Filed Pursuant to Rule 424(b)5
Registration No. 333-233722

PROSPECTUS

40,000,000 Units Consisting of Shares of Common Stock or Pre-Funded Warrants to Purchase Shares of Common Stock and Class B Warrants to Purchase Shares of Common Stock

We are offering units consisting of (i) 40,000,000 shares of our common stock and (ii) class B warrants, or Class B Warrants, to purchase 40,000,000 shares of our common stock. Each Class B Warrant will have an exercise price of $0.225 per share. Each unit will consist of (i) one share of common stock (or Pre-Funded Warrant in lieu thereof) and (ii) one Class B Warrant. The Class B Warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date.

We are also offering to purchasers, if any, whose purchase of units would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, in lieu of units including shares of common stock, units including pre-funded warrants, or Pre-Funded Warrants. The purchase price of each unit including a Pre-Funded Warrant will equal the price per unit including a share of common stock, minus $0.001, and the exercise price of each Pre-Funded Warrant will equal $0.001 per share. For each unit including a Pre-Funded Warrant purchased in this offering, we will reduce the number of units including a share of common stock being sold in this offering by one.

Pursuant to this prospectus, we are also offering the shares of common stock issuable upon exercise of the Class B Warrants and the Pre-Funded Warrants.

Each Pre-Funded Warrant is exercisable for one share of our common stock (subject to adjustment as provided for therein) at any time at the option of the holder until such Pre-Funded Warrant is exercised in full, provided that the holder will be prohibited from exercising Pre-Funded Warrants for shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

The shares of common stock and Pre-Funded Warrants, if any, can each be purchased in this offering only with the accompanying Class B Warrants (other than pursuant to the underwriters' option to purchase additional units) as part of units, but the components of the units will immediately separate upon issuance.

Our common stock is listed on The Nasdaq Capital Market under the symbol "TTNP". On October 15, 2019, the last reported sale price of our common stock on The Nasdaq Capital Market was $0.3675 per share. There is no established trading market for the Class B Warrants or Pre-Funded Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Class B Warrants or Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Class B Warrants and the Pre-Funded Warrants will be limited.

You should read this prospectus, together with additional information described under the headings "Incorporation of Certain Information by Reference" and "Where You Can Find Additional Information," carefully before you invest in any of our securities.

Our business and an investment in our securities involves a high degree of risk. See "Risk Factors" beginning on page 7 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	Per Unit	Total
Public offering	$ 0.225	$9,000,000
Underwriting discounts and commissions(1)	$0.01575	$ 630,000
Proceeds to us, before expenses	$0.20925	$8,370,000

(1) The underwriters will receive compensation in addition to the underwriting discount and commissions. See "Underwriting" beginning on page 30 of this prospectus for a description of compensation payable to the underwriters.

We have granted the underwriters an option for a period of 45 days from the date of this prospectus to purchase up to an additional 6,000,000 shares of common stock and/or Class B Warrants to purchase up to 6,000,000 shares of common stock at the public offering price, less the underwriting discount.

We anticipate that delivery of the units against payment will be made on or about October 18, 2019.

Book-Running Manager

MAXIM GROUP LLC

The date of this prospectus is October 16, 2019

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We have not, and the underwriters have not, authorized anyone to provide you with information that is different from that contained in this prospectus we may authorize to be delivered or made available to you. When you make a decision about whether to invest in our securities, you should not rely upon any information other than the information in this prospectus that we may authorize to be delivered or made available to you. Neither the delivery of this prospectus nor the sale of our securities means that the information contained in this prospectus is correct after the date of this prospectus. This prospectus is not an offer to sell or the solicitation of an offer to buy our securities in any circumstances under which the offer or solicitation is unlawful.

For investors outside the United States: We have not, and the underwriters have not, taken any action that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities covered hereby and the distribution of this prospectus outside the United States.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. Our management estimates have not been verified by any independent source, and we have not independently verified any third-party information. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Cautionary Note Regarding Forward-Looking Statements."

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties thereto, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

ProNeura™ is a trademark and Probuphine® is a registered trademark of Titan Pharmaceuticals, Inc. Sixmo-buprenorphine is a registered trademark of L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A. ("Molteni"). This prospectus also includes trademarks, tradenames and service marks that are the property of other organizations. Solely for convenience, trademarks and tradenames referred to in this prospectus appear (after the first usage) without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

SUMMARY

This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read this prospectus and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under "Risk Factors" and our financial statements and notes thereto that are incorporated by reference in this prospectus. Unless otherwise indicated herein, the terms "Titan," "we," "our," "us," or "the Company" refer to Titan Pharmaceuticals, Inc.

Company Overview

We are a pharmaceutical company developing therapeutics utilizing our proprietary long-term drug delivery platform, ProNeura, for the treatment of select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit. We have been transitioning to a commercial stage enterprise following the reacquisition of Probuphine® (buprenorphine) implant, or Probuphine, on May 25, 2018 from our former licensee. Probuphine is the first product based on our ProNeura technology approved in the U.S., Canada and the European Union, or EU, for the maintenance treatment of opioid use disorder, or OUD, in clinically stable patients on 8 mg or less a day of oral buprenorphine. ProNeura consists of a small, solid rod made from a mixture of ethylene-vinyl acetate, or EVA, and a drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the inside part of the upper arm, in a short physician office-based outpatient procedure and is removed in a similar manner at the end of the treatment period. Once implanted, the drug substance is released continuously through the process of diffusion-controlled dissolution, maintaining a stable blood level of the selected drug, thereby avoiding the fluctuating peak and trough levels of oral dosing that often pose problems in certain disease settings, including OUD.

Since the reacquisition, we have been implementing a strategic plan aimed at building the foundation to support an effective U.S. product relaunch, including the establishment of a small experienced commercial team to target select OUD market segments best suited for Probuphine, as well as the engagement of new strategic partners in the product order and distribution process. Despite limited resources, we have made significant progress in identifying and addressing the challenges associated with the initial product launch by our former licensee, including expanding access to treatment and educating and supporting the provider and patient communities. The product order and distribution process has been streamlined through establishment of new relationships with specialty pharmacies and the establishment of a new central patient services hub. Product awareness is being expanded through the introduction of our *Step Into Stability* marketing campaign that highlights the unique long-term treatment features of Probuphine. We believe that with sufficient capital resources, Probuphine has the potential to be an important weapon in the battle against OUD and we intend to use a substantial portion of the proceeds of this offering to expand our commercial capabilities, either internally, through relationships with third parties or a combination of both, to accomplish this goal. In furtherance of our efforts, we have recently restructured our outstanding loan agreement as described below and informed the FDA of our need to delay commencement of certain required post-approval clinical trials.

Our Market Opportunity

Opioid Use Disorder is a severe, chronic, relapsing brain disease characterized by compulsive drug seeking and use, despite the harmful consequences. Sufferers experience cravings for opioids, which is frequently accompanied by lack of impulse control. OUD is a progressive disease that is characterized by cycles of relapse and remission and often results in disability or death if left untreated. It is estimated that during 2018, there were over two million people with OUD. According to government publications, the U.S. societal costs of opioid abuse total over $78 billion annually in health care, criminal justice and lost productivity costs. Approximately 130 people die each day as a direct result of their addiction, with approximately 35% of such deaths being attributable to prescription opioids. The U.S. government considers OUD an epidemic and has made available substantial funds through federal and state agencies to control the spread of the epidemic and support evidence-based treatments.

Current treatment approaches to OUD include abstinence-based programs, a rarely successful therapeutic approach when used in isolation, drug counseling and medication assisted therapies, or MAT. The current MAT gold standard is buprenorphine, a medication that has the ability to control the withdrawal symptoms and cravings without inducing opioid euphoria in patients. U.S. sales of formulations that deliver buprenorphine to treat OUD now exceed $2 billion annually.

However, notwithstanding the opioid crisis our nation is facing, less than 50% of the patient population with OUD is being medically treated. Only 5% of U.S. physicians are currently certified to prescribe buprenorphine and only a fraction of those physicians are responsible for writing approximately 90% of all buprenorphine prescriptions. More than one-half of U.S. counties do not have a single buprenorphine prescriber.

To date, the vast majority of buprenorphine prescriptions have been for daily-dosed sublingual formulations. There are important clinical challenges associated with daily dosed formulations, including:

- the potential for lack of compliance;
- the potential for reinforcement of drug-taking behavior; and
- the delivery of fluctuating levels of medication in the blood.

While the U.S. Food and Drug Administration, or FDA, has recently approved a monthly depot formulation of buprenorphine that is now being marketed, Probuphine is the only product on the market to provide six-month, continuous, non-fluctuating blood levels of buprenorphine for maintenance treatment of OUD, thereby potentially addressing the challenges that can be seen with daily dosed formulations. In addition, as an implant, it may lower the potential for diversion and non-adherence associated with sublingual formulations. We believe that Probuphine can play an important role in combatting the opioid epidemic and will benefit from the changing emphasis in clinical practice to move towards longer-term treatment options.

