject to the licensing, quota, and regulatory requirements of the Controlled Substances Act. Failure to comply with the Controlled Substances Act and the regulations promulgated thereunder could subject companies to loss or suspension of those licenses and to civil or criminal penalties.

### ***Anti-Kickback, False Claims Laws & The Prescription Drug Marketing Act***

In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical industry in recent years. These laws include anti-kickback statutes and false claims statutes. The federal healthcare program anti-kickback statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce; or in return for; purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Violations of the anti-kickback statute are punishable by imprisonment, criminal fines, civil monetary penalties, and exclusion from participation in federal healthcare programs. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution or other regulatory sanctions, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to have a false claim paid. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly inflating drug prices they report to pricing services, which in turn were used by the government to set Medicare and Medicaid reimbursement rates, and for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

### **Foreign Regulatory Issues**

Sales of pharmaceutical products outside the United States are subject to foreign regulatory requirements that vary widely from country to country. Whether or not FDA approval has been obtained, approval of a product by a comparable regulatory authority of a foreign country must generally be obtained prior to the commencement of marketing in that country. Although the time required to obtain such approval may be longer or shorter than that required for FDA approval, the requirements for FDA approval are among the most detailed in the world and FDA approval generally takes longer than foreign regulatory approvals.

### **Employees**

At December 31, 2012, we had 13 full-time employees, 2 part-time employees and several consultants.

**Item 1A. Risk Factors**

***FDA approval of Probuphine may be delayed.***

At December 31, 2012, we had cash of approximately \$18.1 million, which, together with the FDA's reimbursement of the \$2.0 million NDA filing fee, we believe is sufficient to fund our current operations through June 2014. In the event that the FDA issues a complete response letter requiring additional clinical and manufacturing development prior to approval that would require expenditures in excess of certain amounts specified in our agreement with Braeburn, Braeburn will have the right to either terminate the agreement or, in the event the FDA ultimately approves Probuphine for sale in the U.S., reduce the amount of the \$50 million milestone payment payable to us by the amount of our obligations for the additional development expenses.

If Braeburn were to terminate the agreement, we would not have sufficient funds available to us to complete the FDA approval process and commercialize Probuphine and, as a result, our business and prospects would be materially adversely impacted. Furthermore, continuation of our current Parkinson's disease development program and the initiation of any additional programs will depend upon our receipt of the \$50 million milestone payment and if such payment is not received or is significantly reduced our ability to fund any new product development programs will be materially impaired.

***FDA approval of Probuphine may be denied.***

The FDA has targeted April 30, 2013 for FDA action on the Probuphine NDA that we submitted in October 2012. The FDA may deny approval of Probuphine for many reasons, including:

we may be unable to demonstrate to the satisfaction of the FDA that Probuphine is safe and effective for the treatment of opioid dependence in adults;

the FDA may disagree with our interpretation of data from non-clinical studies or clinical trials;

we may be unable to demonstrate that Probuphine's clinical and other benefits outweigh any safety or other perceived risks; or

the FDA may fail to approve the manufacturing processes or facilities of the third-party manufacturers with which we have contracted.

If Probuphine fails to receive FDA approval, our business and prospects will be materially adversely impacted.

***The timing and amount of revenues from Probuphine, if any, will be wholly dependent on the efforts of third parties.***

We have granted an exclusive license to Braeburn for the commercialization of Probuphine in the United States and Canada. If approved by the FDA, 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 in the Territory. Braeburn is a recently formed company and does not have a track record upon which investors can rely on making an investment decision. Additionally, 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, none of which have commenced to date. 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.

***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.***

Even if Probuphine or any other product candidate we may in the future develop receives regulatory approval, they 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 product candidate is approved but 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 are dependent upon key collaborative relationships and license agreements.***

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We will rely significantly on the resources of third parties to market and commercialize Probuphine, if approved, as well as any other products we may develop. For example, our ability to ultimately derive revenues from Probuphine in the Territory is dependent upon Braeburn implementing a successful marketing program for the treatment of opioid dependence in adults and pursuing development and commercialization of the product for other indications. Beyond any contractual rights, we cannot control the amount or timing of resources that any



existing or future corporate partner devotes to product development and commercialization efforts for our product candidates. We depend on our ability to maintain existing collaborative relationships, 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. 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.

***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.***

Our liability insurance coverage 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. 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.

***Healthcare reform and restrictions on reimbursements may limit our financial returns.***

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Braeburn's ability to commercialize Probuphine in the Territory and our ability or the ability of any future collaborators to commercialize Probuphine outside the Territory or to commercialize any other products we may

successfully develop will depend in part on the extent to which government health administration authorities, private health insurers and other organizations will reimburse consumers for the cost of these products. These third parties are increasingly challenging both the need for and the price of new drug products. Significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third party reimbursement may not be available for our own or our collaborator's drug products to enable us or them to maintain price levels sufficient to realize an appropriate return on their and our investments in research and product development.

***We may not be able to retain our key management and scientific personnel.***

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 and Marc Rubin, our President and Executive Chairman, respectively, and our Executive Vice President and Chief Development Officer, all of whom are parties to employment agreements with us. 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 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.

***Our common stock is deemed to be a penny stock, which may make it more difficult for investors to sell their shares due to suitability requirements.***

Our common stock is subject to Rule 15c-1 through 15c-9 under the Securities Exchange Act of 1934, as amended (the Exchange Act), which imposes certain sales practice requirements on broker-dealers which sell our common stock to persons other than established customers and accredited investors (generally, individuals with a net worth in excess of \$1,000,000 or annual incomes exceeding \$200,000 (or \$300,000 together with their spouses)). For transactions covered by this rule, a broker-dealer must make a special suitability determination for the purchaser and have received the purchaser's written consent to the transaction prior to the sale. This rule adversely affects the ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares of common stock.

Additionally, our common stock is subject to the SEC regulations for penny stock. Penny stock includes any equity security that is not listed on a national exchange and has a market price of less than \$5.00 per share, subject to certain exceptions. The regulations require that prior to any non-exempt buy/sell transaction in a penny stock, a disclosure schedule set forth by the SEC relating to the penny stock market must be delivered to the



purchaser of such penny stock. This disclosure must include the amount of commissions payable to both the broker-dealer and the registered representative and current price quotations for the common stock. The regulations also require that monthly statements be sent to holders of penny stock that disclose recent price information for the penny stock and information of the limited market for penny stocks. These requirements adversely affect the market liquidity of our common stock.

***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, 2012, we had federal net operating loss and tax credit carryforwards of \$215.7 million and \$7.6 million, respectively, and state net operating loss and tax credit carryforwards of \$146.7 million and \$7.8 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.

**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 three-year operating lease expiring in June 2013. It is our intention to renew this lease for a multi-year period prior to June 2013, and 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.

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**PART II**
**Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.****(a) Price Range of Securities**

Since June 2, 2010, our common stock has been quoted on the OTC Bulletin Board under the symbol TTNP.OB. The following table sets forth, for the periods indicated, the high and low sales prices per share of our common stock as reported by the OTC Bulletin Board. The quotations reflect inter-dealer prices without retail markups, markdowns, or commissions and may not represent actual transactions. For current price information, stockholders are urged to consult publicly available sources.

	<b>High</b>	<b>Low</b>
<b>Fiscal 2012</b>		
Fourth Quarter	\$ 1.23	\$ 0.76
Third Quarter	\$ 1.05	\$ 0.65
Second Quarter	\$ 1.13	\$ 0.65
First Quarter	\$ 1.40	\$ 1.05
<b>Fiscal 2011</b>		
Fourth Quarter	\$ 1.78	\$ 1.06
Third Quarter	\$ 2.08	\$ 1.30
Second Quarter	\$ 2.22	\$ 1.30
First Quarter	\$ 1.81	\$ 1.17

**(b) Approximate Number of Equity Security Holders**

As of March 15, 2013, there were approximately 141 record holders of our common stock.

**(c) Dividends**

We have never paid a cash dividend on our common stock and anticipate that for the foreseeable future any earnings will be retained for use in our business and, accordingly, do not anticipate the payment of cash dividends.



**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 Securities Exchange Act of 1934, as amended (the Exchange Act), except to the extent that we specifically incorporate it by reference into a document filed under the Securities Act of 1933, as amended (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, and (ii) a peer group index consisting of companies reporting under the Standard Industrial Classification Code 2834 (Pharmaceutical Preparations). The graph assumes \$100 invested on December 31, 2007 and assumes dividends reinvested. Measurement points are at the last trading day of the fiscal years ended December 31, 2008, 2009, 2010, 2011 and 2012. 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 AND**

**SIC CODE INDEX**

**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 consolidated 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.

	2012	Years Ended December 31,			2008
		2011	2010	2009	
(in thousands, except per share data)					
<b>Statement of Operations Data:</b>					
Total revenue	\$ 7,117	\$ 4,068	\$ 10,093	\$ 79	\$ 73
Operating expenses:					
Research and development	10,610	11,206	12,855	2,456	16,235
General and administrative	4,877	3,368	3,263	3,438	9,756
Other income (expense), net	(6,810)	(4,697)	(809)	(71)	484
Net loss	(15,180)	(15,203)	(6,834)	(5,886)	(25,434)
Gain on retirement of preferred stock upon dissolution of subsidiary			1,241		
Net loss applicable to common stockholders	\$ (15,180)	\$ (15,203)	\$ (5,593)	\$ (5,886)	\$ (25,434)
Basic and diluted net loss per common share	\$ (0.23)	\$ (0.26)	\$ (0.09)	\$ (0.10)	\$ (0.44)
Shares used in computing:					
Basic and diluted net loss per common share	66,509	59,324	59,248	58,473	58,285
	2012	2011	2010	2009	2008
As of December 31, (in thousands)					
<b>Balance Sheet Data:</b>					
Cash	\$ 18,102	\$ 5,406	\$ 3,180	\$ 3,300	\$ 4,672
Working capital (deficit)	2,042	4,839	(706)	2,069	2,759
Total assets	24,827	10,217	4,752	3,726	5,668
Total stockholders' (deficit) equity	(23,128)	(20,079)	(6,053)	(1,448)	1,793

**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, intend, 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 consolidated 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 biopharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs focus primarily on important pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. Such collaborations have helped to fund product development and have enabled us to retain significant economic interest in our products.

Our principal asset is Probuphine<sup>®</sup>, the first slow release implant formulation of buprenorphine, designed to maintain a stable, around the clock blood level of the medicine in patients for six months following a single treatment. The clinical and manufacturing development of Probuphine for the treatment of opioid dependence in adult patients is complete. The NDA seeking approval for treatment of opioid dependence has been accepted by the FDA for a Priority Review. Priority Review designation is given to therapies that offer potential major advances in treatment, including improved safety, or provide a treatment where no adequate therapy exists. Based upon the PDUFA, the FDA has set a target date of April 30, 2013 for FDA action on the NDA. An FDA advisory committee review has been scheduled for March 21, 2013.

In December 2012, we entered into a license agreement with Braeburn that grants Braeburn exclusive commercialization rights to Probuphine<sup>®</sup> in the United States and Canada. We received a non-refundable up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses) and will receive a \$50 million milestone payment upon the approval of the NDA by the FDA. Additionally, we will be eligible to receive up to \$130 million upon achievement of specified sales milestones and up to \$35 million in regulatory milestones in the event of future NDA submissions and approvals for additional indications, including chronic pain. We will receive tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties. In addition to the potential milestone payments, Apple Tree Partners IV, Braeburn's parent company, has allocated in excess of \$75 million to launch, commercialize and continue the development of Probuphine.

Probuphine is the first product to utilize ProNeura, our novel, proprietary, continuous drug delivery technology. Our ProNeura technology has the potential to be used in developing products for the treatment of other chronic conditions, such as Parkinson's disease, where maintaining stable, around the clock blood levels of a drug can benefit the patient and improve medical outcomes.

Under a sublicense agreement with Novartis, we are entitled to royalty revenue of 8-10% of net sales of Fanapt<sup>®</sup> (iloperidone), an atypical antipsychotic compound being marketed in the U.S. by Novartis for the

treatment of schizophrenia, based on a licensed U.S. patent that expires in October 2016 (excluding the potential of a six month pediatric extension). We have entered into several agreements with Deerfield, a healthcare investment fund, which entitle Deerfield to most of the future royalty revenues related to Fanapt in exchange for cash and debt considerations, the proceeds from which we have been using to advance the development of Probuphine and for general corporate purposes. We have retained a portion of the royalty revenue from the net sales of Fanapt in excess of specified annual threshold levels; however, based on sales levels to date, it is unlikely that we will receive any revenue from Fanapt in the next several years, if ever.

