TITAN PHARMACEUTICALS INC
Form 424B5
September 24, 2018
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Filed Pursuant to Rule 424(b)(5)
Registration Statement No. 333-226841

PROSPECTUS

5,100,000 Class A Units Consisting of Common Stock and Warrants and
8,225 Class B Units Consisting of Series A Convertible Preferred Stock and Warrants

We are offering 5,100,000 Class A Units consisting of one share of our common stock and one warrant to purchase one share of our common stock, at an exercise price equal to $0.25, which warrants will be exercisable upon issuance and will expire five years from date of issuance. The shares of common stock and warrants that are part of a Class A Unit are immediately separable and will be issued separately in this offering.

We are also offering to those purchasers, if any, whose purchase of Class A Units in this offering 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, in lieu of purchasing Class A Units, to purchase Class B Units. Each Class B Unit will consist of one share of our newly designated Series A Convertible Preferred Stock, or the Series A Preferred, with a stated value of $1,000 and convertible into 4,000 shares of our common stock at a conversion price of $0.25, together with warrants to purchase 4,000 shares of our common stock, at an exercise price of $0.25 per share. The shares of Series A Preferred do not generally have any voting rights unless and until converted into shares of common stock. The shares of Series A Preferred and warrants that are part of a Class B Unit are immediately separable and will be issued separately in this offering.

The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series A Preferred shares convert their shares to common stock.

Our common stock is listed on The Nasdaq Capital Market under the symbol “TTNP”. On September 20, 2018, the last reported sale price of our common stock on The Nasdaq Capital Market was $0.50 per share.

The Series A Preferred included in the Class B Units will be convertible into an aggregate of 32,900,000 shares of Common Stock and the warrants included in the Class B Units will be exercisable for an aggregate of 32,900,000 shares of Common Stock.

There is no established trading market for the warrants or the Series A Preferred, and we do not expect an active trading market to develop. We do not intend to list the warrants or the Series A Preferred on any securities exchange or other trading market. Without an active trading market, the liquidity of the warrants and the Series A Preferred will be limited.

Our business and an investment in our securities involves a high degree of risk. See “Risk Factors” beginning on page 9 of this prospectus for a discussion of information that you should consider before investing 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 Class A Unit(2)	Per Class B Unit	Total

Public offering	$ 0.25	$ 1,000	$ 9,500,000
Underwriting discounts and commissions(1)	$ 0.0175	$ 70	$ 654,675
Proceeds to us, before expenses	$ 0.2325	$ 930	$ 8,845,325

(1)
The underwriters will receive compensation in addition to the underwriting discount and commissions. See "Underwriting" beginning on page 48 of this prospectus for a description of compensation payable to the underwriters.

(2)
An underwriting discount of $0.00875 per Class A Unit is applicable to 1,180,000 Class A Units and the proceeds to us, before expenses, on these units is $0.24125 per unit.

Several members of our board of directors are purchasing an aggregate of $295,000 of Class A Units in this offering at the public offering price per unit. See "Underwriting" for a description of the compensation payable to the underwriters on proceeds received from these investors.
We have granted a 45-day option to the underwriters to purchase an additional 5,700,000 shares of common stock and/or additional warrants to purchase 5,700,000 shares of common stock.
The underwriters expect to deliver the securities against payment therefor on or about September 25, 2018.
Sole Book-Running Manager
A.G.P.
Co-Manager
CIM Securities, LLC
September 20, 2018

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You should rely only on the information contained or incorporated by reference in this prospectus. Neither we nor the underwriters have authorized anyone to provide you with information different from, or in addition to, that contained or incorporated by reference in this prospectus or any free writing prospectus prepared by or on behalf of us or to which we may have referred you in connection with this offering. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor any of the underwriters is making an offer to sell or seeking offers to buy these securities in any jurisdiction where, or to any person to whom, the offer or sale is not permitted. The information contained or incorporated by reference in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock, and the information in any free writing prospectus that we may provide you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and future growth prospects may have changed since those dates

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. The industry publications and industry data contained in this prospectus have been obtained from sources believed to be reliable.

For investors outside the United States: Neither we nor any of the underwriters have 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 of the United States.

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PROSPECTUS 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 proprietary therapeutics utilizing our proprietary long-term drug delivery platform for the treatment of select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit. We are currently transitioning to a commercial stage enterprise having recently re-acquired Probuphine®, a product approved in the U.S. for management of opiate dependence.