Our Commercial Strategy

Since reacquiring the rights to Probuphine in mid-2018, we have been working to maximize the impact of the limited resources at our disposal by putting in place a small, focused team of people with key and deep expertise in the field of addiction, while establishing the many relationships and programs that are required to build our infrastructure and grow our commercial capabilities. We believe we have made important progress in laying the groundwork and establishing the foundation to successfully transition into a company with full commercial potential. Some of our key accomplishments have included:

- Refining and validating our market segmentation strategy;
- Expanding our specialty pharmacy network by adding key pharmacies with national coverage and robust coordination of care capabilities among patients, third party payors and the Risk Evaluation and Mitigation Strategies, or REMS, certified healthcare providers;
- Streamlining the distribution process with the achievement of significantly shortening the time from prescription to product delivery;
- Expanding the number of public and private insurance plans and other third party payors that cover Probuphine under the medical and pharmacy benefits;
- Implementing a comprehensive regulatory and compliance program;
- Rolling out new healthcare provider, caregiver and patient education programs; and
- Growing the number of certified healthcare providers of Probuphine.

Market Segmentation Strategy. Our overall market strategy for Probuphine is focused on the following market segments that provide long-term maintenance therapy for OUD patients: (i) high prescribing physicians with long-term, recovery-oriented treatment programs; (ii) residential treatment facilities and public and private substance abuse programs; (iii) academic institutions with addiction treatment and training programs; and (iv) the criminal justice system.

Specialty Pharmacy Network. We believe one of the key aspects of a successful commercial strategy for a specialty product such as Probuphine is the development of a primary distribution model based on strong relationships with specialty pharmacies, or SPs, that have the ability to provide coordination of care among the healthcare providers, patients' insurance, billing and payment processes and the safe and prompt shipping and delivery of product to the prescribing healthcare providers. To date, we established arrangements with top tier SPs, including AllianceRx Walgreens, CVS Caremark, Accredo Specialty Pharmacy, Avella, Acaria Health, and Southside Specialty Pharmacy, which we believe collectively have the ability to cover substantially all geographic regions in the U.S. We will selectively expand our network of SPs with the goal of achieving broad product access for healthcare providers and patients.

Streamlined Distribution Process. Prior to 2019, the process from prescription to product delivery was lengthy (up to three months), complicated and resulted in a high level of coverage denials. We are implementing Probuphine ProNet, an online REMS certified healthcare providers' portal and have retained AppianRx as our new patient services 'hub' to coordinate with the healthcare providers, insurance companies and pharmacies to improve prescription processing times (currently as few as 1–2 weeks in most cases) and substantially reduce the number of denials due to errors and omissions.

Third Party Payors. Market acceptance of Probuphine as a preferred treatment option for OUD depends, in large part, on the availability of insurance coverage from a broad range of third party payors. We have established a Medicaid Drug Rebate program, a 340B Price, and Medicare Part B coverage and have executed an interim Federal Supply Schedule Agreement with the Department of Veteran Affairs. We recently entered into a purchase agreement with one of the largest managed care organization in the U.S. We believe that approximately 94% of insurance plans now offer some degree of coverage for Probuphine under the medical benefit.

Educational Programs and Branding Initiatives. We believe that one of the hurdles we have faced in our product relaunch was the lack of product awareness among healthcare providers and OUD patients and their families and caregivers. Accordingly, we have been working to develop and implement an effective communications campaign and educational programs aimed at increasing market awareness. We recently initiated our *Step Into Stability* campaign and have maintained a strong presence at key conferences, including the American Society of Addiction Medicine (ASAM), with the goal of substantially increasing awareness of what we believe are the unique benefits of Probuphine as a treatment option for the eligible patient population.

Regulatory Compliance Program. We have implemented a legal, regulatory and compliance program that governs all aspects of Probuphine commercialization from promotion to distribution with the goal of ensuring that we and our employees manage our business and conduct in accordance with the letter and spirit of the law.

Healthcare Providers. As soon as we reacquired the rights to Probuphine, we undertook an in-depth analysis of the large group of healthcare providers that had been trained in the use of and/or certified to prescribe Probuphine, as well as the smaller subgroup of providers that had prescribed the product for their patients. Our strategy has been and will continue to be to identify those healthcare providers that have the appropriate patient populations in maintenance therapy and where practice economics, including the potential for fewer office visits per patient, are not of paramount concern when prescribing an OUD medication. Our goal is to continue to expand the number of current active providers, including by providing training to qualified nurse practitioners and physician assistants who are now eligible to prescribe buprenorphine.

Product Pipeline

Our ProNeura continuous drug delivery platform was developed to address the need for a simple, practical method to achieve continuous long-term drug delivery while maintaining a stable blood level, and, depending on the characteristics of the compound to be delivered, can potentially provide treatment on an outpatient basis over extended periods of up to 12 months. We believe that the benefits of this technology have been demonstrated by the clinical results seen to date with Probuphine. We have demonstrated the feasibility of the ProNeura platform with small molecules, hormones, and bio-active peptides. The delivery system works with both hydrophobic and hydrophilic molecules. We have also shown the flexibility of the

platform by experimenting with the release characteristics of the EVA implants, layering the implants with varying concentrations of drug, and generating implants of different sizes and porosity to achieve a desired delivery profile. Formulation development is conducted at a dedicated pilot plant established by Titan at the South West Research Institute, or SWRI, in San Antonio, Texas that includes cGMP manufacturing and testing capabilities and provides us access to support services from the vast array of SWRI groups with expertise in manufacturing and material sciences.

To date, we have conducted limited research and development on the use of ProNeura to administer ropinirole, a drug used in the treatment of Parkinson's disease and we are currently conducting non-clinical studies with a nalmefene implant for the potential treatment of OUD under a $8.7 million grant from the National Institutes of Health. We have also conducted feasibility assessments and implant formulation activities with drugs used in the areas of malaria prophylaxis, chronic pain, type 2 diabetes and hypothyroidism, some of which work has been done in collaboration with third parties. Our primary focus at this time, however, is on the commercialization of Probuphine, and further research and development efforts on a product pipeline based on this platform technology will depend on the availability of funding, either through corporate collaborations, grants or other sources.

Recent Developments

On September 10, 2019, we entered into an amendment to our existing loan agreement, or Loan Agreement, with Molteni and Horizon Technology Finance Corporation, or Horizon, with the goal of reducing our cash burn rate to enable us to focus on commercialization activities. Under the amendment to the Loan Agreement, the interest-only payment and forbearance periods were extended by one year to December 31, 2020 and the maturity date was extended by one year to June 1, 2022. In connection with the amendment to the Loan Agreement, the final payments to the lenders were increased by an aggregate of $312,500 (exclusive of a restructuring fee payable to Horizon) and the conversion provisions related to Molteni's portion of the loan amount were revised to eliminate the mandatory conversion feature, to reduce the conversion price to the lower of (i) $0.74 or (ii) the public offering price of the shares offered hereby, and (iii) to cap the number of shares issuable upon conversion to 3,422,777.

On September 10, 2019, we also entered into an amendment to the agreement, or the Purchase Agreement, pursuant to which Molteni acquired the European intellectual property related to Probuphine and the exclusive right to commercialize the Titan-supplied product in the Molteni territory. The amendment reduced the percentage earn-out payments on net sales from the original range of low-teens to mid-twenties to low-teens to mid-teens. We also agreed to delay payments of any earn-outs until the later of (i) January 1, 2021 or (ii) the one year anniversary of completion of compliance by our manufacturer with EU requirements (currently anticipated to occur by the end of this year). The milestone payments under the Purchase Agreement remain unchanged.

Corporate Information

We were incorporated under the laws of the State of Delaware on February 7, 1992. Our principal executive offices are located 400 Oyster Point Boulevard, Suite 505, South San Francisco, CA 94080. Our telephone number is (650) 244-4990. Our website address is www.titanpharm.com. We make our periodic and current reports that are filed with the SEC available, free of charge, on our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, and that can be accessed through, our website is not incorporated into and is not a part of this prospectus.