### *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 consolidated 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, 2012 and 2011 to be applicable:

#### *Revenue Recognition*

We generate revenue principally from royalty payments, 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) collectibility is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

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 collectibility is reasonably assured. Pursuant to certain license agreements, we earn royalties on the sale of Fanapt by Novartis in the U.S. As described in Note 8, Royalty Liability, we are obligated to pay royalties on such sales to Sanofi-Aventis and Deerfield. As we have no performance obligations under the license agreements, we have recorded the royalties earned, net of royalties we are obligated to pay, as revenue in our Consolidated Statement of Operations.

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 or if we do not have objective or reliable evidence of the fair value of the undelivered component, 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.

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.

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.

#### *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, 2012, 2011 and 2010 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 consolidated 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 Accrual*

We also record accruals for estimated ongoing clinical trial costs. Clinical trial costs represent costs incurred by clinical research organizations, ( 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 Condensed Consolidated Statements of Operations and Comprehensive Loss.

#### *Liquidity and Capital Resources*

	2012	2011	2010
	(in thousands)		
<b>As of December 31:</b>			
Cash	\$ 18,102	\$ 5,406	\$ 3,180
Working capital	\$ 2,042	\$ 4,839	\$ (706)
Current ratio	1.1:1	1.9:1	0.9:1
<b>Years Ended December 31:</b>			
Cash (used in) provided by operating activities	\$ 1,830	\$ (14,476)	\$ (4,657)
Cash used in investing activities	\$ (1,154)	\$ (234)	\$ (28)
Cash provided by financing activities	\$ 12,020	\$ 16,936	\$ 4,565

We have funded our operations since inception primarily through sales of our debt and equity securities, as well as with proceeds from warrant and option exercises, corporate licensing and collaborative agreements, and government-sponsored research. At December 31, 2012, we had approximately \$18.1 million of cash compared to approximately \$5.4 million at December 31, 2011.

Our operating activities provided approximately \$1.8 million during the year ended December 31, 2012. This consisted primarily of the net loss for the period of approximately \$15.2 million, approximately \$0.3 million related to the non-cash interest expense on our royalty liability and approximately \$1.4 million related to net changes in operating assets and liabilities. This was offset in part by approximately \$14.4 million related to deferred revenue in connection with the license agreement with Braeburn, approximately \$1.8 million related to net non-cash losses on changes in the fair value of warrants, non-cash charges of approximately \$17,000 related to depreciation, and approximately \$2.6 million related to stock-based compensation expenses. Uses of cash in operating activities were primarily to fund product development programs and administrative expenses. The license agreement with Sanofi-Aventis require us to pay royalties on future product sales. In addition, in order to maintain license and other rights while products are under development, we must comply with customary licensee obligations, including the payment of patent-related costs, annual minimum license fees, meeting project-funding milestones and diligent efforts in product development. The aggregate commitments we have under these agreements, including minimum license payments, for the next 12 months is approximately \$3,000. See Item 1. Business License Agreements.

Net cash used in investing activities of approximately \$1.2 million during the year ended December 31, 2012 primarily related to purchases of equipment.

Net cash provided by financing activities of approximately \$12.0 million during the year ended December 31, 2012 consisted of approximately \$7.5 million of net proceeds from the sale of common stock and warrants, net of issuance costs and \$4.9 million of net proceeds from the exercise of warrants to purchase common stock. This was offset in part by payments of approximately \$0.4 million related to payments on our long-term debt.

On March 15, 2011, we entered into several agreements with entities affiliated with Deerfield pursuant to which Deerfield agreed to provide \$20.0 million in funding to us. Funding occurred on April 5, 2011. Pursuant to the terms of a facility agreement, we issued Deerfield 8.5% promissory notes in the aggregate principal amount of \$20.0 million. We paid Deerfield a facility fee of \$0.5 million and issued them warrants to purchase 6,000,000 shares of our common stock (the Deerfield Warrants). Deerfield has the right to have the long-term debt repaid at 110% of the principal amount in the event we complete a major transaction, which includes, but is not limited to, a merger or sale of our company or the sale of Fanapt or Probuphine. Under a royalty agreement, in exchange for \$3.0 million that was recorded as royalty liability, we agreed to pay Deerfield 2.5% of the aggregate royalties on net sales of Fanapt, subsequent to the funding date, constituting a portion of the royalty revenue we receive from Novartis. The agreements with Deerfield also provide us with the option to repurchase the royalty rights for \$40.0 million.

On April 5, 2011, we used approximately \$7.6 million of proceeds from the Deerfield funding to repay Oxford Financing Corporation in full, including required final payments aggregating \$480,000.

On November 14, 2011, we entered into several agreements with Deerfield pursuant to which we agreed to pay them a substantial portion of the remaining future royalties on the sales of Fanapt in exchange for \$5.0 million in cash that was recorded as royalty liability, a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. Deerfield is entitled to the balance of our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% we previously agreed to pay to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level. We retain 60% of the royalties on net sales of Fanapt above the threshold levels, subject to an agreement that half of any such retained royalties will go towards repayment of our outstanding debt to Deerfield. Funding of the transaction took place on November 25, 2011.

In February 2013, we amended the terms of the Deerfield Warrants, which are currently exercisable at \$1.25 per share, to permit payment of the exercise price through the reduction of the outstanding loan. In February and March 2013, Deerfield exercised an aggregate of 6,000,000 warrants resulting in a reduction of our outstanding indebtedness to Deerfield of \$7.5 million and, accordingly, the Deerfield debt will be fully repaid upon payment of \$2.5 million in April 2013.

On April 9, 2012, we entered into subscription agreements with certain institutional investors for the purchase and sale, in a registered direct offering, of (i) 6,517,648 shares of our common stock (the Shares), (ii) six-year warrants to purchase 6,517,648 shares of common stock (the Series A Warrants) and (iii) six-month warrants to purchase 6,517,648 shares of common stock (the Series B Warrants and, together with the Series A Warrants, the Warrants) for gross proceeds of \$5,540,000. The closing of the sale of the Shares and Warrants occurred on April 13, 2012 and April 18, 2012. Net proceeds were approximately \$5.0 million. Prior to their expiration, Series B Warrants to purchase 5,761,765 shares of our common stock were exercised resulting in gross proceeds to us of approximately \$4.9 million.

On September 12, 2012, we entered into a stock purchase and option agreement with an affiliate of Braeburn pursuant to which we sold 3,400,000 shares of our common stock for an aggregate purchase price of \$4.25 million, or \$1.25 per share, and agreed to an exclusive option period for execution of the proposed license agreement.

On December 13, 2012, we entered into a license agreement with Braeburn pursuant to which we granted Braeburn an exclusive right and license to commercialize Probuphine® in the Territory. We will retain all of the rights to Probuphine® outside the Territory. In consideration of the rights granted to Braeburn under the license agreement, Braeburn paid to us an upfront, non-refundable license fee of \$15.75 million (approximately \$15.0 million, net of expenses). Upon FDA approval of the NDA for Probuphine®, Braeburn will be required to make a \$50 million milestone payment to us and ownership of the NDA will transfer to Braeburn. We are also eligible to receive up to an additional \$130 million upon the achievement of specified sales milestones and up to \$35 million in regulatory milestones. Braeburn will also pay us tiered royalties ranging from the mid-teens to the low twenties.

We believe that our working capital at December 31, 2012, together with the FDA's reimbursement of the NDA filing fee, is sufficient to fund our planned operations through June 2014. In the event that the FDA issues a complete response letter requiring us to conduct additional clinical studies that would require expenditures in excess of certain amounts specified in our agreement with Braeburn, Braeburn will have the right to either terminate the agreement or reduce the amount of the \$50 million milestone payment payable to us in the event the FDA ultimately approves Probuphine. If Braeburn were to terminate the agreement, we would not have sufficient funds available to us to complete the FDA approval process and commercialize Probuphine and, as a result, our business and prospects would be materially adversely impacted. Furthermore, continuation of our current Parkinson's disease development program and the initiation of any additional programs will depend upon our receipt of the \$50 million milestone payment and if such payment is not received or is significantly reduced our ability to fund any new product development programs will be materially impaired and we may need to obtain additional financing, either through the sale of debt or equity securities, to continue our Probuphine program and other product development activities. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue one or more of our product development activities.

The following table sets forth the aggregate contractual cash obligations as of December 31, 2012 (in thousands):

Contractual obligations	Total	Payments Due by Period			
		< 1 year	1-3 years	3-5 years	5 years+
Operating leases	\$ 121	\$ 121	\$	\$	\$
Debt obligation(1)	11,771	3,262	5,885	2,624	
<b>Total contractual cash obligations</b>	<b>\$ 11,892</b>	<b>\$ 3,383</b>	<b>\$ 5,885</b>	<b>\$ 2,624</b>	<b>\$</b>

(1) Excludes payments related to the royalty liability with Deerfield under the March 2011 and November 2011 Royalty Agreements.

### **Results of Operations**

#### *Year Ended December 31, 2012 Compared to Year Ended December 31, 2011*

Our net loss applicable to common stockholders for 2012 was approximately \$15.2 million, or approximately \$0.23 per share, compared to our net loss applicable to common stockholders of approximately \$15.2 million, or approximately \$0.26 per share, for 2011. Our net loss for 2012 includes a non-cash loss of approximately \$1.8 million resulting from increases in the fair value of warrants issued as part of the March 2011 Deerfield transaction and the April 2012 financing transaction.

We generated royalty revenues during 2012 of approximately \$4.8 million compared to approximately \$3.6 million during 2011. We generated grant revenues during 2012 of approximately \$42,000 compared to approximately \$0.5 million during 2011. We generated licensing revenues of approximately \$2.3 million during 2012. The licensing revenue consisted of approximately \$1.7 million related to the premium paid on our common



stock as part of the September 2012 stock purchase and option agreement with an affiliate of Braeburn and approximately \$0.6 million related to the amortization of the non-refundable up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses) related to our licensing agreement with Braeburn. There were no revenues from licensing agreements in 2011. Royalty revenues during 2012 and 2011 consisted of royalties on sales of Fanapt. Grant revenues during 2012 and 2011 consisted of proceeds from NIH grants related to our Probuphine and ProNeura related programs.

Research and development expenses for 2012 were approximately \$10.6 million compared to approximately \$11.2 million in 2011, a decrease of approximately \$0.6 million, or 5%. The decrease in research and development costs was primarily associated with a decrease in external research and development expenses related to the Phase 3 clinical trials of our Probuphine product which were completed in 2011. This was offset by expenses related to the preparation and submission of an NDA for a Probuphine product with the FDA in October 2012. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. During 2012, our external research and development expenses relating to our Probuphine product development program were approximately \$5.4 million compared to approximately \$7.7 million for 2011. 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 report, 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 products or product candidates.

General and administrative expenses for 2012 were approximately \$4.9 million, compared to approximately \$3.4 million in 2011, an increase of approximately \$1.5 million, or 44%. The increase in general and administrative expenses was primarily related to increases in non-cash stock compensation costs of approximately \$0.8 million, employee-related costs of approximately \$0.3 million, consulting and professional fees of approximately \$0.3 million, fees paid to members of our board of Directors of approximately \$0.1 million and facilities-related costs of approximately \$0.1 million. This was offset in part by decreases in travel-related costs of approximately \$0.1 million.

Net other expense for 2012 was approximately \$6.8 million, compared to approximately \$4.7 million in 2011. The increase in net other expense during 2012 was primarily related to interest expense, net of approximately \$4.9 million on the Deerfield long-term debt and a \$1.8 million non-cash loss related to increases in the fair value of the warrants issued to Deerfield and the warrants issued as part of the April 2012 financing transaction.

*Year Ended December 31, 2011 Compared to Year Ended December 31, 2010*

Our net loss applicable to common stockholders for 2011 was approximately \$15.2 million, or approximately \$0.26 per share, compared to our net loss applicable to common stockholders of approximately \$5.6 million, or approximately \$0.09 per share, for 2010. Our net loss for 2011 includes a non-cash gain of \$1.9 million resulting from changes in the fair value of warrants issued as part of the March 2011 Deerfield transaction.

We generated royalty revenues during 2011 of approximately \$3.6 million compared to approximately \$2.5 million during 2010. We generated grant revenues during 2011 of approximately \$0.5 million compared to approximately \$7.6 million during 2010. We generated no revenues from licensing agreements in 2011 compared to approximately \$24,000 during 2010. Royalty revenues during 2011 and 2010 consisted of royalties on sales of Fanapt. Grant revenues during 2011 and 2010 consisted of proceeds from the NIH grants related to our Probuphine and ProNeura related programs.