Probuphine, our first product candidate based on our proprietary ProNeura™ platform, is a subdermal implant that provides continuous delivery of buprenorphine for six months. Probuphine was approved by the United States Food and Drug Administration, or FDA, in May 2016 for the maintenance treatment of opioid dependence in patients who are stable on low to moderate doses of daily sublingual buprenorphine treatment. We licensed development and commercialization rights of Probuphine for the U.S. and Canadian markets to Braeburn Pharmaceuticals, Inc., or Braeburn, in December 2012. Braeburn subsequently sublicensed the Canadian rights to Knight Therapeutics Inc., or Knight, in February 2016. In April 2018, Knight announced that it had received regulatory approval from Health Canada to commercialize the product for the maintenance treatment of stable patients with opioid use disorder.

In early 2018, Braeburn substantially reduced its field sales force and medical liaison personnel following its receipt of a complete response letter from the FDA for its weekly and monthly depot injection products. Anticipating a negative impact on Probuphine sales in the U.S., we began discussing with Braeburn terms for the return of the Probuphine U.S. commercialization rights to Titan. On May 25, 2018, we entered into an agreement with Braeburn under which we received a $1 million payment from Braeburn and Braeburn's undertaking to provide transition services through 2018 to assist with commercialization activities and help maintain continuity in product supply for patients and their physicians.

Since reacquiring the rights, we have begun implementation of a strategy to relaunch Probuphine to targeted market segments that we believe are best suited to benefit from this product. We intend to use a substantial portion of the proceeds of this offering to build our infrastructure, including a small sales and marketing team, which will enable us to successfully transition to a commercial enterprise and position Probuphine as a specialty product.

On March 21, 2018, we entered into an agreement, or the Purchase Agreement, with L. Molteni & C. Dei Frattelli Alitti Società Di Esercizio S.P.A., or Molteni, pursuant to which Molteni acquired the European intellectual property related to Probuphine and exclusive right to commercialize the Titan supplied product in Europe, as well as certain countries of the Commonwealth of Independent States, the Middle East and North Africa, or the Molteni Territory, in exchange for upfront, milestone and earn-out payments for up to 15 years on net sales of Probuphine in the Molteni Territory. We are working with Molteni in connection with the Marketing Authorization Application, or MAA, currently under review by the European Medicines Agency, or EMA, with the goal of receiving approval to commercialize Probuphine in the European Union, or EU, in the first half of 2019.

We believe that our ProNeura long term drug delivery platform has the potential to be used in the treatment of other chronic conditions where maintaining stable, around the clock blood levels of a medication may benefit the patient and improve medical outcomes. Our long-term goal is to expand our product pipeline using the ProNeura implant platform, and, depending on available funds, we have been opportunistically evaluating other drugs and disease settings for use with the ProNeura platform in

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potential treatment applications such as Parkinson's disease, where conventional treatment is limited by variability in blood drug levels and poor patient compliance. The pursuit of any of these programs in the short-term will depend on our ability to obtain the necessary funding through either government grants or third party collaborations.

Our Market Opportunity

Opioid Use Disorder, or OUD, is a severe, chronic, relapsing brain disease characterized by compulsive drug seeking and use, despite the harmful consequences. Sufferers experience cravings of opioids, 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 2016, 2.3 million people were diagnosed with OUD and close to 12 million people used opioids. According to government publications, the U.S. societal costs of opioid abuse total $78.5 billion annually and over 115 people die each day as a direct result of their addiction. 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 12-step programs, a rarely successful therapeutic approach, drug counseling and medication assisted therapies, or MAT. Cravings may persist for years even in the face of abstinence from illicit opiates, leading to a high incidence of relapse in patients not maintained on longer term MAT. The current MAT gold standard is daily treatment with sublingual buprenorphine, a medication that controls the withdrawal symptoms and cravings without inducing opioid euphoria in patients. A 30-day depot formulation was recently approved by the FDA and similar depot buprenorphine products are under FDA review in both weekly and monthly formulations. Unlike methadone, sublingual buprenorphine can be prescribed as an outpatient treatment, making it a convenient option for patients, and U.S. sales of formulations of buprenorphine are approximately $2.0 billion annually. There are challenges, however, associated with daily dosed formulations, including:

- voluntary compliance;
- potential reinforcement of drug-taking behavior;
- variable levels of medication in the blood; and
- diversion, abuse and accidental pediatric overdose.