THE OFFERING

Securities offered by us	40,000,000 units, each consisting of (i) one share of common stock (or Pre-Funded Warrant in lieu thereof) and (ii) one Class B Warrant.
Common stock offered by us	40,000,000 shares.
Pre-Funded Warrants offered by us	We are also offering to those purchasers, if any, whose purchase of common stock in this offering would otherwise result in such purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding common stock immediately following the consummation of this offering, the opportunity, in lieu of purchasing units including common stock, to purchase units including Pre-Funded Warrants to purchase up to 40,000,000 shares of our common stock. The purchase price of each unit including a Pre-Funded Warrant will equal the price per unit at which the units including shares of common stock are being sold to the public in this offering, minus $0.001, and the exercise price of each Pre-Funded Warrant will be $0.001 per share of common stock. Each Pre-Funded Warrant will be exercisable immediately upon issuance and will not expire. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of such Pre-Funded Warrants. Each Pre-Funded Warrant is exercisable for one share of our common stock (subject to adjustment as provided therein) at any time at the option of the holder, provided that the holder will be prohibited from exercising its Pre-Funded Warrant for shares of our common stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.
Class B Warrants offered by us	Class B Warrants to purchase up to 40,000,000 shares of our common stock. Each Class B Warrant will have an exercise price of $0.225 per share, will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the Class B Warrants.
Common stock outstanding after this offering	57,113,885 shares (or 97,113,885 shares if the Class B Warrants sold in this offering are exercised in full). The foregoing assumes only shares of common stock are sold in this offering. Each Pre-Funded Warrant purchased in this offering in lieu of common stock will reduce the number of shares of common stock being sold in the offering by one.
Use of proceeds	We estimate that the net proceeds from our sale of units in this offering will be approximately $8.1 million, after deducting underwriting discounts and commissions and estimated

	offering expenses payable by us. We currently expect to use the net proceeds from this offering for general corporate purposes and to fund ongoing operations and expansion of our commercial operations. For additional information please refer to the section entitled "Use of Proceeds" on page 25 of this prospectus.
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider the "Risk Factors" section of this prospectus for a discussion of factors to consider before deciding to invest in the units.
Market Symbol and trading	Our common stock is listed on The Nasdaq Capital Market under the symbol "TTNP." There is no established trading market for the Class B Warrants or Pre-Funded Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Class B Warrants, or Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Class B Warrants and Pre-Funded Warrants will be limited.

Unless otherwise stated, all information contained in this prospectus assumes no investor purchased units including Pre-Funded Warrants in lieu of common stock sold in this offering.

The number of shares of our common stock to be outstanding after this offering is based on 17,113,885 shares of our common stock outstanding as of October 15, 2019 and excludes as of such date:

- 1,245,465 shares of our common stock issuable upon the exercise of outstanding options with a weighted average exercise price of $6.02 per share;
- 8,341,762 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of $1.23 per share (assuming an adjustment to the exercise price of our 2018 public offering warrants as a result of this offering to $0.60);
- 3,422,777 shares of our common stock issuable upon the conversion of outstanding debt; and
- 524,137 additional shares of our common stock reserved for future issuance under our 2015 equity incentive plan.

Except as otherwise indicated herein, all information in this prospectus, including the number of shares that will be outstanding after this offering, assumes no exercise by the underwriters of their option to purchase additional securities.

In addition, all information in this prospectus reflects a one-for-six reverse stock split of our issued and outstanding shares of common stock, options and warrants effected on January 24, 2019 and the corresponding adjustment of all common stock prices per share and stock option and warrant exercise prices per share and conversion ratios.

RISK FACTORS

Any investment in our securities involves a high degree of risk. Investors should carefully consider the risks described below and all of the information contained or incorporated by reference in this prospectus before deciding whether to purchase our common stock. Our business, financial condition or results of operations could be materially adversely affected by these risks if any of them actually occur. This prospectus also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of certain factors, including the risks we face as described below and elsewhere in this prospectus.

Risks Related to Our Business

We may not be successful in completing the transition from a research and development company to a commercial enterprise.

Since we regained the U.S. commercial rights to Probuphine in May 2018 and began our transition to a commercial enterprise, we have been building the infrastructure necessary to successfully relaunch Probuphine. While we have been able to make significant progress in identifying and addressing the various hurdles to Probuphine uptake, our commercialization efforts to date have been hampered by resource constraints and product sales have been limited. While we intend to use the proceeds of this offering to expand our commercial capabilities, there can be no assurance that our sales and marketing efforts focused on our market segmentation strategy will be effective or that we will successfully complete the transition to a fully-functioning commercial stage company.

If Probuphine does not achieve broad market acceptance by physicians, patients or others in the medical community or coverage by third-party payors, our business will not succeed.

The commercial success of Probuphine will depend upon its acceptance by physicians, patients, healthcare payors and the medical community. Coverage and reimbursement of Probuphine by third party payors is also necessary for commercial success. Probuphine's adoption by physicians has been hindered both by the REMS requirements mandated by the product label, which are more expansive than those required for other buprenorphine products, as well as the current payment and reimbursement model, which differs from some of the existing treatment options for opioid addiction. For example, the current standard of care for outpatient treatment of opioid addiction is oral daily buprenorphine, which typically requires frequent patient visits and a per visit fee, which the patient may pay directly to the healthcare provider in cash. Reimbursement for an implantable drug product that requires administration by a healthcare provider requires drug codes as well as a separate procedure code for the insertion and removal procedures and less frequent office visits. Physicians may prefer more frequent patient visits and the accompanying reimbursement and payment model, which oftentimes includes cash payments. The commercial success of Probuphine depends on several factors, including:

- our ability to train and certify healthcare providers to insert and remove implants of Probuphine in accordance with the REMS;
- the perceived and actual advantages of Probuphine over current and emerging treatment options;
- the willingness of healthcare providers to prescribe, and the target patient population to try novel products;
- our ability to identify healthcare providers that have the right patient populations and where practice economics are not the primary driver when prescribing an OUD medication;
- the competitiveness of our pricing;
- the willingness of healthcare providers to accept alternative reimbursement models, such as the "buy-and-bill" system, where prescribers are required to buy Probuphine inventory themselves and then bill patients or payors following the procedure, or the specialty pharmacy distribution model, where a specialty pharmacy carries inventory and ships it to healthcare providers as requested and prescribed, and directly handles the subsequent billing and payment process with payors;

- our ability to provide adequate support to physicians and other healthcare providers to lessen the burden of current reimbursement models;
- our ability to establish and maintain adequate levels of coverage for Probuphine from commercial health plans and government health programs, which we refer to collectively as third-party payors, particularly in light of the availability of other branded and generic competitive products;
- the willingness for patients to pay out-of-pocket in the absence of third-party coverage and the success of patient assistance programs;
- our ability to promote products through marketing and sales activities and any other arrangements; and
- our ability to successfully educate prescribers and patients on the applicable product's efficacy and safety.

In light of the difficulties encountered to date, we cannot predict either the timing or the degree to which Probuphine will be accepted by the medical community. If we are unable to generate ample revenue from Probuphine, we will be unable to fund the required post-approval clinical studies or our research and development programs without additional financing, which may not be available on acceptable terms, and our business will be materially harmed.

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.

The New Drug Application, or NDA, for Probuphine mandated the post-approval completion of several Phase IV clinical trials. One of the required studies is being conducted collectively by a consortium led by another company. We are solely responsible for the conduct of the other studies; however, in light of the small number of patients using the product and our limited resources, we have informed the FDA of our need to delay the commencement of certain of these trials. There can be no assurance that we will ultimately have the necessary resources we need to initiate and complete the necessary clinical trials, or that the FDA will provide us with the time to do so. In such event, we may be subject to FDA notification of failure to comply with post-marketing requirements, possible sanctions, including monetary penalties and/or suspension of Probuphine commercial activities.

The Probuphine REMS program has negatively impacted sales and may continue to do so, which could materially adversely impact our business prospects.

The REMS program required by the FDA is designed to mitigate the risk of complications of migration, protrusion, expulsion and nerve damage associated with the insertion and removal of Probuphine and the risks of accidental overdose, misuse and abuse. The REMS program requires training and certification of healthcare providers who prescribe and implant Probuphine and provide patient counseling. Probuphine distribution is restricted to healthcare providers who have completed training and received certification under the REMS program. We believe the REMS program has been an obstacle to acceptance of Probuphine to date by the medical community. Healthcare providers may be unwilling to undergo training and certification in order to be able to prescribe or implant Probuphine due to time

constraints or concerns with the product. If we are unable to adequately address this issue, our ability (or the ability of potential future commercial partners) to generate revenue from sales of Probuphine could be materially compromised, which would have a material adverse effect on our business, results of operations, financial condition and prospects. In addition, if a patient suffers an injury during the insertion and removal of Probuphine, we may become liable to patients, clinicians or others or it may result in a determination that we are non-compliant with the REMS program. Non-compliance with the REMS program would bring serious consequences to us, including warning letters from the FDA, fines, criminal charges and/or other prohibitions and exclusions as well as reputational damage.

The FDA-approved product labeling for Probuphine allows prescribing for a limited patient population.