Research and development expenses for 2011 were approximately \$11.2 million compared to approximately \$12.9 million in 2010, a decrease of approximately \$1.7 million, or 13%. The decrease in research and development costs was primarily associated with a decrease in external research and development expenses related to the Phase 3 clinical trials of our Probuphine product which were completed in 2011. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. During 2011, our external research and development expenses relating to our Probuphine product development program were approximately \$7.7 million compared to approximately \$10.1 million for 2010. 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 report, 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 products or product candidates.

General and administrative expenses for 2011 were approximately \$3.4 million, compared to approximately \$3.3 million in 2010, an increase of approximately \$0.1 million, or 3%. The increase in general and administrative expenses was primarily related to increases in non-cash stock compensation costs of approximately \$0.3 million, employee-related costs of approximately \$0.3 million, marketing-related costs of approximately \$0.2 million. This was offset in part by decreases in legal fees of approximately \$0.3 million, consulting and professional fees of approximately \$0.3 million, and facilities-related costs of \$0.1 million.

Net other expense for 2011 was approximately \$4.7 million, compared to approximately \$0.8 million in 2010. The increase in net other expense during 2011 was primarily related to interest expense of approximately \$6.2 million on the Deerfield long-term debt and \$0.2 million of interest expense related to the Oxford loans. This was offset in part by a \$1.9 million non-cash gain related to decreases in the fair value of the Deerfield warrants.

*Year Ended December 31, 2010 Compared to Year Ended December 31, 2009*

Our net loss applicable to common stockholders for 2010 was approximately \$5.6 million, or approximately \$0.09 per share, compared to our net loss applicable to common stockholders of approximately \$5.9 million, or approximately \$0.10 per share, for 2009. Our net loss for 2010 includes a non-cash gain of \$1.2 million resulting from the retirement of preferred stock upon dissolution of Ingenex, Inc., our majority-owned subsidiary.

We generated royalty revenues during 2010 of approximately \$2.5 million. We had no royalty revenue during 2009. We generated grant revenues during 2010 of approximately \$7.6 million. We had no grant revenue during 2009. We generated revenues of \$24,000 from licensing agreements in 2010 compared to approximately \$79,000 during 2009. Royalty revenues during 2010 consisted of royalties on sales of Fanapt. Grant revenues during 2010 consisted of proceeds from the NIH grants related to our Probuphine and ProNeura related programs.

Research and development expenses for 2010 were approximately \$12.9 million compared to approximately \$2.5 million in 2009, an increase of approximately \$10.4 million, or 416%. The increase in research and development costs was primarily associated with an increase in external research and development expenses related to the initiation and ongoing expenses of the Phase 3 clinical trials related to our Probuphine product. External research and development expenses include direct expenses such as clinical research organization charges, investigator and review board fees, patient expense reimbursements and contract manufacturing expenses. During 2010, our external research and development expenses relating to our Probuphine product development program were approximately \$10.1 million compared to approximately \$0.7 million for 2009. 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 report, 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 products or product candidates.

General and administrative expenses for 2010 were approximately \$3.3 million, compared to approximately \$3.4 million in 2009, a decrease of approximately \$0.1 million, or 3%. The decrease in general and administrative expenses was primarily related to decreases in non-cash stock compensation costs of approximately \$0.7 million and facilities-related costs of \$0.5 million. This was offset in part by increases in employee-related costs of approximately \$0.2 million, legal fees of approximately \$0.5 million, and consulting and professional fees of approximately \$0.3 million.

Net other expense for 2010 was approximately \$0.8 million compared to approximately \$71,000 in 2009. Net other expense in 2010 consisted primarily of interest expense of approximately \$0.7 million and loan fees of approximately \$0.1 million resulting from our loans with Oxford and tax-related expenses of approximately \$6,000. Net other expense in 2009 consisted primarily of financing-related expenses of approximately \$60,000, interest expense of approximately \$9,000 and tax-related expenses of approximately \$10,000 offset by interest income of approximately \$2,000 and net gain of approximately \$6,000 resulting from the sale of certain assets.

#### ***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, 2012 and 2011.

#### **Item 8. Consolidated Financial Statements and Supplementary Data.**

The response to this item is included in a separate section of this Report. See [Index to Consolidated 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 of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, and includes those policies and procedures that:

(1) Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;

(2) Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with 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, 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, 2012.

The attestation report concerning the effectiveness of our internal controls over financial reporting as of December 31, 2012 issued by OUM & Co. LLP, an independent registered public accounting firm, appears in Item 8 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 of 1934) 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)	58	Executive Chairman of the Board	November 2007
Sunil Bhonsle	63	President and Director	February 2004
Victor J. Bauer (2)(3)	77	Director	November 1997
Eurelio M. Cavalier (1)(3)(4)	80	Director	September 1998
Hubert E. Huckel (1)(2)(3)	81	Director	October 1995
M. David MacFarlane (2)(4)	72	Director	May 2002
Ley S. Smith (1)(2)(4)	78	Director	July 2000

- (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.

**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 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.

**Victor J. Bauer, Ph.D.** serves as the Executive Vice President of Concordia Pharmaceuticals, LLC, a biopharmaceutical company he co-founded in 2004. From February 1997 through March 2003, Dr. Bauer was employed by Titan, most recently as our Executive Director of Corporate Development. From April 1996 until its merger into Titan, Dr. Bauer also served as a director and Chairman of Theracell. From December 1992 until February 1997, Dr. Bauer was a self-employed consultant to companies in the pharmaceutical and biotechnology industries. Prior to that time, Dr. Bauer was with Hoechst-Roussel Pharmaceuticals Inc., where he served as President from 1988 through 1992.

**Eurelio M. Cavalier** was employed in various capacities by Eli Lilly & Co. from 1958 until his retirement in 1994, serving as Vice President Sales from 1976 to 1982 and Group Vice President U.S. Pharmaceutical Business Unit from 1982 to 1993.

**Hubert E. Huckel, M.D.** served in various positions with The Hoechst Group from 1964 until his retirement in December 1992. At the time of his retirement, Dr. Huckel was Chairman of the Board of Hoechst-Roussel Pharmaceuticals, Inc., Chairman and President of Hoechst-Roussel Agri-Vet Company and a member of the Executive Committee of Hoechst Celanese Corporation. Dr. Huckel co-founded Concordia Pharmaceuticals, LLC, a biopharmaceutical company, in 2004. He currently serves on the board of directors of Catalyst Pharmaceuticals, Inc. and Concordia Pharmaceuticals, LLC.

**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.

**Ley S. Smith** served in various positions with The Upjohn Company and Pharmacia & Upjohn from 1958 until his retirement in November 1997. From 1991 to 1993 he served as Vice Chairman of the Board of The Upjohn Company, and from 1993 to 1995 he was President and Chief Operating Officer of The Upjohn Company. At the time of his retirement, Mr. Smith was Executive Vice President of Pharmacia & Upjohn, and President of Pharmacia & Upjohn's U.S. Pharma Product Center.

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 of directors, 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 Securities Exchange Act of 1934, as amended (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 2012.

#### **Code of Ethics**

We have adopted a Code of Business Conduct and Ethics (the Code) that applies to our directors, officers and employees, including our principal executive officer and principal financial and accounting officer, respectively. The Code is filed as Exhibit 14.1 here to and is incorporated by reference into this annual report. A written copy of the Code will be provided upon request at no charge by writing to our Chief Financial Officer, Titan Pharmaceuticals, Inc., 400 Oyster Point Boulevard, Suite 505, South San Francisco, California 94080.

#### **Changes in Director Nomination Process for Stockholders**

None.

### **Formation of Audit Committee and Financial Expert**

The Audit Committee (which is formed in compliance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934) consists of Ley S. Smith, M. David MacFarlane, Victor J. Bauer and Hubert E. Huckel, each of whom meets the independence requirements and standards currently established by the NYSE Amex (formerly the American Stock Exchange) and the SEC. In addition, the Board of Directors has determined that Mr. Ley Smith is an audit committee financial expert and independent as defined under the relevant rules of the SEC and the NYSE Amex.

### **Item 11. Executive Compensation Compensation Committee Report**

The Compensation Committee has reviewed and discussed with management the following discussion and analysis of our executive compensation included in this Annual Report on Form 10-K. Based on such review and discussion with management, the Compensation Committee recommended to the board of directors that the following disclosure be included in this Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

The Compensation Committee:

Eurelio M. Cavalier

Hubert E. Huckel

Victor J. Bauer

### **Overview**

During 2010, 2011 and 2012, Dr. Rubin and Mr. Bhonsle continued as our Executive Chairman and President, respectively, with compensation packages structured to reflect our current level of operations and resources. 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, 2012. 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, 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. During 2012, our compensation philosophy has continued to evolve to accommodate our changing circumstances, operational needs and limited financial resources during this period.

During 2012, our operations continued to focus on efforts to realize maximum shareholder value from activities associated with our Probuphine and ProNeura development programs. Accordingly, our Compensation Committee continued a compensation plan which provides base salary and potential earnings through stock option and restricted stock awards.

During 2011 and 2010, our operations continued to focus on efforts to realize maximum shareholder value from both Fanapt and activities associated with our Probuphine development program. Accordingly, our Compensation Committee implemented a compensation plan which provides base salary and potential earnings through stock option and restricted stock awards.

### **Base Salaries**

During 2012, the base salary of our named executives was reflective of the availability of resources and level of continuing operations. Dr. Rubin continues to receive an annual salary of \$210,000 and Mr. Bhonsle continues to receive an annual salary of \$300,000 through December 31, 2013, at which time we expect to have new compensation arrangements in place. In the event new compensation arrangements with Dr. Rubin and Mr. Bhonsle have not been determined prior to December 31, 2013, Dr. Rubin and Mr. Bhonsle will either (i) make a determination to continue their employment at their then existing respective compensation levels or (ii) terminate their employment arrangements with our company. See Employment Agreements below. In December 2012, following the completion of the License Agreement, Dr. Rubin and Mr. Bhonsle received cash bonuses of \$53,000 and 75,000, respectively.

During 2011, the base salary of our named executives was reflective of the availability of resources and level of continuing operations. As a result of an amendment to his employment agreement, effective January 1, 2011, Dr. Rubin began receiving an annual salary of \$210,000 and Mr. Bhonsle continued to receive an annual salary of \$300,000 through December 31, 2011.

During 2010, the base salary of our named executives was reflective of the availability of resources and level of continuing operations. Dr. Rubin did not receive a cash salary during 2010. As a result of an amendment to his employment agreement, effective March 1, 2010, Mr. Bhonsle's base annual salary was set at \$300,000, essentially his 2008 level.

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 shareholders' interests and, prior to our adoption of FAS 123(R), resulted in less compensation expense for us relative to other types of equity awards. Generally, all grants of stock options to our employees were 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.

The vesting of certain of our named executive officers' stock options is accelerated pursuant to the terms of their employment agreements in certain change in control or other material events. These terms are more fully described in Employment Agreements and Potential Payments upon Termination or Change in Control.

In May 2009, Dr. Rubin was awarded a stock option grant of 1,000,000 shares with immediate vesting of 25% of the grant and the remainder to vest monthly over four years. This was the only compensation provided to Dr. Rubin during 2009. During 2010, Dr. Rubin was awarded 36,000 and 82,800 shares of restricted stock in May and July 2010, respectively. These awards vested over four and six month periods with all restricted shares fully vested by December 31, 2010. Similarly, upon the confirmation of Mr. Bhonsle as the President, he was awarded a stock option grant to purchase 700,000 shares of common stock with immediate vesting of 25% and the remainder to vest monthly over four years. During 2011, Dr. Rubin was awarded a stock option grant to purchase 150,000 shares of common stock with the vesting of 25% after six months and the remainder to vest monthly over the following 18 months. During 2011, Mr. Bhonsle was awarded a stock option grant to purchase 200,000 shares of common stock with the vesting of 25% after six months and the remainder to vest monthly over the following 18 months. During 2012, Dr. Rubin was awarded a fully vested stock option grant to purchase 250,000 shares of common stock. During 2012, Mr. Bhonsle was awarded a fully vested stock option grant to purchase 300,000 shares of common stock.