Probuphine is a safe, effective long-term, subdermal treatment for selected patients that addresses these challenges by:

- releasing buprenorphine continuously for six months;
- providing a stable level of medication in the blood, avoiding peaks and troughs of oral dosing; and
- minimizing or eliminating the potential for diversion or accidental overdose.

Our Commercial Strategy for Probuphine Relaunch

We are currently transitioning all the Probuphine commercialization activities from Braeburn to Titan which include the supply chain and logistics functions, as well as the Medical Affairs and Risk Evaluation Mitigation Strategy, or REMS, training and reporting activities. We expect to complete most of the transition during the third quarter of 2018, and expect to commence the relaunch of Probuphine under the Titan brand in the fourth quarter of 2018. We are pursuing a targeted market strategy that focuses on establishing inroads into select market segments where Probuphine can provide meaningful benefit for the patient allowing for sustained market penetration and sales growth. We plan to

establish a small commercial team of approximately 10 specialists with experience in product marketing and supply chain logistics, medical liaison and training functions, third party payer medical access and field sales. This team will focus initially on the following key market segment:

- High Probuphine-prescribing physicians with long-term recovery oriented treatment programs. There are a substantial number of certified physicians who are currently treating OUD with Probuphine, all of whom are identified in our data base. Our plan in the short term is

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to focus on the top tier of prescribers to facilitate the growth of their businesses through increased utilization of Probuphine. Utilizing some of the top tier providers, in the medium to long term we will establish centers of excellence that will provide sites for referrals from other health care providers. In addition, our medical access specialists will provide resources to help lessen the complexity of the supply chain and reimbursement process. In the longer term, some top tier Probuphine providers will also engage in investigator sponsored research which can generate new and clinically meaningful data, some of which will help us assess the potential for label expansion.

We will also begin laying the groundwork in the following three market segments, with the goal of expanding these activities assuming success with our initial marketing efforts and our ability to raise additional funds:

- Residential treatment facilities. Historically, these facilities have mostly relied on 12-step programs with the goal of complete and sustained abstinence while avoiding any MAT. However, the success of such programs has not withstood scrutiny, as it has been increasingly recognized that a very high percentage of patients with opiate addiction ultimately relapse. Consequently, the use of MAT as part of the management of OUD has been increasing, and is expected to rise substantially in the near term. Our plan is to establish alliances with a few large programs.

- Academic institutions with addiction treatment and training programs. We plan to form alliances with institutions that already have the necessary trained personnel and equipment for doing small procedures, and facilitate the introduction and/or increased use of Probuphine for appropriate patients. This will also serve to introduce Probuphine to the next generation of addiction specialists. In the longer term, we expect that key opinion leaders, or KOLs, at some of these sites will initiate investigator sponsored studies which can generate clinically meaningful data while helping us assess the potential for label expansion.

- Criminal justice system. In recent years there has been increasing recognition that the rate of recidivism among inmates with opiate addiction is very high. In addition, the incidence of overdose and death is high for recently released inmates who have “detoxed” while incarcerated (often through abrupt withdrawal or “cold turkey”). Early data suggests the use of MAT in this population can decrease recidivism and the incidence of overdose deaths. Our plan is to initially establish pilot projects with a few select criminal justice programs, such as the one we recently initiated in the State of Nevada, with the goal of generating meaningful data that potentially supports the use of Probuphine in this setting.

We expect that demonstration of early success in these market segments will serve to increase partnering opportunities, which will then sustain and accelerate future growth of Probuphine.

Risks Related to Our Business

- We may not be successful in transitioning from a research and development company to a commercial enterprise.

- We will require funds in addition to the proceeds of this offering to implement our commercial strategy and complete the Phase IV trials required by the FDA.

- 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 suffer.

- We must comply with extensive government regulations.

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

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

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

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

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

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

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

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

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

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

- We face intense competition.

- 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.

- We may not be able to implement our business plan if we are unable to attract and retain key personnel and consultants.

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.

This prospectus may contain references to our trademark and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company.

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THE OFFERING

Class A Units offered

5,100,000 Class A Units with each Class A Unit consisting of one share of our common stock and a warrant to purchase one share of our common stock at an exercise price equal to $0.25. The Class A Units will not be certificated and the share of common stock and warrant that are part of such unit will be immediately separable and will be issued separately in this offering.