Probuphine was approved with an indicated use limited to the long-term maintenance treatment of opioid dependence in clinically stable patients on 8 mg or less a day of oral buprenorphine. The approved labeling also contains other limitations on use and a black box warning regarding certain risks/hazards associated with the product. If potential purchasers or those influencing purchasing decisions, such as physicians and pharmacists or third party payers, react negatively to Probuphine because of their perception of the limitations or safety risks in the approved product labeling, it may result in lower product acceptance and lower product revenues. In addition, our promotion of Probuphine must reflect only the specific approved indication as well as other limitations on use, and disclose the safety risks associated with the use of Probuphine as set out in the approved product labeling. We must submit all promotional materials to the FDA at the time of their first use. If the FDA raises concerns regarding our promotional materials or messages, we may be required to modify or discontinue using them and provide corrective information to healthcare practitioners, and we may face other adverse enforcement action.

Probuphine is a controlled substance subject to Drug Enforcement Agency regulations and failure to comply with these regulations, or the cost of compliance with these regulations, may adversely affect our business.

Probuphine contains buprenorphine, a regulated Schedule III "controlled substance" under the Controlled Substances Act, which establishes, among other things, certain registration, production quotas, security, recordkeeping, reporting, import, export and other requirements administered by the U.S. Drug Enforcement Agency, or DEA. The DEA regulates controlled substances as Schedule I, II, III, IV or V substances. Schedule I substances by definition have no established medicinal use and may not be marketed or sold in the United States. A pharmaceutical product may be listed as Schedule II, III, IV or V, with Schedule II substances considered to present the highest risk of abuse and Schedule V substances the lowest relative risk of abuse among such substances. Our failure to comply with DEA requirements could result in the loss of our ability to supply Probuphine, significant restrictions on Probuphine, civil penalties or criminal prosecution.

The DEA, and some states, also conduct periodic inspections of registered establishments that handle controlled substances. Facilities that conduct research, manufacture, store, distribute, import or export controlled substances must be registered to perform these activities and have the security, control and inventory mechanisms required by the DEA to prevent drug loss and diversion. Failure to maintain compliance, particularly non-compliance resulting in loss or diversion, can result in regulatory action that could have a material adverse effect on our business, results of operations, financial condition and prospects. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal proceedings.

Individual states also have controlled substances laws. Though state controlled substances laws often mirror federal law, because the states are separate jurisdictions, they may separately schedule drugs, as well. While some states automatically schedule a drug when the DEA does so, in other states there has to be rulemaking or a legislative action. State scheduling may delay commercial sale of any controlled substance drug product for which we obtain federal regulatory approval and adverse scheduling could have a material adverse effect on the commercial attractiveness of such product. We or our partners must also obtain separate state registrations in order to be able to obtain, handle, and distribute controlled substances for clinical trials or commercial sale, and failure to meet applicable regulatory requirements could lead to enforcement and sanctions from the states in addition to those from the DEA or otherwise arising under federal law.

We may be subject to enforcement action if we engage in improper marketing or promotion of Probuphine.

Our promotional materials and training methods must comply with the U.S. Federal Food, Drug and Cosmetic Act, or FDCA, and FDA regulations and other applicable laws and regulations, including the prohibition of the promotion of unapproved, or "off-label", use. Companies may not promote drugs for off-label use, which include uses that are not described in the product's labeling and that differ from those approved by the FDA. Physicians may prescribe drug products for off-label uses and such off-label uses are common across some medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDCA and FDA regulations restrict communications on the subject of off-label uses of drug products by pharmaceutical companies. The Office of Inspector General of the Department of Health and Human Services, or OIG, the FDA, and the Department of Justice, or DOJ, all actively enforce laws and regulations prohibiting promotion of off-label use and the promotion of products for which marketing approval has not been obtained. Other federal, state and foreign regulatory agencies, including the U.S. Federal Trade Commission, have issued guidelines and regulations that govern how we promote our products, including how we use endorsements and testimonials.

If we are found to be out of compliance with the requirements and restrictions described above, and we are investigated for or found to have improperly promoted off-label use, we may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions, and the off-label use of our products may increase the risk of product liability claims. In addition, management's attention could be diverted from our business operations and our reputation could be damaged.

In addition to FDA and related regulatory requirements, we are subject to health care "fraud and abuse" laws, such as the federal False Claims Act, the anti-kickback provisions of the federal Social Security Act, and other state and federal laws and regulations. Federal and state anti-kickback laws prohibit, among other things, payments or other remuneration to induce or reward someone to purchase, prescribe, endorse, or recommend a product that is reimbursed under federal or state healthcare programs. If we provide payments or other remuneration to a healthcare professional to induce the prescribing of our products, we could face liability under state and federal anti-kickback laws.

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 get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product or submitting inflated best price information to the Medicaid Rebate program. 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 payer. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines, and imprisonment. Even if it is determined that we have not violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would harm our business, prospects, operating results, and financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be challenged under one or more of such laws.

Additionally, requirements under the federal Open Payments program, created under Section 6002 of the Affordable Care Act and its implementing regulations, require that manufacturers of drugs for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to the U.S. Department of Health and Human Services, or HHS, information related to "payments or other transfers of value" provided to U.S. physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals. The Open Payments program also requires that manufacturers and applicable group purchasing organizations report annually to HHS ownership and investment interests held in them by physicians (as defined above) and their immediate family members. Manufacturers' reports are filed annually with the Centers for Medicare & Medicaid Services, or CMS, by each March 31, covering the previous calendar year. CMS posts disclosed information on a publicly available website. There are also an increasing number of state laws that restrict or prohibit pharmaceutical manufacturers' interactions with health care providers licensed in the respective states, and

that require pharmaceutical manufacturers to, among other things, establish comprehensive compliance programs, adopt marketing codes of conduct, file periodic reports with state authorities regarding sales, marketing, pricing, and other activities, and register/license their sales representatives. A number of state laws require manufacturers to file reports regarding payments and items of value provided to health care providers (similar to the federal Open Payments program). Many of these laws contain ambiguities as to what is required to comply with the laws. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state and federal authorities.

Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including criminal and significant civil monetary penalties, damages, fines, imprisonment, exclusion from participation in government healthcare programs, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, private qui tam actions brought by individual whistleblowers in the name of the government or refusal to allow us to enter into supply contracts, including government contracts and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. With respect to any of our products sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable privacy laws and post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

We obtain some of our raw materials, components and finished goods from a single source or a limited group of suppliers. The partial or complete loss of one of these suppliers could cause significant production delays, an inability to meet customer demand and a substantial loss in revenue.

We use a number of single-source suppliers for certain of our raw materials, components and finished goods, including:

- the supplier of the active ingredient for Probuphine;
- the manufacturer of the finished Probuphine implants;
- the supplier of finished product sterilization services; and
- the manufacturer of the Probuphine applicator.

Our use of these and other single-source suppliers of raw materials, components and finished goods exposes us to several risks, including disruptions in supply, price increases, late deliveries and an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation or customers switching to competitive products. Any interruption in supply could be particularly damaging to our ability to develop and commercialize Probuphine.

Finding alternative sources for these raw materials, components and finished goods would be difficult and in many cases entail a significant amount of time, disruption and cost. Any disruption in supply from any single-source supplier or manufacturing location could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

We rely on third parties to provide services in connection with the manufacture and distribution of Probuphine, and these third parties may not perform satisfactorily.

We do not own or operate, and currently do not plan to own or operate, facilities for production and packaging of Probuphine or our other product candidates. We are dependent on third parties for the timely supply of specified raw materials, maintaining our manufacturing equipment, trained personnel at the contract manufacturing vendor, formulation or packaging services, product distribution services, customer service activities and product returns processing. We are similarly dependent on third parties for the manufacture and sterilization of Probuphine applicators and the assembly and distribution of packaged kits.

Our reliance on third parties for the activities described above will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product in accordance with regulatory requirements, or proprietary specifications, or adhere to product processing best practices, or if there are disagreements between us and these third parties, our business could be materially adversely impacted.

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

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

While we have made progress in obtaining insurance coverage for Probuphine from a significant number of providers, we believe retention and further expansion of third-party coverage is necessary for greater uptake of the product. Even if coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use Probuphine unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products.

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

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

We depend on a small number of employees and consultants.

As a company with a limited number of personnel, we are highly dependent on the services of our executive management and the loss of one or more of such individuals could substantially impair our ongoing commercialization efforts. Moreover, our commercial success will be dependent upon our ability to

attract and maintain an effective sales and marketing team. We have faced and will continue to face intense competition for sales and marketing personnel with the necessary experience in addiction, reimbursement, specialty pharmacies and our targeted markets. We also intend to explore the opportunity to retain a senior executive with the depth and breadth of commercialization experience to complete our transition from a research and development company to a fully-functioning commercial enterprise. We compete in our hiring efforts with other pharmaceutical and biotechnology companies and it may be difficult and could take an extended period of time because of the limited number of individuals in our industry with the range of skills and experience required and because of our limited resources.

In addition, we retain scientific and clinical advisors and consultants to assist us in all aspects of our business. Competition to hire and retain consultants from a limited pool is intense. Further, because these advisors are not our employees, they may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us, and typically they will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours.