#### Compensation Committee Interlocks and Insider Participation

Members of our Compensation Committee of the board of directors were Eurelio M. Cavalier, Hubert E. Huckel and Victor J. Bauer. No member of our Compensation Committee was, or has been, an officer or employee of Titan or any of our subsidiaries, except for Victor J. Bauer, who was employed by Titan from February 1997 through March 2003 as our Executive Director of Corporate Development and from April 1996 until its merger into Titan, Dr. Bauer also served as a Director and Chairman of a former subsidiary.

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.

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**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(1)	Year	Salary (\$)	Bonus (\$)	Options(2) (\$)	Awards(2) (\$)	All Other Compensation (\$)	Total Compensation (\$)
Marc Rubin, M.D.(3)(4) Executive Chairman	2012	\$ 210,000	\$ 53,000	\$ 273,450	\$	\$	\$ 536,450
	2011	210,000		201,015			411,015
	2010				152,982		152,982
Louis R. Bucalo, M.D.(5) Former Executive Chairman	2012						
	2011						
	2010	70,312					70,312
Sunil Bhonsle President and Chief Financial Officer	2012	300,000	75,000	328,140			703,140
	2011	300,000		268,020			568,020
	2010	277,473					277,473

- (1) The positions listed are the most recent held by such individuals.
- (2) 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. Consolidated Financial Statements Notes to Consolidated Financial Statements Note 12 Stock Plans.
- (3) Dr. Rubin did not receive a salary during 2010.
- (4) Dr. Rubin was awarded 36,000 and 82,800 shares of restricted stock on March 1, 2010 and July 1, 2010, respectively, instead of a cash salary. These shares were fully vested as of December 31, 2010.
- (5) Dr. Bucalo's employment was terminated in April 2008 and he received salary continuation payments until April 2010. During 2010, Dr. Bucalo received salary continuation payments of \$70,312, respectively. His outstanding options continued to vest under the terms of his severance agreement through April 2010, at which time they were cancelled unexercised.

For a description of the material terms of employment agreements with our current and former named executive officers, see Employment Agreements.

## GRANTS OF PLAN-BASED AWARDS

Name	Grant Date	Approval Date(1)	Number of Shares of Common Stock Underlying Options (#)	Exercise or Base Price of Option Awards (\$/Sh)	Grant Date Fair Value of Stock and Option Awards\$(2)
Marc Rubin, M.D.	1/3/2012	12/28/2011	250,000(3)	\$ 1.15	\$ 273,450
Sunil Bhonsle	1/3/2012	12/28/2011	300,000(3)	\$ 1.15	\$ 328,140

- (1) All grants were approved by the Compensation Committee on the dates indicated.
- (2) Valuation assumptions are found under Titan Pharmaceuticals, Inc. Consolidated Financial Statements Notes to Consolidated Financial Statements Note 12 Stock Plans.
- (3) These options were 100% vested on 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.

**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 7.4 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. Options to purchase an aggregate of 4,280,153 shares of our common stock are currently outstanding under the 2002 Plan.

**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 1,750,000 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 Stock Option Plan expired by its terms in August 2011. Options to purchase an aggregate of 1,199,500 shares of our common stock are currently outstanding under the 2001 NQ Plan.

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**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, 2012.

Name	Option Awards			
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Marc Rubin, M.D.	437,500		\$ 2.40	10/01/2017
	2,500		1.52	5/30/2018
	5,000		1.52	5/30/2018
	550,937	64,063(1)	0.79	5/17/2019
	100,000		0.79	5/17/2019
	5,000		0.79	5/17/2019
	10,000		0.79	5/17/2019
	270,938	14,062(1)	0.79	5/17/2019
	125,000	25,000(3)	1.40	4/15/2021
	250,000		1.15	1/3/2022
Sunil Bhonsle	50,000		1.50	3/1/2013
	60,000		3.69	2/9/2014
	70,000		2.62	2/7/2015
	80,137		1.40	1/3/2016
	11,250		2.35	8/29/2016
	76,666		3.13	1/3/2017
	5,000		1.52	5/30/2018
	277,710	32,290(2)	0.79	5/17/2019
	100,000		0.79	5/17/2019
	10,000		0.79	5/17/2019
	367,604	22,396(2)	0.79	5/17/2019
	166,667	33,333(3)	1.40	4/15/2021
	300,000		1.15	1/3/2022

- (1) These options vest in 48 equal monthly installments beginning on May 17, 2009.
- (2) These options vest in 48 equal monthly installments beginning on May 17, 2009, with the vesting of 100,000 shares contingent upon the sale or partnering of the Probuphine program.
- (3) These options vest over a 24 month period beginning on April 15, 2011 with 25% vesting after six months and the balance vesting in 18 monthly installments over the remaining vesting period.

No options were exercised by our named executive officers during 2012.

**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, Mr. Bhonsle and Dr. Bucalo participated.

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**Employment Agreements*****Marc Rubin***

In May 2009, in connection with our re-engagement of our executive officers following the FDA's approval of Fanapt, we entered into a new employment agreement with Dr. Rubin to serve as our Executive Chairman (the Rubin Agreement). Pursuant to the Rubin Agreement, as such agreement was amended effective March 1, 2010, June 15, 2010 and December 27, 2010, he received no cash salary through December 2010. In May 2009, we granted Dr. Rubin options to purchase 1,000,000 shares of our common stock that vest as follows: 25% immediately and the balance monthly over a four-year period. Notwithstanding the foregoing, all unvested options held by Dr. Rubin automatically will become vested and exercisable immediately prior to the occurrence of a change of control. One half of the options will accelerate in the event we sell or transfer all or substantially all of our rights in iloperidone. In addition, in the event that we declare a dividend or similar distribution following such sale or transfer, we have agreed to retain for Dr. Rubin's benefit an amount equal to the dividend amount for distribution to him only upon the actual vesting and exercise by him of the unvested options. In consideration for entering into the March 1, 2010 amendment agreement, we issued Dr. Rubin 36,000 restricted shares that vested in four monthly installments through June 30, 2010. In consideration for entering into the June 15, 2010 amendment agreement, we issued Dr. Rubin 82,800 restricted shares that vested in six monthly installments through December 31, 2010. In consideration for entering into the December 27, 2010 amendment agreement, we agreed to pay Dr. Rubin an annual salary of \$210,000 for the period of January 1, 2011 through December 31, 2011. On December 30, 2011, we agreed to extend the term of Dr. Rubin's employment with us through December 31, 2012 at an annual salary of \$210,000 for the period of January 1, 2012 through December 31, 2012. On December 31, 2012, we agreed to extend the term of Dr. Rubin's employment with us through December 31, 2013 at an annual salary of \$210,000 for the period of January 1, 2013 through December 31, 2013. The Rubin Agreement contains non-competition provisions applicable during the term of employment.

***Sunil Bhonsle***

In May 2009, in connection with our re-engagement of our executive officers following the FDA's approval of Fanapt, we entered into a new employment agreement with Mr. Bhonsle to serve as our President (the Bhonsle Agreement). The Bhonsle Agreement provided that until February 28, 2010, he was entitled to a cash salary of \$200,000 per annum, payment of which was deferred until we began receiving royalty payments from Fanapt. Mr. Bhonsle was granted options to purchase 700,000 shares of our common stock that vest as follows: 25% immediately and the balance monthly over a four-year period; provided, however, that the vesting of 100,000 shares is also contingent upon the sale or partnering of the Probuphine program. Notwithstanding the foregoing, all unvested options held by Mr. Bhonsle automatically will become vested and exercisable immediately prior to the occurrence of a change of control. Effective March 1, 2010, we amended the Bhonsle Agreement to provide that from the effective date through June 30, 2010, he was entitled to a salary of \$300,000 per annum. The amendment also provides that one half of the options will accelerate in the event we sell or transfer all or substantially all of our rights in iloperidone. In addition, in the event that we declare a dividend or similar distribution following such sale or transfer, we have agreed to retain for Mr. Bhonsle's benefit an amount equal to the dividend amount for distribution to him only upon the actual vesting and exercise by him of the unvested options. Effective July 1, 2010, as further amended effective December 27, 2010 and December 30, 2011, we amended the Bhonsle Agreement to provide that Mr. Bhonsle would continue to be entitled to a salary of \$300,000 per annum through December 31, 2012. On December 31, 2012, we agreed to extend the term of Mr. Bhonsle's employment with us through December 31, 2013 at an annual salary of \$300,000 for the period of January 1, 2013 through December 31, 2013. The Bhonsle Agreement contains non-competition provisions applicable during the term of employment.

**POTENTIAL PAYMENTS UPON TERMINATION OR CHANGE IN CONTROL**

Pursuant to the Rubin Agreement and the Bhonsle Agreement, assuming a change of control had taken place as of December 31, 2012, Dr. Rubin and Mr. Bhonsle would have been entitled to accelerated vesting of their outstanding stock options described in the table below:

	<b>Value of Equity Awards: Termination Without Cause or For Good Reason(1)</b>	<b>Value of Equity Awards: In Connection With a Change in Control(1)</b>
Marc Rubin, M.D.	None	Fully Vested. 103,125 options with value of \$16,408
Sunil Bhonsle.	None	Fully Vested. 88,019 options with value of \$11,486

- (1) Value is based on the aggregate difference between the respective exercise prices and the closing sale price of our common stock on December 31, 2012, which was \$1.10 per share.

**DIRECTOR COMPENSATION****Summary of Director Compensation**

Non-employee directors are entitled to receive a fee for each meeting attended and all directors are entitled to receive stock options pursuant to our stockholder-approved stock option plans, including an initial grant of 10,000 options upon becoming a director, an annual grant of 20,000 options thereafter, and an annual grant of 5,000 options for each committee on which they serve. Directors are not precluded from serving us in any other capacity and receiving compensation therefor. Non-employee directors have also historically received an annual retainer fee of \$15,000 in addition to the fee received for each meeting attended. Non-employee directors receive \$500 for each telephonic board meeting attended.

The following table summarizes compensation that our directors earned during 2012 for services as members of our board.

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	Options Awards (\$)	Non-Equity Incentive Plan Compensation (\$)	Change in Pension Value and Nonqualified Deferred Earnings (\$)	All Other Compensation (\$)	Total (\$)
Victor J. Bauer, Ph.D.	\$ 29,500	\$	\$ 32,889	\$	\$	\$	\$ 62,389
Eurelio M. Cavalier	29,000		38,370				67,370
Hubert E. Huckel, M.D.	29,500		38,370				67,870
M. David MacFarlane, Ph.D.	29,500		32,889				62,389
Ley S. Smith	29,500		38,370				67,870

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

The following table sets forth, as of March 11, 2013, certain information concerning the beneficial ownership of our common stock by (i) each stockholder known by us to own beneficially five percent or more of our outstanding common stock; (ii) each director; (iii) each named executive officer; and (iv) all of our executive officers and directors as a group, and their percentage ownership and voting power.

Name and Address of Beneficial Owner(1)	Shares Beneficially Owned(2)	Percent of Shares Beneficially Owned
Marc Rubin, M.D.	2,376,575(3)	2.8%
Victor J. Bauer, Ph.D.	286,144(4)	*
Sunil Bhonsle	1,968,373(5)	2.4%
Eurelio M. Cavalier	437,500(6)	*
Hubert E. Huckel, M.D.	449,835(7)	*
M. David MacFarlane, Ph.D.	317,500(8)	*
Ley S. Smith	367,500(9)	*
First Eagle Investment Management, LLC	7,446,205(10)	9.1%
All executive officers and directors as a group (7) persons	6,203,427	7.2%

\* 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 11, 2013 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 1,844,375 shares issuable upon exercise of outstanding options.
  - (4) Includes 250,000 shares issuable upon exercise of outstanding options.
  - (5) Includes (i) 1,602,116 shares issuable upon exercise of outstanding options and (ii) 300,757 shares held in a family trust for which he serves as trustee.
  - (6) Includes 255,000 shares issuable upon exercise of outstanding options.
  - (7) Includes (i) 265,000 shares issuable upon exercise of outstanding options and (ii) 789 shares held by his wife.
  - (8) Includes 195,000 shares issuable upon exercise of outstanding options.
  - (9) Includes 255,000 shares issuable upon exercise of outstanding options.
  - (10) Derived from a Schedule 13G/A filed by First Eagle Investment Management, LLC on February 11, 2013. Includes warrants to purchase 1,562,500 shares of common stock. The holder's address is 1345 Avenue of the Americas, New York, New York 10105.