Class B Units offered

8,225 Class B Units are also being offered to those purchasers, if any, whose purchase of Class A Units in this offering 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. Each Class B Unit will consist of one share of our Series A Preferred, with a stated value of $1,000 and convertible into 4,000 shares of our common stock, at a conversion price of $0.25, together with warrants to purchase 4,000 shares of common stock, at an exercise price of $0.25 per share. The shares of Series A Preferred generally do not have any voting rights but are convertible into shares of common stock. The Class B Units will not be certificated and the shares of Series A Preferred and warrants that are part of such unit are immediately separable and will be issued separately in this offering.

Warrants

Each warrant included in the Units will have an exercise price equal to $0.25, will be exercisable upon issuance, and will expire five years from the date of issuance.

Underwriters' option to purchase additional securities

We have granted a 45-day option to the underwriters to purchase 5,700,000 shares of common stock and/or additional warrants to purchase 5,700,000 shares of common stock.

Common stock to be outstanding immediately after this offering

26,303,744 shares. If the underwriters' option to purchase additional securities is exercised in full, the total number of shares of our common stock outstanding immediately following the option exercise will be 27,068,744 shares. Excludes shares of common stock that may be issued upon exercise of the warrants and conversion of the Series A Preferred to be issued in this offering. Excludes shares of common stock that may be issued upon exercise of the warrants and conversion of the Series A Preferred to be issued in this offering and exercise of the representative's warrants.

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Series A Convertible
Preferred Stock

The Series A Preferred will be convertible into shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences, rights and limitations) at any time at the option of the holder, at the conversion price of $0.25. See “Description of Securities — Preferred Stock — Series A Convertible Preferred Stock” for a discussion of the terms of the Series A Preferred.

Use of proceeds

We estimate that the net proceeds in this offering will be approximately $8.5 million, or approximately $9.8 million if the underwriters exercise their option to purchase additional securities in full, at the public offering price of $0.25 per Class A Unit and $1,000 per Class B Unit, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We anticipate that we will use the net proceeds from this offering for our operations and for other general corporate purposes, including, but not limited to, building our infrastructure, including a small sales and marketing team, to commercialize Probuphine, start-up costs for two of the Phase IV trials required by the FDA and general working capital. See “Use of Proceeds” on page 29.

Risk factors

See “Risk Factors” beginning on page 9 and the other information included in this prospectus for a discussion of factors you should carefully consider before investing in our securities.

Nasdaq Capital Market
symbol

Our common stock currently trades on The Nasdaq Capital Market under the symbol “TTNP”

There is no established public trading market for the warrants or Series A Preferred, and we do not expect an active trading market to develop. We do not intend to list the warrants or the Series A Preferred on any securities exchange or other trading market. Without an active trading market, the liquidity of the warrants and the Series A Preferred will be limited.

The number of shares of our common stock that will be outstanding immediately after this offering is based on 21,203,744 shares of common stock outstanding as of September 20, 2018, and excludes as of such date:

- 3,498,650 shares of common stock issuable upon exercise of outstanding options at a weighted average exercise price of $3.39 per share, of which 3,089,899 shares are vested as of such date;

- 1,119,750 shares of common stock reserved for future issuance under the Titan Pharmaceuticals, Inc. 2015 Omnibus Equity Incentive Plan, as amended, or the 2015 Plan;

- 1,708,181 shares of common stock issuable upon exercise of warrants outstanding at a weighted average exercise price of $2.37;

- 3,126,316 shares of common stock issuable upon conversion of $3.0 million principal amount of outstanding indebtedness;

- shares of our common stock issuable upon exercise of the warrants to be issued in this offering; and

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- shares of our common stock issuable upon conversion of the Series A Preferred to be issued in this offering.

The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series A Preferred shares convert their shares to common stock.

To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series A Preferred issued as part of the Class B Units.

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 and excludes shares of our common stock issuable upon exercise of the representative's warrants (4% of the shares of common stock sold in this offering, including shares issuable upon conversion of the Series B Preferred but excluding any securities sold upon exercise of the underwriter's option to purchase additional securities or shares issuable upon exercise of the warrants).

Several members of our board of directors are purchasing an aggregate of $295,000 of Class A Units or Class B Units in this offering at the public offering price per unit. See "Underwriting" for a description of the compensation payable to the underwriters on proceeds received from these investors.