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.

The commercial opportunity for Probuphine could be significantly harmed if competitors are able to develop alternative formulations and/or drug delivery technologies outside the scope of our capabilities. Our principal competition in the opioid addiction treatment market comes from manufacturers of oral buprenorphine products, including Indivior PLC, which markets the Suboxone™ and Subutex™ brands, as well from manufacturers of weekly or monthly injectable treatments, including Sublocade™ which was recently launched by Indivior PLC. Lower priced generic forms of the oral product have also recently come to market. Our competitors may also develop, acquire or license products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than we are in manufacturing and marketing their products. In addition, state pharmacy laws may permit pharmacists to substitute generic products for branded products if the products are therapeutic equivalents, or may permit pharmacists and pharmacy benefit managers to seek prescriber authorization to substitute generics in place of our products, which could significantly diminish demand for Probuphine. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with Probuphine, our business, results of operations, financial condition and prospects may be materially adversely affected.

We are solely reliant on the efforts of third parties to commercialize Probuphine outside of the United States.

Our ability to generate revenues from the sale of Probuphine in the European Union and the rest of the Molteni Territory will be wholly dependent on Molteni's ability to successfully launch and commercialize the product in the Molteni Territory. We are similarly dependent on the efforts of Knight Therapeutics Inc., or Knight, with respect to product commercialization in Canada. We do not have control over the amount and timing of resources that Molteni or Knight will dedicate to these efforts. We will be similarly dependent on the development, regulatory and marketing efforts of third parties with respect to revenues, if any, from sales of Probuphine in additional territories.

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.

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

To date, we have conducted limited research and development activities based on our ProNeura delivery system beyond Probuphine. We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical studies and clinical trials, regulatory approvals and eventual commercialization of ProNeura for Parkinson's disease or any therapeutic based on our ProNeura platform technology. If we are unable to obtain substantial government grants, enter into third party collaborations or generate sufficient revenues from the sale of Probuphine to fund our ProNeura programs, we will need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in obtaining the requisite funding for our ProNeura programs, we will be unable to initiate clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, forego sales and marketing efforts and forego attractive business opportunities.

We will also seek to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

Our ability to successfully develop any future product candidates based on our ProNeura drug delivery technology is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including: delays in product development, clinical testing, or manufacturing; unplanned expenditures in product development, clinical testing, or manufacturing; failure to receive regulatory approvals; emergence of superior or equivalent products; inability to manufacture on our own, or through any others, product candidates on a commercial scale; and failure to achieve market acceptance. Because of these risks, our research and development efforts may not result in any commercially viable products. If a significant portion of these development efforts are not successfully completed, required regulatory approvals are not obtained or any approved products are not commercially successfully, our business, financial condition, and results of operations may be materially harmed.

Our development and commercialization strategy for ProNeura depends, in part, upon the FDA's prior findings regarding the safety and efficacy of the active drug incorporated into the implant based on data not developed by us, but upon which the FDA may rely in reviewing our NDA submissions. The current strategy for our ProNeura development programs is based, in part, on the expectation that the products we develop will be eligible for approval through the regulatory pathway under Section 505(b)(2) of the FDCA. Section 505(b)(2) of the FDCA allows an NDA to rely in part on data in the public domain or the FDA's

prior conclusions regarding the safety and effectiveness of an approved drug product, which could expedite our development programs by potentially decreasing the amount of clinical data that would need to be generated in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, we may need to conduct additional clinical trials, provide additional data and information, and meet additional standards for product approval. If this were to occur, the time and financial resources required to obtain FDA approval for any additional ProNeura products, and complications and risks associated with regulatory approval, would likely substantially increase. Moreover, inability to pursue the Section 505(b)(2) regulatory pathway may result in new competitive products reaching the market more quickly than those we have under development, which would adversely impact our competitive position and prospects. Even if we are able to utilize the Section 505(b)(2) regulatory pathway, there is no guarantee that this regulatory pathway will ultimately lead to accelerated product development or earlier approval. Moreover, notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years, some pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2). If the FDA changes its interpretation of Section 505(b)(2), or if the FDA's interpretation is successfully challenged in court, this result could delay or even prevent the FDA from approving any Section 505(b)(2) NDAs that we submit. Such a result could require us to conduct additional testing and costly clinical trials, which could substantially delay or prevent the approval and launch of any new ProNeura products.

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

In order to obtain FDA approval to market a new drug product based on our ProNeura drug delivery technology, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct "adequate and well controlled" clinical trials. Conducting clinical trials is a lengthy, time-consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per trial. Delays associated with products for which we are directly conducting clinical trials may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example:

- inability to manufacture sufficient quantities of qualified materials under cGMP, for use in clinical trials;
- slower than expected rates of patient recruitment;
- failure to recruit a sufficient number of patients; modification of clinical trial protocols;
- changes in regulatory requirements for clinical trials;
- the lack of effectiveness during clinical trials;
- the emergence of unforeseen safety issues;
- delays, suspension, or termination of the clinical trials due to the institutional review board responsible for overseeing the study at a particular study site; and
- government or regulatory delays or "clinical holds" requiring suspension or termination of the trials.

The results from early clinical trials are not necessarily predictive of results obtained in later clinical trials. Accordingly, even if we obtain positive results from early clinical trials, we may not achieve the same success in future clinical trials. Clinical trials may not demonstrate statistically significant safety and effectiveness to obtain the requisite regulatory approvals for product candidates. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

We face risks associated with third parties conducting preclinical studies and clinical trials of our products.

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 cGMP 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.

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

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

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

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

- obtain and keep patent protection for our products, methods and technologies on a domestic and 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.

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

In the United States, there have been a number of legislative and regulatory changes to the healthcare system in ways that could affect our future results of operations and the future results of operations of our potential customers. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 established a new Part D prescription drug benefit, which became effective January 1, 2006. Under the prescription drug benefit, Medicare beneficiaries can obtain prescription drug coverage from private sector plans that are permitted to limit the number of prescription drugs that are covered in each therapeutic category and class on their formularies. If our products are not widely included on the formularies of these plans, our ability to market our products may be adversely affected. Furthermore, there have been and continue to be a number of initiatives at the federal and state levels that seek to reduce healthcare costs. In March 2010, the Patient Protection and Affordable Health Care Act of 2010, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, or collectively "ACA", was signed into law, which includes measures to significantly change the way health care is financed by both governmental and private insurers.

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

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This can reduce demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

Additionally, given recent federal and state government initiatives directed at lowering the total cost of healthcare, Congress and state legislatures will likely continue to focus on healthcare reform, the cost of prescription drugs and the reform of the Medicare and Medicaid programs. While we cannot predict the

full outcome of any such legislation, it may result in decreased reimbursement for prescription drugs, which may further exacerbate industry-wide pressure to reduce prescription drug prices. This could harm our ability to market our products and generate revenues. In addition, legislation has been introduced in Congress that, if enacted, would permit more widespread importation or re-importation of pharmaceutical products from foreign countries into the United States, including from countries where the products are sold at lower prices than in the United States. Such legislation, or similar regulatory changes, could lead to a decision to decrease our prices to better compete, which, in turn, could adversely affect our business, results of operations, financial condition and prospects. It is also possible that other legislative proposals having similar effects will be adopted.

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

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions and our collaborators, and directly from individuals.

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of personal information. In addition, most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Although we are not directly subject to HIPAA, we could potentially be subject to criminal penalties if we, our affiliates, or our agents knowingly obtain or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

Risks Related to Our Financial Condition and Need for Additional Capital

We have incurred net losses in almost every year since our inception and we may never achieve or sustain profitability.

We have incurred net losses in almost every year since our inception. Our financial statements have been prepared assuming that we will continue as a going concern. For the years ended December 31, 2018 and 2017 and the six months ended June 30, 2019, we had net losses of approximately $9.3 million, $14.3 million and $9.7 million, respectively, and had net cash used in operating activities of approximately $8.4 million, $12.7 million and $8.5 million, respectively. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to continue to incur net losses and negative operating cash flow for the foreseeable future, and we expect these losses to increase as we build out our sales, marketing and support capabilities in connection with our commercial activities. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate significant revenues. There can be no assurance that we will ever achieve profitability.

We will require additional proceeds to fund our operations and to continue as a going concern.