**Equity Compensation Plan Information**

The following table sets forth aggregate information regarding our equity compensation plans in effect as of December 31, 2012:

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	4,280,153	\$ 1.35	
Equity compensation plans not approved by security holders(1)(2)(3)	2,562,000	\$ 1.34	
<b>Total</b>	<b>6,842,153</b>	<b>\$ 1.35</b>	

- (1) In August 2002, we amended our 2001 Employee Non-Qualified Stock Option Plan. Pursuant to this amendment, a total of 1,750,000 shares of common stock were reserved and authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan. At December 31, 2012, 1,199,500 of these non-qualified stock options remained outstanding.
- (2) In October 2007, we granted 1,500,000 non-qualified stock options outside of our stock option plans to our Chief Executive Officer, at an exercise price of \$2.40, vesting equally over 48 months from the date of grant. At December 31, 2012, 437,500 of these non-qualified stock options remained outstanding.
- (3) In May 2009, we granted 615,000 and 310,000 non-qualified stock options outside of our stock option plans to our Executive Chairman and President, respectively, at an exercise price of \$0.79, vesting equally over 48 months from the date of grant.

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

The following members of our board of directors, representing a majority of our board, meet the independence requirements and standards currently established by the NYSE MKT: Victor J. Bauer, Eurelio M. Cavalier, Hubert E. Huckel, M. David MacFarlane and Ley S. Smith.

*Certain Relationships and Related Transactions. None.*

*Director Independence.* The following members of our Board of Directors meet the independence requirements and standards currently established by the NYSE MKT: Victor J. Bauer, Eurelio M. Cavalier, Hubert E. Huckel, M. David MacFarlane, and Ley S. Smith.

During the fiscal year ended December 31, 2012, the Board of Directors met nine times and no director attended fewer than 75% of the meetings of the Board of Directors and Board of Directors committees of which the director was a member.

*Compensation Committee.* The Compensation Committee makes recommendations to the Board of Directors concerning salaries and incentive compensation for our officers, including our Chief Executive Officer, and employees and administers our stock option plans. The Compensation Committee consists of Eurelio M. Cavalier, Hubert E. Huckel and Victor J. Bauer, each of whom meets the independence requirements and standards currently established by the NYSE MKT. The Compensation Committee did not meet or take action by written consent during the fiscal year ended December 31, 2012.

*Nominating Committee.* The purpose of the Nominating Committee is to assist the Board of Directors in identifying qualified individuals to become board members, in determining the composition of the Board of Directors and in monitoring the process to assess Board effectiveness. The Nominating Committee consists of Eurelio M. Cavalier, M. David MacFarlane and Ley S. Smith, each of whom meets the independence requirements and standards currently established by the NYSE MKT. The Nominating Committee did not meet or take action by written consent during the fiscal year ended December 31, 2012.

*Audit Committee.* The Audit Committee (which is formed in compliance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934) consists of Ley S. Smith, M. David MacFarlane, Victor J. Bauer and Hubert E. Huckel, each of whom meets the independence requirements and standards currently established by the NYSE MKT and the SEC. In addition, the Board of Directors has determined that Mr. Ley S. Smith is an audit committee financial expert 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, 2012, the Audit Committee met four times.

**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, 2012 and 2011 were as follows:

	2012	2011
Audit Fees	\$ 177,000	\$ 142,000
Audit-Related Fees	50,000	51,400
Tax Fees	36,395	39,835
All Other Fees		
<b>Total</b>	<b>\$ 263,395</b>	<b>\$ 233,235</b>

**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, 2012 and 2011, 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 the Company's financial statements for the year ended December 31, 2012, 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 Consolidated 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.**

**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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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 consolidated balance sheets of Titan Pharmaceuticals, Inc. as of December 31, 2012 and 2011, the related consolidated statements of operations and comprehensive loss, stockholders' deficit and cash flows for each of the three years in the period ended December 31, 2012. 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. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements audited by us present fairly, in all material respects, the consolidated financial position of Titan Pharmaceuticals, Inc. at December 31, 2012 and 2011, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2012, in conformity with U.S. generally accepted accounting principles.

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, 2012, based on criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 14, 2013 expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California

March 14, 2013

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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, 2012, based on criteria established in *Internal Control - Integrated Framework* 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 Management's Annual Report on Internal Control Over Financial Reporting included in Item 9A. 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, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and 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 U.S. 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 U.S. 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, 2012, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Titan Pharmaceuticals, Inc. as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for each of the three years in the period ended December 31, 2012, and our report dated March 14, 2013, expressed an unqualified opinion thereon.

/s/ OUM & Co. LLP

San Francisco, California

March 14, 2013

## TITAN PHARMACEUTICALS, INC.

## CONSOLIDATED BALANCE SHEETS

	December 31,	
	2012	2011
	(in thousands, except share and per share data )	
<b>Assets</b>		
Current assets:		
Cash	\$ 18,102	\$ 5,406
Receivables	4,646	3,720
Prepaid expenses and other current assets	687	836
Total current assets	23,435	9,962
Property and equipment, net	1,392	255
Total Assets	\$ 24,827	\$ 10,217
<b>Liabilities and Stockholders Deficit</b>		
Current liabilities:		
Accounts payable	\$ 3,767	\$ 4,789
Accrued clinical trials expenses	532	161
Other accrued liabilities	219	173
Deferred contract revenue	14,375	
Current portion of long-term debt	2,500	
Total current liabilities	21,393	5,123
Warrant liability	8,240	3,611
Royalty liability	8,962	9,309
Long-term debt, net of discount	9,360	12,253
Total Liabilities	47,955	30,296
Commitments and contingencies		
Stockholders deficit:		
Preferred stock, \$0.001 par value per share; 5,000,000 shares authorized, none issued and outstanding:		
Common stock, at amounts paid in, \$0.001 par value per share; 125,000,000 shares authorized, 75,215,713 and 59,386,542 shares issued and outstanding at December 31, 2012 and 2011, respectively.	265,986	256,436
Additional paid-in capital	21,014	18,433
Accumulated deficit	(310,128)	(294,948)
Total stockholders deficit	(23,128)	(20,079)
Total Liabilities and Stockholders Deficit	\$ 24,827	\$ 10,217

See accompanying notes to consolidated financial statements.



## TITAN PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	Years ended December 31,		
	2012	2011	2010
	(in thousands, except per share amount)		
Revenue:			
Royalty revenue	\$ 4,750	\$ 3,585	\$ 2,512
License revenue	2,325		24
Grant revenue	42	483	7,557
Total revenue	7,117	4,068	10,093
Operating expenses:			
Research and development	10,610	11,206	12,855
General and administrative	4,877	3,368	3,263
Total operating expenses	15,487	14,574	16,118
Loss from operations	(8,370)	(10,506)	(6,025)
Other income (expense):			
Interest expense, net	(4,861)	(6,430)	(678)
Other expense, net	(183)	(129)	(131)
Non-cash gain (loss) on changes in the fair value of warrants	(1,766)	1,862	
Other expense, net	(6,810)	(4,697)	(809)
Net loss and comprehensive loss	(15,180)	(15,203)	(6,834)
Gain on retirement of preferred stock upon dissolution of subsidiary			1,241
Net loss applicable to common stockholders	\$ (15,180)	\$ (15,203)	\$ (5,593)
Basic and diluted net loss per common share	\$ (0.23)	\$ (0.26)	\$ (0.09)
Weighted average shares used in computing basic and diluted net loss per common share	66,509	59,324	59,248

See accompanying notes to consolidated financial statements.

## TITAN PHARMACEUTICALS, INC

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS DEFICIT

(in thousands)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders Deficit
	Shares	Amount				
<b>Balances at December 31, 2009</b>	<b>59,248</b>	<b>\$ 256,436</b>	<b>\$ 15,027</b>	<b>\$ (272,911)</b>	<b>\$</b>	<b>\$ (1,448)</b>
Comprehensive loss:						
Net loss				(6,834)		(6,834)
Unrealized gain or loss on marketable securities						
Comprehensive loss						(6,834)
Retirement of preferred stock upon dissolution of Ingenex, Inc.			1,241			1,241
Issuance of warrants to purchase common stock			255			255
Compensation related to stock options			733			733
<b>Balances at December 31, 2010</b>	<b>59,248</b>	<b>256,436</b>	<b>17,256</b>	<b>(279,745)</b>		<b>(6,053)</b>
Comprehensive loss:						
Net loss				(15,203)		(15,203)
Unrealized gain or loss on marketable securities						
Comprehensive loss						(15,203)
Issuance of common stock upon vesting of restricted stock awards	139					
Compensation related to stock options			1,177			1,177
<b>Balances at December 31, 2011</b>	<b>59,387</b>	<b>256,436</b>	<b>18,433</b>	<b>(294,948)</b>		<b>(20,079)</b>
Comprehensive loss:						
Net loss				(15,180)		(15,180)
Unrealized gain or loss on marketable securities						
Comprehensive loss						(15,180)
Issuance of common stock, net of issuance costs	9,917	4,653				4,653
Issuance of common stock upon exercise of warrants	5,762	4,897				4,897
Issuance of common stock upon vesting of restricted stock awards, net	150					
Compensation related to stock options			2,581			2,581
<b>Balances at December 31, 2012</b>	<b>75,216</b>	<b>\$ 265,986</b>	<b>\$ 21,014</b>	<b>\$ (310,128)</b>	<b>\$</b>	<b>\$ (23,128)</b>

See accompanying notes to consolidated financial statements.

## TITAN PHARMACEUTICALS, INC.

## CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years ended December 31,		
	2012	2011	2010
	(in thousands)		
<b>Cash flows from operating activities:</b>			
Net loss	\$ (15,180)	\$ (15,203)	\$ (6,834)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	17	32	85
Amortization of discount on long-term debt		1,520	132
Interest on royalty liability	(347)	1,309	
Non-cash (gain) loss on changes in fair value of warrants	1,766	(1,862)	
Stock-based compensation	2,581	1,177	733
Changes in operating assets and liabilities:			
Receivables	(926)	(2,495)	(1,159)
Prepaid expenses and other assets	149	(542)	(44)
Accounts payable	(1,022)	2,332	2,122
Other accrued liabilities	417	(744)	308
Deferred contract revenue	14,375		
<b>Net cash provided by (used in) operating activities</b>	<b>1,830</b>	<b>(14,476)</b>	<b>(4,657)</b>
<b>Cash flows from investing activities:</b>			
Purchases of furniture and equipment	(1,154)	(236)	(28)
Disposals of furniture and equipment		2	
<b>Net cash used in investing activities</b>	<b>(1,154)</b>	<b>(234)</b>	<b>(28)</b>
<b>Cash flows from financing activities:</b>			
Proceeds from issuance of common stock and warrants, net of issuance costs	7,516		
Proceeds from the exercise of warrants, net of issuance costs	4,897		
Proceeds from royalty financing		8,000	
Proceeds from long-term debt, net		16,500	5,000
Payments on long-term debt	(393)	(7,564)	(435)
<b>Net cash provided by financing activities</b>	<b>12,020</b>	<b>16,936</b>	<b>4,565</b>
<b>Net increase (decrease) in cash</b>	<b>12,696</b>	<b>2,226</b>	<b>(120)</b>
Cash at beginning of period	5,406	3,180	3,300
<b>Cash at end of period</b>	<b>\$ 18,102</b>	<b>\$ 5,406</b>	<b>\$ 3,180</b>
<b>Supplemental disclosure of cash flow information</b>			
Interest paid	\$ 2,576	\$ 1,652	\$ 678
<b>Schedule of non-cash transactions</b>			
Retirement of preferred stock upon dissolution of Ingenex, Inc.	\$	\$	\$ 1,241

See accompanying notes to consolidated financial statements.

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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**1. Organization and Summary of Significant Accounting Policies**

*The Company and its Subsidiaries*

We are a biopharmaceutical company developing proprietary therapeutics for the treatment of serious medical disorders. Our product development programs focus primarily on important pharmaceutical markets with significant unmet medical needs and commercial potential. We are directly developing our product candidates and also utilize corporate, academic and government partnerships as appropriate. Such collaborations have helped to fund product development and have enabled us to retain significant economic interest in our products. We operate in only one business segment, the development of pharmaceutical products.

Our principal asset is Probuphine<sup>®</sup>, the first slow release implant formulation of buprenorphine, designed to maintain a stable, round the clock blood level of the medicine in patients for six months following a single treatment. An NDA seeking approval of Probuphine for the treatment of opioid dependence in adult patients has been accepted by the FDA for a Priority Review. Based upon the Prescription Drug User Fee Act (PDUFA), the FDA has set a target date of April 30, 2013 for FDA action on the NDA.