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SUMMARY CONSOLIDATED FINANCIAL DATA

(in thousands, except per share data)

The following table summarizes our selected financial data for the periods and as of the dates indicated. Our selected statements of operations data for the years ended December 31, 2017 and 2016, respectively, and our selected balance sheet data as of December 31, 2017 and 2016, have been derived from our audited financial statements, which are incorporated by reference in this prospectus. Our selected statements of operations data for each of the six month periods ended June 30, 2018 and 2017, and our selected balance sheet data as of June 30, 2018, have been derived from our unaudited financial statements, which are incorporated by reference in this prospectus. The interim unaudited financial statements have been prepared on the same basis as the annual audited financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for a fair presentation of the information for the periods presented. Our financial statements are prepared and presented in accordance with generally accepted accounting principles in the United States. Our historical results are not necessarily indicative of the results to be expected for any future periods. Our selected financial data should be read together with the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and with our financial statements and their related notes, which are incorporated by reference in this prospectus.

	Six Months Ended June 30,		Years Ended December 31,	
	2018	2017	2017	2016
	(Unaudited)			
Statement of Operations Data:				
Total revenue	$ 3,732	$ 117	$ 215	$ 15,065
Operating expenses:				
Cost of goods sold	70	—	—	—
Research and development	3,713	4,627	9,648	6,126
General and administrative	2,995	2,548	5,069	4,596
Other income (expense), net	(428)	602	195	792
Net income (loss) applicable to common stockholders	$ (3,474)	$ (6,456)	$ (14,307)	$ 5,135
Basic net income (loss) per common share	$ (0.16)	$ (0.30)	$ (0.67)	$ 0.25
Diluted net income (loss) per common share	$ (0.16)	$ (0.33)	$ (0.70)	$ 0.20
Shares used in computing:				
Basic net income (loss) per common share	21,204	21,199	21,203	20,744
Diluted net income (loss) per common share	21,204	21,201	21,228	21,459

	As of June 30, 2018 (Unaudited)
Balance Sheet Data:	
Cash and cash equivalents	$ 1,614
Total assets	$ 4,617
Total liabilities	$ 5,930
Total stockholders’ equity (deficit)	$ (1,313)

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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 transitioning from a research and development company to a commercial enterprise.

Since our inception, we have been engaged in product research and development and have never directly commercialized any product. Since we regained the U.S. commercial rights to Probuphine in May 2018, we have been largely dependent on Braeburn's provision of support services, as well as those of advisors and consultants, as we transition to a commercial enterprise. We do not currently employ a sales force or have any internal sales and marketing capabilities. Without hiring or contracting for an experienced and active sales force, we will not be in a position to relaunch Probuphine and sales, if any, will continue to be limited. We will face intense competition for sales and marketing personnel with the necessary experience in addiction, reimbursement, specialty pharmacies and our targeted markets and there can be no assurance that we will be successful in our efforts to transition to a 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 suffer.

Although Braeburn commenced a full commercial launch of Probuphine in the first quarter of 2017, minimal progress was made and for the year ended December 31, 2017 we derived royalty revenues of only $215,000 from sales of Probuphine. The commercial success of Probuphine and our product relaunch 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. Since its initial commercial launch by Braeburn, Probuphine's adoption by physicians has been hindered both by the Risk Evaluation and Mitigation Strategy, or 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 our Probuphine over current and emerging treatment options;
- the willingness of healthcare providers to prescribe, and the target patient population to try novel products;
- the competitiveness of our pricing;
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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

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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 royalty revenue from Probuphine, we will be unable to fund our research and development programs without additional financing, which may not be available on acceptable terms, and our business will be materially harmed.

We 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. Prior to the reversion of the commercialization rights to us, Braeburn had been in negotiations with the FDA with respect to the various trial protocols and had not commenced the required clinical trials. Upon transfer of the NDA back to us, we began communicating with the FDA regarding the Phase IV requirements. There can be no assurance that the FDA will provide us with the time we need to initiate and complete the necessary clinical trials, or that we will have the necessary resources to do so, as the proceeds of this offering will only be sufficient to fund start-up costs for two of the required studies. In such event, we may be subject to possible sanctions, including monetary penalties or suspension of Probuphine commercial activities. Furthermore, unexpected negative findings from a Phase IV trial could negatively impact the product label and/or acceptance by patients, healthcare providers and insurers.