We currently estimate that our available cash and cash equivalents at June 30, 2019, together with the approximately $1.8 million received from our August 2019 financing, will be sufficient to fund our operations through October 2019. We believe that the proceeds of this offering will be sufficient to fund our working capital needs and our Probuphine commercial efforts into the third quarter 2020. We will be required to demonstrate sufficient progress in commercializing Probuphine in this relatively short period of time in order to be able to raise additional funds to undertake the Phase IV clinical trials required by the FDA and potentially finance further expansion of our commercial operations. We will also require additional funds to advance our ProNeura development programs and to complete the regulatory approval process necessary to commercialize any products we might develop. While we are currently evaluating the

alternatives available to us, including government grants and third-party collaborations for one or more of our ProNeura programs, our efforts to address our liquidity requirements may not be successful. We plan to seek stockholder approval of an amendment to our certificate of incorporation to effect either an increase in the number of authorized shares of common stock or a reverse split in order to have shares available for future equity financings. There can be no assurance that we will receive such stockholder approval or that any source of capital will be available to us on acceptable terms. In addition, if one or more of the risks discussed in these risk factors occur or our expenses exceed our expectations, we may be required to raise further additional funds sooner than anticipated.

Following this offering, we will have a limited number of authorized shares of common stock available for issuance and will need to seek stockholder approval to amend our charter to either effect an increase in our authorized shares of common stock or a reverse split.

Immediately following this offering, we will have only 14,351,972 authorized but unissued or unreserved shares of our common stock (2,351,972 if the over-allotment option is exercised in full). We will need to continue to seek additional funding in order to conduct the required Phase IV clinical trials and expand our product development and commercial operations and will not have shares of common stock available for any additional equity financings. We will seek stockholder approval of an amendment to our certificate of incorporation to effect either an increase in the number of authorized shares of common stock or a reverse split in order to fund our business. If we do not receive the requisite stockholder approval to enable us to issue equity in the future, our operations will likely be materially adversely impacted.

In addition, an increase in the authorized number of shares of common stock and the subsequent issuance of such shares could have the effect of delaying or preventing a change in control of our company without further action by our stockholders. Shares of authorized and unissued common stock could, within the limits imposed by applicable law, be issued in one or more transactions which would make a change in control of our company more difficult, and therefore less likely. Furthermore, there are risks associated with effecting a reverse split, including a decline in the market price of our common stock and the possibility of certain shareholders owning “odd lots” of less than 100 shares, which may be more difficult to sell, or require greater transaction costs per share to sell, than shares in “round lots” of even multiples of 100 shares. In addition, because holders of our common stock have no preemptive rights to purchase or subscribe for any unissued stock of our company, the availability of a greater number of authorized shares, whether as a result of a reverse split or an increase in the authorized number, could result in additional dilution to existing stockholders and investors in this offering.

Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution.

Our cash requirements may vary from those now planned and may be affected by numerous factors, including the results of our commercialization efforts and future research and development activities. We expect our expenses to increase in connection with our ongoing activities, particularly as we expand our infrastructure and, assuming funding is available, undertake the required Phase IV clinical trials and continue the research and development and initiate and conduct clinical trials of our product candidates. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. We expect to seek additional funding through a combination of equity offerings or debt financings. Our securities may be offered to other investors at a price lower than the price per share offered to current stockholders, or upon terms which may be deemed more favorable than those offered to current stockholders. In addition, the issuance of securities in any future financing may dilute an investor’s equity ownership and have the effect of depressing the market price for our securities. Moreover, we may issue derivative securities, including options and/or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders. No assurance can be given as to our ability to procure additional financing on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and/or may have to curtail certain, if not all, of our business objectives and plans.

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, 2018, we had federal net operating loss and tax credit carryforwards of $263.6 million and $8.8 million, respectively, and state net operating loss and tax credit carryforwards of $107.8 million and $9.0 million, respectively, available to offset future taxable income, if any. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change and we cannot assure you that our net operating loss and tax carryforwards will continue to be available.

Our loan agreement contains restrictions on our operations and could result in certain adverse results.

Our Loan Agreement contains a variety of affirmative covenants, including, without limitation, payment obligations, information delivery requirements and certain notice requirements. Additionally, we are bound by certain negative covenants setting forth actions that are not permitted to be taken during the term of the Restated Loan Agreement without consent of Molteni, as the majority lender, including, without limitation, incurring certain additional indebtedness, making certain asset dispositions, entering into certain mergers, acquisitions or other business combination transactions or incurring any nonpermitted lien or other encumbrance on our assets. Subject to certain forbearance provisions in effect through December 31, 2020, upon the occurrence of an event of default under the Restated Loan Agreement (subject to any applicable cure periods), all amounts owed thereunder would begin to bear interest at a rate that is 5.0% higher than the rate that would otherwise be applicable and the outstanding loan may be declared immediately due and payable. Furthermore, the loan is secured by a perfected security interest in all of our assets, including our Probuphine and ProNeura intellectual property, which could be foreclosed.

Risks Related to this Offering and our Common Stock

If you purchase units in this offering, you will incur immediate and substantial dilution in the book value of your shares.

After giving effect to the sale of 40,000,000 units in this offering, at a public offering price of $0.225 per unit, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us and attributing no value to the Class B warrants sold in this offering, purchasers of our common stock in this offering will incur immediate dilution of $(0.086) per share in the net tangible book value of the common stock they acquire. In the event that you exercise your Class B warrants, you may experience additional dilution to the extent that the exercise price of the warrants is higher than the tangible book value per share of our common stock. For a further description of the dilution that investors in this offering may experience, see “Dilution.”

In addition, to the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, you may experience further dilution.

We have broad discretion in the use of the net proceeds we receive from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds we receive in this offering, including for any of the purposes described in the section entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether our management is using the net proceeds appropriately. Because of the number and variability of factors that will determine our use of our net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business and cause the price of our common stock to decline. Pending their use, we may invest our net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

Future sales of substantial amounts of our common stock could adversely affect the market price of our common stock.

Assuming we receive the necessary stockholder approval to increase our available authorized but unissued shares, we may choose to raise additional capital due to market conditions or strategic

considerations even if we believe we have sufficient funds for our current or future operating plans. If additional capital is raised through the sale of equity or convertible debt securities, or perceptions that those sales could occur, the issuance of these securities could result in further dilution to investors purchasing our common stock in this offering or result in downward pressure on the price of our common stock, and our ability to raise capital in the future.

Holders of our Class B Warrants and Pre-Funded Warrants will have no rights as a common stockholder until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of your Class B Warrants or Pre-Funded Warrants, you will have no rights with respect to shares of our common stock issuable upon exercise of such warrants. Upon exercise of your Class B Warrants or Pre-Funded Warrants, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The Warrants may not have any value.

Each Class B will have an exercise price of $0.225, subject to adjustment as provided therein, and will expire on the fifth anniversary of the date of issuance. In the event our common stock price does not exceed the exercise price of the Class B Warrants during the period when the Class B Warrants are exercisable, the Class B Warrants may not have any value.

There is no public market for the Class B Warrants to purchase shares of our common stock or Pre-Funded Warrants being offered in this offering.

There is no established public trading market for the Class B Warrants or Pre-Funded Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Class B Warrants or Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system, including The Nasdaq Capital Market. Without an active trading market, the liquidity of the Class B Warrants and Pre-Funded Warrants will be limited.

Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock.

On August 20, 2019, we received a notice from the Nasdaq Capital Market, or Nasdaq, that because our stockholders' equity is less than $2,500,000, we are no longer in compliance with the minimum stockholders' equity requirement for continued listing pursuant to Nasdaq Listing Rule 5550(b)(1). At June 30, 2019, we had a stockholders' deficit of approximately $571,000. The proceeds of this offering, together with the proceeds from the August 2019 financing will enable us to achieve the minimum stockholders' equity requirement. In addition, on September 19, 2019, we received a letter from Nasdaq notifying us that the market price of our common stock has been below the $1.00 minimum bid price requirement for continued listing and requiring us to regain compliance with the minimum bid price requirement within 180 days. If we fail to satisfy the continued listing requirements of Nasdaq, such stockholders' equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to de-list our common stock. Such a de-listing would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a de-listing, we would take actions to restore our compliance with Nasdaq's listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Our share price may be volatile, which could prevent you from being able to sell your shares at or above your purchase price.

The market price of shares of our common stock has been and may continue to be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results of our Probuphine commercial efforts;

- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated fluctuations in our competitors' operating results or growth rate;
- competition from existing products or new products that may emerge;
- announcements by us, our potential future collaborators or our competitors of significant acquisitions, strategic collaborations, joint ventures, or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- inconsistent trading volume levels of our shares;
- additions or departures of key personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

The stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock and could subject us to securities class action litigation.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will depend on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our stock or change their opinion of our stock, our share price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions provide that:

- the authorized number of directors can be changed only by resolution of our board of directors;

- our bylaws may be amended or repealed by our board of directors or our stockholders;
- stockholders may not call special meetings of the stockholders or fill vacancies on the board of directors;
- our board of directors is authorized to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a "poison pill" to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve;
- our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and
- our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

We have never paid any cash dividends and have no plans to pay any cash dividends in the future.