In December 2012, we entered into a license agreement with Braeburn Pharmaceuticals Sprl that grants Braeburn exclusive commercialization rights to Probuphine in the United States and Canada. We received a non-refundable up-front license fee of \$15.75 million (approximately \$15.0 million, net of expenses) and will receive a \$50 million milestone payment upon approval by the FDA of the NDA. Additionally, we will be eligible to receive up to \$130 million upon achievement of specified sales milestones and up to \$35 million in regulatory milestones for additional indications, including chronic pain. We will receive tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties. In addition to the potential milestone payments, Apple Tree Partners IV, Braeburn's parent company, has allocated in excess of \$75 million to launch, commercialize and continue the development of Probuphine.

The accompanying financial statements have been prepared assuming we will continue as a going concern. We believe that our working capital at December 31, 2012, together with the FDA's reimbursement of the NDA filing fee, is sufficient to fund our planned operations through June 2014. In the event that the FDA issues a complete response letter requiring us to conduct additional clinical studies that would require expenditures in excess of certain amounts specified in our agreement with Braeburn, Braeburn will have the right to either terminate the agreement or reduce the amount of the \$50 million milestone payment payable to us in the event the FDA ultimately approves of Probuphine. If Braeburn were to terminate the agreement, we would not have sufficient funds available to us to complete the FDA approval process and commercialize Probuphine and, as a result, our business and prospects will be materially adversely impacted. Furthermore, continuation of our current Parkinson's disease development program and the initiation of any additional programs will depend upon our receipt of the \$50 million milestone payment and if such payment is not received or is significantly reduced our ability to fund any new product development programs will be materially impaired and we may need to obtain additional financing, either through the sale of debt or equity securities, to continue our Probuphine program and other product development activities. If we are unable to complete a debt or equity offering, or otherwise obtain sufficient financing when and if needed, we may be required to reduce, defer or discontinue one or more of our product development activities.

*Basis of Presentation and Consolidation*

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States and include the accounts of Titan Pharmaceuticals, Inc. and its former majority-owned subsidiary. All significant intercompany balances and transactions are eliminated.

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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

*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 consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

*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 of directors totaled \$2.6 million, \$1.2 million and \$0.7 million for the years ended December 31, 2012, 2011 and 2010, 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 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 Consolidated Statements of Operations and Comprehensive 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. Our marketable securities, consisting primarily of high-grade debt securities including money market funds, 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 did not have cash equivalents or marketable securities as of December 31, 2012 and 2011 and for any of the periods presented.

*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.

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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

***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) collectibility is reasonably assured. For each source of revenue, we comply with the above revenue recognition criteria in the following manner:

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 collectability is reasonably assured. 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.

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.

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.

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 collectibility is reasonably assured. Pursuant to certain license agreements, we earn royalties on the sale of Fanapt by Novartis in the U.S. As described in Note 7, Commitments and Contingencies, we are obligated to pay royalties on such sales to Sanofi-Aventis and another third party. As we have no performance obligations under the license agreements, we have recorded the royalties earned, net of royalties we are obligated to pay, as revenue in our consolidated statement of operations.

***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



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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 & 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 Loss Per Share***

We calculate basic net loss per share using the weighted average common shares outstanding for the period. Diluted net income per share would include the impact of other dilutive equity instruments, primarily our options and warrants. For the years ended December 31, 2012, 2011 and 2010, options and warrants totaled 19.7 million, 18.6 million and 12.1 million shares, respectively. We reported net losses for all years presented and, therefore, options and warrants were excluded from the calculation of diluted net loss per share as they were anti-dilutive.

***Comprehensive Income (Loss)***

Comprehensive income (loss) is comprised of net loss and other comprehensive income (loss). We had no unrealized gains or losses at December 31, 2012 and 2011. Comprehensive loss for the years ended December 31, 2012, 2011 and 2010 was \$15.2 million, \$15.2 million and \$6.8 million, respectively.

***Recent Accounting Pronouncements***

In June 2011, the FASB issued Accounting Standards Update ( ASU ) No. 2011-05 *Presentation of Comprehensive Income* that improves the comparability, consistency, and transparency of financial reporting and increases the prominence of items reported in other comprehensive income by eliminating the option to present components of other comprehensive income as part of the statement of changes in stockholders equity. The amendments in this standard require that all non-owner changes in stockholders equity be presented either in a single continuous statement of comprehensive income or in two separate but consecutive statements. Under either method, adjustments must be displayed for items that are reclassified from other comprehensive income ( OCI ) to net income, in both net income and OCI. The standard does not change the current option for presenting components of OCI gross or net of the effect of income taxes, provided that such tax effects are presented in the statement in which OCI is presented or disclosed in the notes to the financial statements. Additionally, the standard does not affect the calculation or reporting of earnings per share. For public entities, the amendments in this ASU are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011 and are to be applied retrospectively, with early adoption permitted. In December 2011, the FASB issued ASU No. 2011-12 to defer the effective date of certain amendments to the presentation of reclassifications of items out of the accumulated other comprehensive income in ASU No 2011-05 to allow the FASB time to redeliberate on the matter. ASU No. 2011-12 is effective at the same time as the amendments in ASU No. 2011-05. The adoption of this standard did not have a material impact on our consolidated financial statements.



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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

In May 2011, the FASB issued ASU No. 2011-04 which amends GAAP to conform to the measurement and disclosure requirements in International Financial Reporting Standards ( IFRS ). The amendments in this ASU change the wording used to describe the requirements in U.S. GAAP for measuring fair value and for disclosing information about fair value measurements. The amendments include the following:

Those that clarify the FASB's intent regarding the application of existing fair value measurement and disclosure requirements; and

Those that change a particular principle or requirement for measuring fair value or for disclosing information about fair value measurements.

In addition, to improve consistency in application across jurisdictions some changes in wording are necessary to ensure that GAAP and IFRS fair value measurement and disclosure requirements are described in the same way (for example, using the word shall rather than should to describe the requirements in GAAP). The amendments in this ASU are to be applied prospectively and are effective during interim and annual periods beginning after December 15, 2011. We will evaluate the requirements and do not believe that the adoption of this update will have a material impact on our consolidated financial statements at this time.

***Subsequent Events***

We have evaluated events that have occurred subsequent to December 31, 2012 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 cash, 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. 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.

During the years ended December 31, 2012 and 2011, as a result of the fair value adjustment of the warrant liabilities, we recorded a non-cash loss on an increase in the fair value of \$1,766,000 and a non-cash gain on a decrease in the fair value of \$1,862,000, respectively, in our statements of operations and comprehensive loss. See Note 9, Warrant Liabilities for further discussion on the calculation of the fair value of the warrant liabilities.

## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following table rolls forward the fair value of the Company's warrant liabilities, the fair value of which is determined by Level 3 inputs for the years ended December 31, 2012 and 2011 (in thousands):

	December 31,	
	2012	2011
Fair value, beginning of period	\$ 3,611	\$
Issuance of warrants	2,863	5,473
Change in fair value	1,766	(1,862)
Fair value, end of period	\$ 8,240	\$ 3,611

## 2. Property and Equipment

Property and equipment consisted of the following at December 31, 2012 and 2011 (in thousands):

	2012	2011
Furniture and office equipment	\$ 388	\$ 388
Leasehold improvements	408	408
Laboratory equipment	2,047	922
Computer equipment	996	967
	3,839	2,685
Less accumulated depreciation and amortization	(2,447)	(2,430)
Property and equipment, net	\$ 1,392	\$ 255

Depreciation and amortization expense was \$17,000, \$32,000 and \$85,000 for the years ended December 31, 2012, 2011 and 2010, 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, \$36,000, and \$61,000 in the years ended December 31, 2012, 2011 and 2010, respectively.

We make no annual payments 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. We are required to make additional benchmark payments as specific milestones are met. Upon commercialization of the product, the license agreement provides that we will pay royalties based on net sales.



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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**5. Iloperidone Sublicense to Novartis Pharma AG**

We entered into an agreement with Novartis in 1997 pursuant to which we granted Novartis a sublicense for the worldwide (with the exception of Japan) development, manufacturing and marketing of iloperidone. In April 2001, we entered into an amendment to the agreement for the development and commercialization of iloperidone in Japan. Under the amendment, in exchange for rights to iloperidone in Japan, we received a \$2.5 million license fee in May 2001. Novartis will make our milestone payments to Sanofi-Aventis during the life of the Novartis agreement, and will also pay to Sanofi-Aventis and us a royalty on future net sales of the product, providing us with a net royalty of 8% on the first \$200.0 million of sales annually and 10% on all sales above \$200.0 million on an annual basis. Novartis has assumed the responsibility for all clinical development, registration, manufacturing and marketing of iloperidone, and we have no remaining obligations under the terms of this agreement, except for maintaining certain usual and customary requirements, such as confidentiality covenants.

In June 2004, we announced that Vanda had acquired from Novartis the worldwide rights to develop and commercialize iloperidone, our proprietary antipsychotic agent in Phase 3 clinical development for the treatment of schizophrenia and related psychotic disorders. All of our rights and economic interests in iloperidone, including royalties on sales of iloperidone, remain essentially unchanged under this agreement.

In May 2009, iloperidone (Fanapt) was approved by the FDA for the treatment of schizophrenia. In October 2009, Novartis acquired from Vanda the rights to commercialize Fanapt in the United States and Canada.

In October 2012, we were notified by Novartis that it had decided to cease further development of the long-acting injectable, or depot, formulation of iloperidone. Novartis will continue to commercialize Fanapt<sup>®</sup>, the oral formulation of iloperidone, in the U.S. and under the terms of the sublicense agreement. In November 2011, we sold substantially all of our remaining future royalties on the sales of Fanapt<sup>®</sup> to Deerfield, and accordingly the future royalty payments owed to us by Novartis will continue to be transmitted to Deerfield upon receipt from Novartis per the terms of the agreement with Deerfield. See Note 8, *Royalty Liability* for further discussion of our royalty liabilities.

**6. Braeburn License**

In December 2012, we entered into a license agreement with Braeburn granting Braeburn exclusive commercialization rights to Probuphine in the United States 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 will receive a \$50.0 million milestone payment upon approval by the FDA of the NDA. We will be eligible to receive up to \$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 will receive tiered royalties on net sales of Probuphine ranging from the mid-teens to the low twenties. In addition, Apple Tree Partners IV, Braeburn's parent company, has allocated in excess of \$75.0 million to launch, commercialize and continue the development of Probuphine.

We have evaluated the revenue components of this license 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 will be recognized on a straight-line basis over the estimated period to reach FDA approval and meet the contract deliverables, including the transition of production and supply services of the product to Braeburn. Based on our understanding of subsequent steps to be performed

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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

following the PDUFA date related to the completion of the transition of production and supply services to Braeburn, we estimate the revenue recognition period for the up-front payment to be approximately 12 months from the date of this agreement. Accordingly, we will recognize revenue for the up-front payment ratably from December 14, 2012, the date of the agreement, through December 14, 2013 at an amount equal to approximately \$1.25 million per month. As of December 31, 2012, we have recognized approximately \$0.6 million in license revenue and recorded deferred revenues of \$14.4 million 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 license agreement, we will receive a \$50.0 million milestone payment from Braeburn within 10 days following the achievement of FDA approval of the product NDA. As such, upon receipt of FDA approval our obligation will be fulfilled. As the milestone payment relates solely to past performance, i.e. FDA approval, we will recognize the \$50.0 million regulatory milestone payment from Braeburn on the date of achievement of FDA approval in accordance with the milestone method of revenue recognition. Following FDA approval, we will be reimbursed by Braeburn for any development services and activities performed by us at Braeburn's request.

The license 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 license agreement, create new obligations or alter, increase or expand, or waive compliance with the license agreement, create new obligations not specified in the license agreement, or alter, increase or expand, or waive compliance by a party with obligations under the license 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 license agreement.

## **7. Commitments and Contingencies**

### ***Financing Agreements***

In December 2009, we entered into a loan and security agreement with Oxford Capital Financing (Oxford) pursuant to which we received a three-year term loan in the principal amount of \$3.0 million that bears interest at the rate of 13% per annum. We paid Oxford an initial facility fee of \$60,000 and are obligated to make a final payment fee of \$180,000. Commencing in January 2010, the loan is repayable in monthly interest payments of \$32,500 through June 2010 followed by monthly interest and principal installments of \$117,665 commencing in July 2010 through December 2012. The loan is secured by our assets and has a provision for pre-payment. We also issued to Oxford, in connection with the loan and security agreement, five-year warrants to purchase 42,254 shares of our common stock at an exercise price of \$2.13 per share. The relative fair value attributable to the warrants of \$88,995 was recorded as a discount to the debt and corresponding credit to additional paid-in capital. The debt discount will be amortized to interest expense over the life of the debt. Interest on the term loan, consisting of the stated interest rate, initial facility fee, final payment fee and amortization of the discount, is being recognized using the interest method. The effective annual interest rate on the loan is approximately 21.1%.