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

There is currently a REMS program in place for Probuphine as required by the FDA. The REMS program was implemented by Braeburn in May 2016 and 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

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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 result in our non-compliance with the REMS program. Non-compliance with the REMS program may bring serious consequences to us, including warning letters from the FDA, fines, criminal charges and 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 warnings and contraindications for risks. 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, or DEA, 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 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

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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 Federal Food, Drug and Cosmetic Act, or the 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 HHS information related to "payments or other transfers of value" provided

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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 ("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 supplier of the finished Probuphine implants; and
- the manufacturer of the Probuphine applicator.

We are in the process of qualifying a new ethylene-vinyl acetate, or EVA, manufacturer. In addition, the vendor that used to sterilize the Probuphine implants indicated that it will no longer sterilize Schedule III controlled substances, including Probuphine. While we are in the process of qualifying another sterilization vendor and will also be transitioning to a new sterilization process, we cannot guarantee that such qualification or transition will be successful. 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.

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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, equipment, contract manufacturing, formulation or packaging services, product distribution services, customer service activities and product returns processing. For example, we contract with DPT Laboratories, Ltd., or DPT, for the manufacture of Probuphine, which in turn depends on delivery of the active ingredient buprenorphine hydrochloride and milled EVA, which we currently source from Teva Pharmaceuticals, Inc. and Southwest Research Institute, respectively. 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.

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, assuming regulatory approval is ultimately obtained, 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 with respect to product launch and commercialization in Canada. We do not have control over the amount and timing of resources that Molteni 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

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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. For instance, we have received a grant from the National Institute of Drug Abuse for developing a Nalmefene implant for treating OUD that requires us to allocate matching funds without which we cannot commence this project. 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.

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

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

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

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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

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

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

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

- obtain and keep patent protection for our products and technologies on an international basis;
- enforce our patents to prevent others from using our inventions;
- maintain and prevent others from using our trade secrets; and
- operate and commercialize products without infringing on the patents or proprietary rights of others.

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

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

- pay substantial damages;
- stop using our technologies and methods;
- stop certain research and development efforts;
- develop non-infringing products or methods; and
- obtain one or more licenses from third parties.

If required, we cannot assure you that we will be able to obtain such licenses on acceptable terms, or at all. If we are sued for infringement, we could encounter substantial delays in development, manufacture and commercialization of

our product candidates. Any litigation, whether to enforce our patent rights or to defend against allegations that we infringe third party rights, will be costly, time consuming, and may distract management from other important tasks. We also rely in our business on trade secrets, know-how and other proprietary information. We seek to protect this information, in part, through the use of confidentiality agreements with employees, consultants, advisors and others. Nonetheless, we cannot assure you that those agreements will provide adequate protection for our trade secrets, know-how or other proprietary information and prevent their unauthorized use or disclosure. To the extent that consultants, key employees or other third parties apply technological information independently developed by them or by others to our proposed products, disputes may arise as to the proprietary rights to such information, which may not be resolved in our favor.

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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, one of which was recently launched by Indivior PLC. 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.

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.

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

Reimbursement for implantable drug products that require administration by a healthcare provider generally requires a drug code, and separate reimbursement codes are required for the insertion and removal procedures. The timely availability of a drug code or procedure code that covers our product or describes the procedures performed using our products, or a change to an existing code that describes such procedures is critical for successful commercialization and the lack of such codes may adversely affect

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reimbursement for our products and these procedures, including lower reimbursement rates, denials and delays in reimbursement if pre-authorization is required. Even if coverage is approved, the resulting reimbursement payment rates might not be adequate or may require co-payments that patients find unacceptably high. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. While Probuphine was approved by the FDA in late May 2016, the procedure codes (G codes) for insertion only, removal only, and insertion plus removal were approved only in late 2017 and went into effect in January 2018.

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

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

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

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

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

Additionally, individual states have become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access, and marketing cost disclosure

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and transparency measures, and designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects.

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

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

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

We may not be able to implement our business plan if we are unable to attract and retain key personnel and consultants.

As a company with a limited number of personnel, we are highly dependent on the services of our executive management and scientific staff, in particular Sunil Bhonsle, our President and Chief Executive Officer, Marc Rubin, our Executive Chairman and Katherine DeVarney our Executive Vice President and Chief Scientific Officer. The loss of one or more of such individuals could substantially impair ongoing research and development programs and could hinder our ability to obtain corporate partners.