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our shares of our preferred or common stock and we do not expect to pay cash dividends in the foreseeable future. In addition, the declaration and payment of cash dividends is restricted under the terms of our existing Loan Agreement. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our preferred or common stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future results of operations and financial position, strategy and plans, and our expectations for future operations, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "should," or "will" or the negative of these terms or other comparable terminology. Although we do not make forward looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. Forward-looking statements included or incorporated by reference in this prospectus or our other filings with the Securities and Exchange Commission, or the SEC, include, but are not necessarily limited to, those relating to uncertainties relating to:

- the commercialization of Probuphine;
- financing and strategic agreements and relationships;
- difficulties or delays in the regulatory approval process;
- uncertainties relating to manufacturing, sales, marketing and distribution of our drug candidates that may be successfully developed and approved for commercialization;
- adverse side effects or inadequate therapeutic efficacy of our drug candidates that could slow or prevent product development or commercialization;
- dependence on third party suppliers;
- the uncertainty of protection for our patents and other intellectual property or trade secrets; and
- competition.

These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under "Risk Factors" or elsewhere in this prospectus, which may cause our or our industry's actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements.

Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by which, that performance or those results will be achieved. Forward-looking statements are based on information available at the time they are made and/or management's good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from what is expressed in or suggested by the forward-looking statements.

Forward-looking statements speak only as of the date they are made. You should not put undue reliance on any forward-looking statements. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information, except to the extent required by applicable securities laws. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.. We caution you not to give undue weight to such projections, assumptions and estimates.

USE OF PROCEEDS

We estimate that the net proceeds of this offering from the sale of 40,000,000 units will be approximately $8.1 million after deducting underwriting discounts and commissions and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Class B Warrants. If the underwriters exercise their option in full to purchase 6,000,000 shares of common stock and Class B Warrants to purchase 6,000,000 shares of common stock, we estimate that the net proceeds of this offering will be approximately $9.4 million.

We currently intend to use the net proceeds of the offering to fund ongoing operations and the growth of our business, including expansion of our sales and marketing capabilities, either internally, through relationships with third parties or a combination of both.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment grade, interest bearing instruments and U.S. government securities.

DILUTION

Purchasers of units in this offering will experience an immediate dilution of the net tangible book value per share of our common stock. Our net tangible book value as of June 30, 2019 was approximately $(571,000), or $(0.04) per share of our common stock. Net tangible book value per share is equal to our total tangible assets less our total liabilities, divided by the number of shares of our outstanding common stock.

Dilution per share of common stock equals the difference between the amount paid by purchasers of common stock in this offering (ascribing no value to the warrants) and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the sale by us of 40,000,000 units at a public offering price of $0.225 per unit after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2019 would have been approximately $7.5 million, or approximately $0.139 per share. This represents an immediate increase in net tangible book value of $0.179 per share to existing stockholders and an immediate decrease in net tangible book value of $(0.086) per share to new investors purchasing units in this offering, attributing none of the unit public offering price to the Class B Warrants offered hereby. The following table illustrates this per share dilution:

Public offering price per unit		$ 0.225
Net tangible book value per share as of June 30, 2019	$ (0.04)	
Increase in net tangible book value per share after this offering	0.179	
As adjusted net tangible book value per share after this offering		0.139
Dilution per share to new investors		$(0.086)

The information above is as of June 30, 2019 and excludes as of such date:

- 1,302,057 shares of our common stock issuable upon the exercise of outstanding options with a weighted average exercise price of $5.82 per share;
- 5,489,450 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of $1.32 per share (assuming an adjustment to the exercise price of our 2018 public offering warrants as a result of this offering to $0.60);
- 3,422,777 shares of our common stock issuable upon the conversion of outstanding debt; and
- 468,303 additional shares of our common stock reserved for future issuance under our 2015 equity incentive plan.

DESCRIPTION OF SECURITIES WE ARE OFFERING

As of the date of this prospectus, our certificate of incorporation authorizes us to issue 125,000,000 shares of common stock, par value $0.001 per share, and 5,000,000 shares of preferred stock, par value $0.001 per share.

We are offering units consisting of (i) 40,000,000 shares of our common stock (or Pre-Funded Warrants in lieu thereof) and (ii) Class B Warrants to purchase 40,000,000 shares of our common stock. Each unit will consist of (i) one share of common stock (or Pre-Funded Warrant in lieu thereof) and (ii) one Class B Warrant. The shares of our common stock and related Class B Warrants will be issued separately. We are also registering the shares of our common stock issuable from time to time upon exercise of the Class B Warrants offered hereby.

The following description of our capital stock is not complete and is subject to and qualified in its entirety by our certificate of incorporation, as amended, and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, and by the relevant provisions of the Delaware General Corporation Law.

Common Stock

Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our certificate of incorporation and bylaws do not provide for cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that are outstanding or that we may designate and issue in the future. All of our outstanding shares of common stock are fully paid and nonassessable.

Our common stock is currently listed on The Nasdaq Capital Market under the trading symbol “TTNP.”

Pre-Funded Warrants

The following summary of certain terms and provisions of the Pre-Funded Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by the provisions of, the Pre-Funded Warrant. Prospective investors should carefully review the terms and provisions of the form of Pre-Funded Warrant for a complete description of the terms and conditions of the Pre-Funded Warrants.

The term “pre-funded” refers to the fact that the purchase price of our common stock in this offering includes almost the entire exercise price that will be paid under the Pre-Funded Warrants, except for a nominal remaining exercise price of $0.001. The purpose of the Pre-Funded Warrants is to enable investors that may have restrictions on their ability to beneficially own more than 4.99% (or, upon election of the holder, 9.99%) of our outstanding common stock following the consummation of this offering the opportunity to invest capital into the Company without triggering their ownership restrictions, by receiving Pre-Funded Warrants in lieu of our common stock which would result in such ownership of more than 4.99% (or 9.99%), and receive the ability to exercise their option to purchase the shares underlying the Pre-Funded Warrants at such nominal price at a later date.

Duration. The Pre-Funded Warrants offered hereby will entitle the holders thereof to purchase shares of our common stock at a nominal exercise price of $0.001 per share, commencing immediately on the date of issuance.

Exercise Limitation. A holder will not have the right to exercise any portion of the Pre-Funded Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election of the holder, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Pre-Funded Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price. The Pre-Funded Warrants will have an exercise price of $0.001 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability. Subject to applicable laws, the Pre-Funded Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. There is no established trading market for the Pre-Funded Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Pre-Funded Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Pre-Funded Warrants will be limited.

Fundamental Transactions. If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Pre-Funded Warrants with the same effect as if such successor entity had been named in the Pre-Funded Warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the Pre-Funded Warrant following such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Pre-Funded Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Pre-Funded Warrant.

Class B Warrants

The following summary of certain terms and provisions of the Class B Warrants offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the Class B Warrant, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions of the form of Class B Warrant for a complete description of the terms and conditions of such warrants.

Form. The Class B Warrants will be issued as individual warrant agreements to the investors.

Exercisability. The Class B Warrants are exercisable at any time after their original issuance, expected to be October 18, 2019, and at any time up to the date that is five years after their original issuance. The Class B Warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the Class B Warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the Class B Warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the Class B Warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the Class B Warrant. No fractional shares of common stock will be issued in connection with the exercise of a Class B Warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

Exercise Limitation. A holder will not have the right to exercise any portion of the Class B Warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, upon election of the holder, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the Class B Warrants. However, any holder may increase or decrease such percentage, provided that any increase will not be effective until the 61st day after such election.

Exercise Price. The Class B Warrants will have an exercise price of $0.225 per share, subject to downward adjustment as described below. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders. In addition, the exercise price of the Class B Warrants will be subject to full-ratchet anti-dilution price protection in the event we issue in a financing or certain other transactions shares of common stock or securities convertible into or exercisable for common stock at a price or having a conversion or exercise price less than the exercise price then in effect.

Transferability. Subject to applicable laws, the Class B Warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing. There is no established trading market for the Class B Warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the Class B Warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the Class B Warrants will be limited.

Fundamental Transactions. If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the Class B Warrants with the same effect as if such successor entity had been named in the warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the warrant following such fundamental transaction.

Rights as a Stockholder. Except as otherwise provided in the Class B Warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a Class B Warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the Class B Warrant.

Transfer Agent

The transfer agent of our common stock being offered hereby is Continental Stock Transfer & Trust Company.

UNDERWRITING

We have entered into an underwriting agreement with the underwriters named below with respect to 40,000,000 units, each unit consisting of (i) one share of common stock (or Pre-Funded Warrant in lieu thereof) and (ii) one Class B Warrant subject to this offering. Subject to certain conditions, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase, the number of shares of our units provided below opposite each underwriter's name. Maxim Group LLC is acting as the representatives of the underwriters.