In September 2010, we amended our loan and security agreement with Oxford pursuant to which we received a 39 month term loan in the principal amount of \$5.0 million that bears interest at the rate of 13% per annum. We paid Oxford an initial facility fee of \$125,000 and are obligated to make a final payment fee of

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**TITAN PHARMACEUTICALS, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

\$300,000. Commencing in October 2010, the loan is repayable in monthly interest payments of \$54,167 through June 2011 followed by monthly interest and principal installments of \$196,108 commencing in July 2011 through December 2013. The loan is secured by our assets and has a provision for pre-payment. We also issued to Oxford, in connection with the loan and security agreement, five-year warrants to purchase 287,356 shares of our common stock at an exercise price of \$0.87 per share. The relative fair value attributable to the warrants of \$254,580 was recorded as a discount to the debt and corresponding credit to additional paid-in capital. The debt discount is being amortized to interest expense over the life of the debt. Interest on the term loan, consisting of the stated interest rate, initial facility fee, final payment fee and amortization of the discount, is being recognized using the interest method. The effective annual interest rate on the loan is approximately 22.6%.

On March 15, 2011, we entered into several agreements pursuant to which Deerfield agreed to provide \$20.0 million in funding to us. Funding occurred on April 5, 2011 and we used approximately \$7.6 million of proceeds from the Deerfield funding to repay Oxford in full, including required final payments aggregating \$480,000. Pursuant to the terms of a facility agreement, we issued Deerfield promissory notes in the aggregate principal amount of \$20.0 million. The long-term debt bears interest at 8.5% per annum, payable quarterly, and was originally repayable over five years, with 10% of the principal amount due on the first anniversary, 15% due on the second anniversary, and 25% due on each of the next three anniversaries. We paid Deerfield a facility fee of \$0.5 million. The long-term debt is secured by our assets and has a provision for pre-payment. Deerfield has the right to have the long-term debt repaid at 110% of the principal amount in the event we complete a major transaction, which includes, but is not limited to, a merger or sale of our company or the sale of Probuphine. In connection with the facility agreement, we issued Deerfield six-year warrants to purchase 6,000,000 shares of our common stock at an exercise price of \$1.57 per share (See Note 9, *Warrant Liabilities* for further discussion). As a result of our April 2012 subscription agreements, and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants was adjusted to \$1.25 per share. (see Note 11, *Stockholders' Deficit* for further discussion). We also entered into a royalty agreement with Deerfield in exchange for \$3.0 million (see Note 8, *Royalty Liability* for further discussion).

We recorded the promissory notes with an aggregate principal amount of \$20.0 million at its face value less a note discount consisting of (i) \$3.0 million cash discount, (ii) a \$500,000 loan fee, and (iii) the \$5.5 million fair value of the associated warrants. The note discount totaling \$9.0 million is being amortized using the interest method. The effective annual interest rate on the note was 33% based on the note discount amortization, stated interest rate and note term.

On November 14, 2011, we entered into several agreements with Deerfield pursuant to which we agreed to pay a substantial portion of the remaining future royalties on the sales of Fanapt to Deerfield in exchange for \$5.0 million in cash that was recorded as royalty liability (see Note 8, *Royalty Liability* for further discussion), a \$10.0 million reduction in the principal amount owed to Deerfield under the existing facility agreement and a revised principal repayment schedule of \$2.5 million per year for four years commencing in April 2013 to retire the remaining long-term debt of \$10.0 million. We evaluated the November 2011 principal reduction and other amendments to the \$20.0 million facility agreement and determined that the modifications should be accounted for as a troubled debt restructuring on a prospective basis. As a result, we will recognize the difference between the carrying value of the long-term debt and the total required future principal and interest payments as interest expense over the remaining term using the interest method.

## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

The following is a schedule of future minimum long-term debt payments at December 31, 2012 (in thousands):

2013	\$ 3,262
2014	3,049
2015	2,836
2016	2,624
2017 and thereafter	
	\$ 11,771

These future minimum long-term debt payments exclude payments related to the royalty liability with Deerfield under the March 2011 and November 2011 royalty agreements. (see Note 16. Subsequent Events for further discussion).

**Lease Commitments**

We lease facilities under operating leases that expire at various dates through June 2013. We also lease certain office equipment under operating leases that expire at various dates through December 2013. Rent expense was \$203,000, \$214,000, and \$257,000 for years ended December 31, 2012, 2011, and 2010, respectively.

The following is a schedule of future minimum lease payments at December 31, 2012 (in thousands):

2013	\$ 121
2014 and thereafter	
	\$ 121

**Legal Proceedings**

There are no ongoing legal proceedings against the Company.

**8. Royalty Liability**

On March 15, 2011, under a royalty agreement, in exchange for \$3.0 million that was recorded as royalty liability, we agreed to pay Deerfield 2.5% of the net sales of Fanapt, constituting a portion of the royalty revenue that we are entitled to under our sublicense agreement with Novartis. The agreements with Deerfield also provide us with the option to repurchase the royalty rights for \$40.0 million.

The \$3.0 million received under the March 2011 royalty agreement was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement includes a provision which allows us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on the royalty liability is being recognized using the interest method based on the estimated future royalties expected to be paid under the royalty agreement. The current effective annual interest rate is 43.1%.

## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

Under the November 14, 2011 royalty agreement, in exchange for additional \$5.0 million royalty liability Deerfield is entitled to the balance of our portion of the royalties on Fanapt (5.5% to 7.5% of net sales, net of the 2.5% previously agreed to have been provided to Deerfield) up to specified threshold levels of net sales of Fanapt and 40% of the royalties above the threshold level. We retain 60% of the royalties on net sales of Fanapt above the threshold levels, subject to an agreement that half of any such retained royalties will go towards repayment of our outstanding debt to Deerfield. Funding occurred on November 25, 2011. The proceeds of this transaction were used to advance the development of Probuphine and for general corporate purposes.

The \$5.0 million received under the November 2011 royalty agreement was recorded as a royalty liability in accordance with the appropriate accounting guidance as the related agreement includes a provision which allows us to repurchase the royalty rights from Deerfield through a payment of a lump sum. Interest on this royalty obligation is being recognized using the interest method based on the estimated future royalties expected to be paid under the royalty agreement. The current effective annual interest rate is 67.3%.

### 9. Warrant Liability

On March 15, 2011, in connection with the Deerfield facility agreement, we issued Deerfield six-year warrants to purchase 6,000,000 shares of our common stock at an initial exercise price of \$1.57 per share ( Deerfield Warrants ). As a result of our April 2012 subscription agreements, and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants was adjusted to \$1.25 per share. (see Note 11, Stockholders' Deficit for further discussion). The Deerfield Warrants were immediately exercisable and expire on March 15, 2017. 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 Consolidated Statement of Operations and Comprehensive Loss. The Lattice model provides for assumptions regarding volatility and risk-free interest rates within the total period to maturity.

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

Assumption	December 31, 2012
Expected price volatility	80%
Expected term (in years)	4.21
Risk-free interest rate	0.58%
Dividend yield	0.00%
Weighted-average fair value of warrants	\$ 0.62

On April 9, 2012, in connection with subscription agreements with certain institutional investors for the purchase and sale of 6,517,648 shares of our common stock, we issued (i) six-year Series A Warrants to purchase 6,517,648 shares of common stock at an exercise price of \$1.15 per share and (ii) six-month Series B Warrants to purchase 6,517,648 shares of common stock at an exercise price of \$0.85 per share. The Series A and Series B 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



**TITAN PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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 Consolidated Statements of Operations and Comprehensive 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, 2012, Series B Warrants to purchase 5,761,765 shares of common stock were exercised at a price of \$0.85 per share. The remaining Series B Warrants to purchase 755,883 shares of common stock expired in October 2012.

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

<b>Assumption</b>	<b>December 31, 2012</b>
Expected price volatility	80%
Expected term (in years)	5.27
Risk-free interest rate	0.78%
Dividend yield	0.00%
Weighted-average fair value of warrants	\$ 0.69

**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, 2012.

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 consolidated financial statements for those milestones that were achieved as of December 31, 2012. 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' Deficit*****Common Stock***

In October 2012, Series B Warrants to purchase 4,627,941 shares of common stock were exercised resulting in gross proceeds of approximately \$3,934,000.

In September 2012, Series B Warrants to purchase 1,133,824 shares of common stock were exercised resulting in gross proceeds of approximately \$964,000.

In September 2012, we entered into a stock purchase and option agreement with an affiliate of Braeburn pursuant to which we sold 3,400,000 shares of our common stock for an aggregate purchase price of

**TITAN PHARMACEUTICALS, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

\$4.25 million, or \$1.25 per share, and agreed to an exclusive option period for execution of the proposed license agreement. The \$1.7 million premium, or \$0.50 per share, has been allocated to the fair value of the option agreement and was recorded as license revenue in 2012.

In April 2012, we entered into subscription agreements with certain institutional investors for the purchase and sale, in a registered direct offering, of (i) 6,517,648 shares of our common stock, (ii) 6,517,648 Series A Warrants and (iii) 6,517,648 Series B Warrants for gross proceeds of \$5,540,000 (the Offering). The Offering closed in April 2012. As a result of the Offering, and pursuant to the terms of the Deerfield Warrants, the exercise price of the Deerfield Warrants (See Note 9, Warrant Liabilities for further discussion) was adjusted to \$1.25 per share.

We recorded the gross proceeds from the Offering, net of (i) issuance costs of \$0.5 million and (ii) the fair value of the Warrants of \$2.9 million (see Note 9, Warrant Liabilities), as common stock paid-in in the Consolidated Balance Sheets.

As of December 31, 2012, warrants to purchase shares of common stock consisted of the following (in thousands, except per share price):

<b>Date Issued</b>	<b>Expiration Date</b>	<b>Exercise Price</b>	<b>Outstanding at December 31, 2012</b>
12/18/2009	12/18/2014	\$ 2.13	42
09/27/2010	09/27/2015	\$ 0.87	288
03/15/2011	03/15/2017	\$ 1.25	6,000
04/13/2012	04/13/2018	\$ 1.15	6,517
			12,847

*Shares Reserved for Future Issuance*

As of December 31, 2012, shares of common stock reserved by us for future issuance consisted of the following (in thousands):

Stock options outstanding	6,842
Shares issuable upon the exercise of warrants	12,847
	19,689

**12. Stock Plans**

In July 2002, we adopted the 2002 Stock Incentive Plan (2002 Plan). The 2002 Plan assumed the options which remain available for grant under our option plans previously approved by stockholders. Under the 2002 Plan and predecessor plans, a total of 7.4 million shares of our common stock were authorized for issuance to employees, officers, directors, consultants, and advisers. In August 2005, we adopted an amendment to the 2002 Stock Incentive Plan (2002 Plan) to (i) permit the issuance of shares of restricted stock and stock appreciation rights to participants under the 2002 Plan, and (ii) increase the number of shares issuable pursuant to grants under the 2002 Plan from 2,000,000 to 3,000,000. Options granted under the 2002 Plan and predecessor plans may either be incentive stock options within the meaning of Section 422 of the Internal Revenue Code and/or options that do not qualify as incentive stock options; however, only employees are eligible to receive incentive stock options. Options granted under the option plans generally expire no later than ten years from the date of grant,

## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

except when the grantee is a 10% shareholder, in which case the maximum term is five years from the date of grant. Options generally vest at the rate of one fourth after one year from the date of grant and the remainder ratably over the subsequent three years, although options with different vesting terms are granted from time-to-time. Generally, the exercise price of any options granted under the 2002 Plan must be at least 100% of the fair market value of our common stock on the date of grant, except when the grantee is a 10% shareholder, in which case the exercise price shall be at least 110% 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, 2012, options to purchase an aggregate of 4,280,153 shares of our common stock were outstanding under the 2002 Plan.

Commencing in 2008, non-employee directors are entitled to receive stock options including an initial grant of 10,000 options upon becoming a director, an annual grant of 20,000 options thereafter, and an annual grant of 5,000 options for each committee on which they serve.