Our ability to commercialize Probuphine effectively depends in large part upon our ability to attract and retain highly qualified sales, marketing and support personnel. 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 breadth 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 formulating our clinical and commercial strategies. 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 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

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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 six months ended June 30, 2018 and 2017, we had net losses of approximately $3.47 million and $6.46 million, respectively, and had net cash used in operating activities of approximately $2.86 million and $5.63 million, respectively. For the year ended December 31, 2017, we had a net losses of approximately $14.31 million and had net cash used in operating activities of approximately $13.04 million. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

To date, we have devoted most of our financial resources to our corporate overhead and research and development, including our drug discovery research, preclinical development activities and clinical trials. 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 add infrastructure and personnel to support our transition to a commercial enterprise. 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 at June 30, 2018, together with the approximately $1.7 million received from Molteni in August and September 2018 and the proceeds of this offering, will be sufficient to fund our Probuphine commercial efforts and Phase IV clinical program through the second quarter of 2019. We will be required to demonstrate sufficient progress in commercializing Probuphine in this short period of time in order to be able to raise additional funds to expand commercial activities for Probuphine. 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 will also need additional funds to complete the required post-approval clinical trials and there can be no assurance 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. The inclusion of a going concern modification in our independent registered public accounting firm's report for the year ended December 31, 2017, or in any future report, may materially and adversely affect our stock price or our ability to raise new capital.

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 depending upon numerous factors, including the results of our initial 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, continue the research and development and initiate and conduct clinical trials of, and seek marketing approval for, our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we will need to

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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, 2017, we had federal net operating loss and tax credit carryforwards of $261.0 million and $8.9 million, respectively, and state net operating loss and tax credit carryforwards of $107.1 million and $8.8 million, respectively, available to offset future taxable income, if any. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change and we cannot assure you that our net operating loss and tax carryforwards will continue to be available.

Our loan agreements contain restrictions on our operations and could result in certain adverse results.

Our Amended and Restated Venture Capital and Loan Agreement, or Loan Agreement, with Molteni and Horizon Technology Finance Corporation, or Horizon, 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 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 non-permitted lien or other encumbrance on our assets. Our September 2018 unsecured convertible loan agreement with Molteni contains comparable negative covenants. Subject to certain forbearance provisions in effect through December 31, 2019, upon the occurrence of an event of default under the 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 upon in the event of a default that is not waived or cured.

Risks Related to this Offering and our Common Stock

Our share price may be volatile, which could subject us to securities class action litigation and prevent you from being able to sell your shares at or above your purchase price.

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

- results of our clinical trials;
- results of clinical trials of our competitors' products;
- 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 changes in our growth rate relative to our competitors;

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- actual or anticipated fluctuations in our competitors' operating results or changes in their 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 management or scientific 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.

Furthermore, 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. In addition, such fluctuations could subject us to securities class action litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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.

There is no active, public market for the warrants or Series A Preferred being offered in this offering.

There is no established public trading market for the warrants or the Series A Preferred being offered in this offering. We do not intend to apply to list the warrants or the Series A Preferred on a securities exchange. Without an active trading market, the liquidity of the warrants and the Series A Preferred will be limited.

Holders of Series A Preferred will have limited voting rights.

Except with respect to certain material changes in the terms of the Series A Preferred and certain other matters and except as may be required by Delaware law, holders of Series A Preferred will have no voting rights. You will have no right to vote for any members of our board of directors.

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Holders of the warrants will not have rights of common stockholders until such warrants are exercised.

The warrants being offered do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay the exercise price prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value.

Future sales of our common stock, or the perception that future sales may occur, may cause the market price of our common stock to decline, even if our business is doing well.

Sales by our stockholders of a substantial number of shares of our common stock in the public market could occur in the future. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock.

Exercise of options or warrants or conversion of convertible securities may have a dilutive effect on your percentage ownership and may result in a dilution of your voting power and an increase in the number of shares of common stock eligible for future resale in the public market, which may negatively impact the trading price of our shares of common stock.

The exercise or conversion of some or all of our outstanding options, warrants, or convertible securities could result in significant dilution in the percentage ownership interest of investors in this offering and in the percentage ownership interest of our existing common stockholders and in a significant dilution of voting rights and earnings per share.