Underwriter	Number of Units
Maxim Group LLC	40,000,000
Total	40,000,000

The underwriters are offering the units subject to their acceptance of our common stock, the Pre-Funded Warrants and the Class B Warrants from us and subject to prior sale. The underwriting agreement provides that the obligations of the underwriters to pay for and accept delivery of the units offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions. The underwriters are obligated to take and pay for all of the shares of our common stock, Pre-Funded Warrants and related Class B Warrants if any such shares of our common stock, Pre-Funded Warrants and related Class B Warrants are taken.

We have granted the underwriters an option for a period of 45 days from the date of this prospectus to purchase up to an additional 6,000,000 shares of common stock and/or Class B Warrants to purchase an aggregate of 6,000,000 shares of common stock at the public offering price, less the underwriting discount.

Underwriter Compensation

We have agreed to pay the underwriters an aggregate fee equal to 7.0% of the gross proceeds of this offering and expect the net proceeds from this offering to be approximately $8.1 million after deducting approximately $630,000 in underwriting commissions and approximately $175,000 in our other estimated offering expenses. We have also agreed to pay the underwriters an accountable expense allowance for certain of the underwriters' expenses relating to the offering up to a maximum aggregate amount of $75,000, including the underwriters' legal fees incurred in this offering.

Right of First Refusal

We have also agreed that if the securities are sold in accordance with the terms of this prospectus, the representative of the underwriters shall have a preferential right for a period of nine (9) months from the commencement of sales of the offering to act as sole lead managing underwriter and sole book runner, for any securities (whether public or private offerings of debt or equity or any combination thereof) we or any subsidiary or successor may seek to sell whether with or without or through an underwriter, placement agent or broker-dealer and whether pursuant to registration under the Securities Act or otherwise. The representative's failure to exercise its preferential right with respect to any particular proposal shall not affect its preferential rights relative to future proposals. The representative shall have the right to designate any other agents or underwriters in any such financing and the economics in connection with a financing that will be split with any additional agent(s) or underwriter(s) will be determined at the sole discretion of the Representative.

Discounts and Expenses

The underwriters have advised us that they propose to offer the shares of our common stock, Pre-Funded Warrants and related Class B Warrants to the public at the respective public offering price set forth on the cover page of this prospectus and to certain dealers at that price less a concession not in excess of $0.0135 per unit. After this offering, the public offering price and concession to dealers may be changed by the representative. No such change shall change the amount of proceeds to be received by us as set forth on the cover page of this prospectus. The shares of our common stock, Pre-Funded Warrants and related Class B Warrants are offered by the underwriters as stated herein, subject to receipt and acceptance by them and subject to their right to reject any order in whole or in part. The underwriters have informed us that they do not intend to confirm sales to any accounts over which they exercise discretionary authority.

The following table shows the public offering price, underwriting discount payable to the underwriters by us and proceeds before expenses to us, assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of common stock and/or Class B Warrants. The underwriting commissions are equal to the combined public offering price per unit, less the amount per unit the underwriters pay us for the units:

	Per Unit	Total (No Exercise)	Total (Full Exercise in shares only)
Public offering price	$ 0.225	$9,000,000	$10,350,000
Underwriting discounts and commissions	$0.01575	$ 630,000	$ 724,500
Proceeds, before expenses, to us	$0.20925	$8,370,000	$ 9,625,500

In addition, we have agreed to reimburse the underwriters for reasonable out-of-pocket expenses not to exceed $75,000 in the aggregate. We estimate that total expenses payable by us in connection with this offering, other than the underwriting discount referred to above, will be approximately $250,000.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act.

Lock-up Agreements

We have agreed, subject to limited exceptions, for a period of three months after the closing of this offering, and our officers and directors have agreed, subject to limited exceptions, for a period of six months after the closing of this offering, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of Maxim Group LLC. Maxim Group LLC may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

Price Stabilization, Short Positions and Penalty Bids

In connection with the offering the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions and penalty bids in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.

- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. A naked short position occurs if the underwriters sell more shares than could be covered by the over-allotment option. This position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. These transactions may be discontinued at any time.

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our shares of common stock. In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transaction, if commenced, will not be discontinued without notice.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on the underwriters' websites and any information contained in any other websites maintained by the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriters, and should not be relied upon by investors.

Other

From time to time, the underwriters and/or their affiliates have provided, and may in the future provide, various investment banking and other financial services for us for which services it has received and, may in the future receive, customary fees.

Except for the services provided in connection with this offering and other than as described below, the underwriters have not provided any investment banking or other financial services during the 180-day period preceding the date of this prospectus.

On August 10, 2019, we completed an offering of 1,480,000 shares of our common stock and pre-funded warrants to purchase up to an aggregate of 1,372,314 shares of our common stock. The shares were sold at a purchase price of $0.75 per share and the pre-funded warrants were sold at a purchase price of $0.74 per pre-funded warrant which represents the per share purchase price for the shares less the $0.01 per share exercise price for each such pre-funded warrant. In addition, in a concurrent private placement, we issued to the purchaser warrants to purchase 2,852,314 shares of our common stock at an exercise price of $1.07 per share, which are exercisable for a period of five years commencing February 9, 2020. Maxim Group LLC acted as placement agent in connection with such transaction.

Offers Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or

indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Loeb & Loeb LLP, New York, New York. The underwriters are being represented by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The financial statements as of and for the years ended December 31, 2018 and 2017 incorporated by reference in this prospectus constituting a part of the registration statement on Form S-1 have been so incorporated in reliance on the report of OUM & Co. LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the Securities and Exchange Commission a registration statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which is part of the registration statement, omits certain information, exhibits, schedules and undertakings set forth in the registration statement. For further information pertaining to us and the securities offered hereby, reference is made to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents or provisions of any documents referred to in this prospectus are not necessarily complete, and in each instance where a copy of the document has been filed as an exhibit to the registration statement, reference is made to the exhibit for a more complete description of the matters involved.

You may read and copy all or any portion of the registration statement without charge at the public reference room of the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the Securities and Exchange Commission at prescribed rates from the public reference room of the Securities and Exchange Commission at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the Securities and Exchange Commission electronically are publicly available through the Securities and Exchange Commission's website at www.sec.gov. The registration statement, including all exhibits and amendments to the registration statement, has been filed electronically with the Securities and Exchange Commission. You may also read all or any portion of the registration statement and certain other filings made with the Securities and Exchange Commission on our website at www.heatbio.com. The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

We are subject to the information and periodic reporting requirements of the Exchange Act and, accordingly, are required to file annual reports containing financial statements audited by an independent public accounting firm, quarterly reports containing unaudited financial data, current reports, proxy statements and other information with the Securities and Exchange Commission. You will be able to inspect and copy such periodic reports, proxy statements and other information at the Securities and Exchange Commission's public reference room, the website of the Securities and Exchange Commission referred to above, and our website at www.titanpharm.com. Except for the specific incorporated reports and documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede some of this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, including filings made after the date of the initial registration statement, until we sell all of the shares covered by this prospectus or the sale of shares by us pursuant to this prospectus is terminated. In no event, however, will any of the information that we furnish to, pursuant to Item 2.02 or Item 7.01 of any Current Report on Form 8-K (including exhibits related thereto) or other applicable SEC rules, rather than file with, the SEC be incorporated by reference or otherwise be included herein, unless such information is expressly incorporated herein by a reference in such furnished Current Report on Form 8-K or other furnished document. The documents we incorporate by reference are:

- our Annual Report on Form 10-K/A for the year ended December 31, 2018, filed with the SEC on April 2, 2019;
- our Quarterly Report on Form 10-Q for the period ended March 31, 2019, filed with the SEC on May 15, 2019;
- our Quarterly Report on Form 10-Q for the period ended June 30, 2019, filed with the SEC on August 14, 2019;
- our Current Reports on Form 8-K filed with the SEC onJanuary 25, 2019, February 14, 2019, February 25, 2019, April 3, 2019, April 26, 2019, June 27, 2019, August 7, 2019, August 23, 2019, September 18, 2019 and September 20, 2019; and
- the description of our common stock contained in our registration statement on Form 8-A (File No. 001-13341) filed under the Exchange Act on October 8, 2015, including any amendment or reports filed for the purpose of updating such descriptions.

Any statement contained in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide each person to whom a prospectus is delivered a copy of all of the information that has been incorporated by reference in this prospectus but not delivered with the prospectus. You may obtain copies of these filings, at no cost, through the "Investor Relations" section of our website (www.titanpharm.com) and you may request a copy of these filings (other than an exhibit to any filing unless we have specifically incorporated that exhibit by reference into the filing), at no cost, by writing or telephoning us at the following address:

400 Oyster Point Boulevard, Suite 505
South San Francisco, CA 94080
(650) 244-4990

Information on, or that can be accessed through, our website is not incorporated into this prospectus or other securities filings and is not a part of these filings.

PROSPECTUS

MAXIM GROUP LLC

October 16, 2019

Through and including November 10, 2019 (25 days after commencement of this offering), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to their unsold allotments or subscriptions.