In August 2001, we adopted the 2001 Employee Non-Qualified Stock Option Plan ( 2001 NQ Plan ) pursuant to which 1,750,000 shares of common stock were authorized for issuance for option grants to employees and consultants who are not officers or directors of Titan. Options granted under the option plans generally expire no later than ten years from the date of grant. Option vesting schedule and exercise price are determined at time of grant by the board of directors. Historically, 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, 2012, options to purchase an aggregate of 1,199,500 shares of our common stock were outstanding under the 2001 NQ Plan.

Activity under our stock plans, as well as non-plan activity, are 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, 2009	2,418	6,090	\$ 3.68
Options granted	(150)	150	\$ 2.36
Options cancelled and expired	1,244	(1,243)	\$ 9.11
Awards granted	(119)	119	\$ 0.00
Balance at December 31, 2010	3,393	5,115	\$ 2.29
Options granted	(734)	734	\$ 1.44
Options cancelled and expired	45	(241)	\$ 15.01
Options forfeited	55	(55)	\$ 1.77
Awards granted	(181)	181	\$ 0.00
Awards issued		(139)	\$ 0.00
Balance at December 31, 2011	2,578	5,595	\$ 1.56
Options granted	(1,718)	1,718	\$ 1.14
Options cancelled and expired	290	(290)	\$ 5.54
Awards issued		(181)	\$ 0.00
Expiration of option plan	(1,150)		\$ 0.00
Balance at December 31, 2012		6,842	\$ 1.33

Our option plans allow for stock options issued as the result of a merger or consolidation of another entity, including the acquisition of minority interest of our subsidiaries, to be added to the maximum number of shares



## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

provided for in the plan ( Substitute Options ). Consequently, Substitute Options are not returned to the shares reserved under the plan when cancelled. During 2012, 2011 and 2010, the number of Substitute Options cancelled was immaterial.

Options for 6.0 million and 4.3 million shares were exercisable at December 31, 2012 and 2011, respectively. The options outstanding at December 31, 2012 have been segregated into four ranges for additional disclosure as follows (options in thousands):

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Life (Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.69 - \$1.53	5,499	7.22	\$ 1.05	4,753	\$ 1.04
\$1.54 - \$2.38	604	4.85	\$ 2.19	542	\$ 2.19
\$2.39 - \$3.22	642	4.27	\$ 2.52	642	\$ 2.52
\$3.23 - \$4.06	97	1.01	\$ 3.55	97	\$ 3.55
\$0.69 - \$4.06	6,842	6.65	\$ 1.33	6,034	\$ 1.35

In addition, Ingenex, Inc., a consolidated subsidiary, had a stock option plan under which options to purchase common stock of Ingenex could have been granted. No options have been granted under such plan since 1997.

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, 2012, 2011 and 2010:

	Years Ended December 31,		
	2012	2011	2010
Weighted-average risk-free interest rate	0.91%	2.3%	2.3%
Expected dividend payments			
Expected holding period (years)(1)	5.1	5.4	4.2
Weighted-average volatility factor(2)	1.75	1.71	1.89
Estimated forfeiture rates for options granted to management(3)	23%	23%	23%
Estimated forfeiture rates for options granted to non-management(3)	41%	41%	41%

(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 the Company's common stock.

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

Based upon the above methodology, the weighted-average fair value of options and awards granted during the years ended December 31, 2012, 2011 and 2010 was \$1.09, \$1.38 and \$2.24, respectively.

## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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, 2012, 2011 and 2010:

(in thousands, except per share amounts)	Years Ended December 31,		
	2012	2011	2010
Research and development	\$ 1,560	\$ 371	\$ 202
General and administrative	1,021	806	531
<b>Total stock-based compensation expenses</b>	<b>\$ 2,581</b>	<b>\$ 1,177</b>	<b>\$ 733</b>
Increase in basic and diluted net loss per share	\$ (0.04)	\$ (0.02)	\$ (0.01)

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.

During the year ended December 31, 2012 we granted 1,718,000 options to employees, directors and consultants to purchase common stock. The following table summarizes option activity for the year ended December 31, 2012:

(in thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2012	5,414	\$ 1.61		
Granted	1,718	1.14		
Cancelled	(290)	5.54		
Outstanding at December 31, 2012	6,842	\$ 1.33	6.65	\$ 722
Exercisable at December 31, 2012	6,035	\$ 1.35	6.44	\$ 675

As of December 31, 2012, there was approximately \$0.3 million of total unrecognized compensation expense related to non-vested stock options. This expense is expected to be recognized over a weighted-average period of 0.18 years.

There were no awards of restricted stock during the year ended December 31, 2012. The following table summarizes restricted stock activity for the year ended December 31, 2012:

(in thousands, except per share amounts)	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2012	181	\$ 0.00		

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Shares issued	(181)	0.00	
Outstanding at December 31, 2012		\$ 0.00	\$
Vested at December 31, 2012		\$	\$

As of December 31, 2012, there was no unrecognized compensation expense related to non-vested awards.

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## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

**13. Non-controlling Interest**

The \$1.2 million received by Ingenex, Inc. upon the issuance of its Series B convertible preferred stock was classified as non-controlling interest in the consolidated balance sheet prior to December 31, 2010. As a result of the Series B preferred stockholders' liquidation preference, the balance was not reduced by any portion of the losses of Ingenex, Inc.

In December 2010, Ingenex, Inc. was dissolved under the laws of Delaware. Upon dissolution, no amounts were distributed to the Series B convertible preferred stockholders. The dissolution was accounted for as an equity transaction, and the preferred stock carrying value, classified as a non-controlling interest, was reclassified to additional paid-in capital in the accompanying consolidated balance sheet at December 31, 2010.

**14. Income Taxes**

As of December 31, 2012, we had net operating loss carryforwards for federal income tax purposes of approximately \$215.7 million that expire at various dates through 2032, and federal research and development tax credits of approximately \$7.6 million that expire at various dates through 2031. We also had net operating loss carryforwards for California income tax purposes of approximately \$146.7 million that expire at various dates through 2032 and state research and development tax credits of approximately \$7.8 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 the Company's stock option plan, 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, 2012 and, accordingly, 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,	
	2012	2011
Deferred tax assets:		
Net operating loss carryforwards	\$ 81,127	\$ 84,328
Research credit carryforwards	12,750	12,484
Other, net	4,190	3,883
Deferred revenue	5,749	
Total deferred tax assets	103,816	100,695
Valuation allowance	(103,816)	(100,695)
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 increased by \$3.1 million during 2012, decreased by \$1.3 million during 2011 and increased by \$0.8 million during 2010.

Under ASC 718, the deferred tax asset for net operating losses as of December 31, 2012 excludes deductions for excess tax benefits related to stock based compensation.





## TITAN PHARMACEUTICALS, INC.

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)

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,		
	2012	2011	2010
Computed at 34%	\$ (5,134)	\$ (5,168)	\$ (2,265)
State taxes	(234)	(228)	(1,347)
Book gains (losses) not currently benefited	3,120	(1,264)	844
Other	1,901	2,746	2,773
Disallowed interest expense	1,363	1,457	
Income from debt restructuring	(1,615)	2,462	
Revaluation of warrant liability	600		
Total	\$ 1	\$ 5	\$ 5

We had no unrecognized tax benefits or any amounts accrued for interest and penalties for the three year period ended December 31, 2012. Our policy will be 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 1995 through 2012, due to net operating losses that are being carried forward for tax purposes.

The Credit for Increasing Research Activities expired for amounts incurred after December 31, 2011. However, The American Taxpayer Relief Act of 2012, which was signed into law on January 2 2013, extended the credit for amounts incurred before January 1, 2014. The Act also retroactively restored the credit for amounts incurred in 2012. However, since the Act was not signed until January 2, 2013 the amount of credit generated in 2012 is not reflected in the deferred tax amounts as of December 31, 2012. The amount of this credit that was generated in 2012 was approximately \$340,000. The deferred tax asset for this credit will be increased by this amount in 2013.

**15. Quarterly Financial Data (Unaudited)**

	First	Second	Third	Fourth
	Quarter	Quarter	Quarter	Quarter
	(in thousands, except per share amount)			
<b>2012</b>				
Total revenue	\$ 1,270	\$ 1,360	\$ 1,228	\$ 3,259
Net loss	\$ (5,163)	\$ (1,724)	\$ (8,013)	\$ (280)
Basic and diluted net loss per share	\$ (0.09)	\$ (0.03)	\$ (0.12)	\$ (0.00)
<b>2011</b>				
Total revenue	\$ 948	\$ 695	\$ 1,012	\$ 1,413
Net loss	\$ (4,512)	\$ (6,989)	\$ (804)	\$ (2,898)
Basic and diluted net loss per share	\$ (0.08)	\$ (0.12)	\$ (0.01)	\$ (0.05)

**16. Subsequent events**

In January 2013, Series A Warrants to purchase 520,776 shares of common stock were exercised resulting in gross proceeds of approximately \$599,000.



On February 6, 2013, the facility agreement dated as of March 11, 2011 with Deerfield was amended to provide that the exercise price of the Deerfield Warrants may be satisfied through a reduction in the principal amount of our outstanding indebtedness to Deerfield. In February and March 2013, Deerfield exercised an aggregate of 6,000,000 warrants resulting in a reduction of our outstanding indebtedness to Deerfield of \$7.5 million and, accordingly, cancellation of our obligation to make the 2014, 2015 and 2016 installment payments under the facility.

**(b) Exhibits**

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3.2	By-laws of the Registrant <sup>1</sup>
3.3	Certificate of Designations of Junior Participating Preferred Stock of Titan Pharmaceuticals, Inc. <sup>15</sup>
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4.2	Registration Rights Agreement dated as of December 8, 2009 <sup>9</sup>
4.3	Warrant to Purchase Common Stock dated December 23, 2009 issued to Oxford Finance Corporation <sup>9</sup>
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10.2	2001 Non-Qualified Employee Stock Option Plan <sup>4</sup>
10.3	2002 Stock Option Plan <sup>5</sup>
10.4	Employment Agreement between the Registrant and Sunil Bhonsle, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012 <sup>9, 16, 19</sup>
10.5	Employment Agreement between the Registrant and Marc Rubin, dated May 16, 2009, as amended by agreements dated February 17, 2010, December 30, 2011 and December 31, 2012 <sup>9, 16, 19</sup>
10.6	Lease for the Registrant's facilities, amended as of October 1, 2004
10.7	Amendments to lease for Registrant's facilities dated May 21, 2007 and March 12, 2009
10.8*	License Agreement between the Registrant and Sanofi-Aventis SA effective as of December 31, 1996 <sup>7</sup>
10.9*	Sublicense Agreement between the Registrant and Novartis Pharma AG dated November 20, 1997 <sup>8</sup>
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No.	Description
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10.18	Royalty Purchase Agreement, dated November 14, 2011, by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
10.19	Amended and Restated Royalty Agreement, dated November 14, 2011 by and among the Company, Deerfield Private Design Fund II, L.P., Deerfield Special Situations Fund, L.P. and Horizon Sante TTNP SARL <sup>14</sup>
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- (1) Incorporated by reference from the Registrant's Registration Statement on Form SB-2 (File No. 33-99386).
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- (3) Incorporated by reference from the Registrant's definitive Proxy Statement filed on July 28, 2000.
- (4) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001.
- (5) Incorporated by reference from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2002.
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- (9) Incorporated by reference from the Registrant's Registration Statement on Form 10.
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- \* Confidential treatment has been granted with respect to portions of this exhibit.
- \*\* Pursuant to Rule 406T of Regulation S-T, the interactive files on Exhibit 101.1 hereto are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933, as amended, are deemed not filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and otherwise are not subject to liability under those sections.

**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 18, 2013

TITAN PHARMACEUTICALS, INC.

By: /s/ SUNIL BHONSLE

Name: **Sunil Bhonsle**

Title: **President**

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.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
/s/ Marc Rubin, M.D. Marc Rubin, M.D.	Executive Chairman	March 18, 2013
/s/ Sunil Bhonsle Sunil Bhonsle	President and Director (principal executive officer and principal financial officer)	March 18, 2013
/s/ Victor J. Bauer, Ph.D. Victor J. Bauer, Ph.D.	Director	March 18, 2013
/s/ Eurelio M. Cavalier Eurelio M. Cavalier	Director	March 18, 2013
/s/ Hubert E. Huckel, M.D. Hubert E. Huckel, M.D.	Director	March 18, 2013
/s/ M. David MacFarlane, Ph.D. M. David MacFarlane, Ph.D.	Director	March 18, 2013
/s/ Ley S. Smith Ley S. Smith	Director	March 18, 2013
/s/ Brian Crowley Brian Crowley	Vice President, Finance (principal accounting officer)	March 18, 2013

**EXHIBIT INDEX**

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