As of September 20, 2018, we had outstanding warrants to purchase up to 1,708,181 shares of our common stock at a weighted exercise price of $2.37 per share and outstanding and options outstanding under our stock incentive plans to purchase up to 3,498,650 shares of our common stock at a weighted average exercise price of $3.39 per share. At such date there was also an aggregate of $3.0 million principal amount of outstanding indebtedness that is convertible into 3,126,316 shares of our common stock. To the extent options and/or warrants and/or conversion rights are exercised (including with respect to the warrants and any Series A Preferred issued in this offering), additional shares of common stock will be issued, and such issuance will dilute stockholders.

Investors in this offering will experience immediate and substantial dilution in net tangible book value.

The public offering price per share of common stock in this offering will be substantially higher than the net tangible book value per share of our outstanding shares of common stock. Accordingly, investors in this offering will pay a price per share that substantially exceeds the net tangible book value per share of our common stock. Investors in this offering will incur immediate dilution of $0.13 per share. See “Dilution” for a more complete description of how the value of your investment will be diluted upon the completion of this offering.

We will seek to raise additional funds, and may finance acquisitions or develop strategic relationships by issuing securities that would dilute your ownership. Depending on the terms available to us, if these activities result in significant dilution, it may negatively impact the trading price of our shares of common stock.

We have financed our operations, and we expect to continue to finance our operations, acquisitions, if any, and the development of strategic relationships by issuing equity and/or convertible securities, which could significantly reduce the percentage ownership of our existing stockholders. Following this offering, raising sufficient capital will likely require an amendment to our certificate of incorporation to increase our authorized capital, an action that will require the affirmative vote of holders of a majority of our then outstanding common stock. Further, any additional financing that we secure, including any debt financing, may require the granting of rights, preferences or privileges senior to, or pari passu with, those of our common stock. Any issuances by us of equity securities may be at or below the prevailing market price of our common stock and in any event may have a dilutive impact on your ownership interest, which could cause the market price of our common stock to decline. We may also raise additional funds through the incurrence of debt or the issuance or sale of other securities or instruments senior to our shares of common

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stock. The holders of any securities or instruments we may issue may have rights superior to the rights of our common stockholders. If we experience dilution from the issuance of additional securities and we grant superior rights to new securities over common stockholders, it may negatively impact the trading price of our shares of common stock and you may lose all or part of your investment.

Our management will have broad discretion over the use of proceeds from this offering and may not use the proceeds effectively.

Our management will have broad discretion over the use of proceeds from this offering. The net proceeds from this offering will be used for our operations and for other general corporate purposes, including, but not limited to, building our infrastructure, including a small sales and marketing team, to commercialize Probuphine, conduct of the Phase IV trials required by the FDA, our internal research and development programs and general working capital. Our management will have considerable discretion in the application of the net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. The net proceeds may be used for corporate purposes that do not improve our operating results or enhance the value of our common stock.

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

On April 9, 2018, we received a notice from 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). Following our submission of a plan of compliance, we were granted an extension of 180 calendar days, or until October 8, 2018, to regain compliance. At June 30, 2018, we had a stockholders' deficit of approximately $1.3 million. The proceeds of this offering, together with the proceeds from Molteni in August 2018, pursuant to the Purchase Agreement will enable us to achieve the minimum stockholders' equity requirement.

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.

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 amended and restated certificate of incorporation and our amended and restated 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;

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- 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.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference in this prospectus contain 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 Exchange Act. All statements other than statements of historical facts contained or incorporated by reference in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “sh
“will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- our ability to implement our business plan;
- our ability to raise additional capital to meet our liquidity needs;
- our ability to generate sufficient proceeds from this offering;
- our ability to generate product revenues;
- our ability to achieve profitability;
- our ability to satisfy U.S. (including the FDA), and international regulatory requirements;
- our ability to obtain market acceptance of our technology and products;
- our ability to compete in the market;
- our ability to advance our clinical trials;
- our ability to fund, design and implement clinical trials;
- our ability to demonstrate that our product candidates are safe for human use and effective for indicated uses;
- our ability to gain acceptance of physicians and patients for use of our products;
-

our dependency on third-party researchers and manufacturers and licensors;

- our ability to effectively implement cost-cutting measures;

- our ability to establish and maintain strategic partnerships, including for the distribution of products;

- our ability to attract and retain sufficient, qualified personnel;

- our ability to obtain or maintain patents or other appropriate protection for the intellectual property;

- our dependency on the intellectual property licensed to us or possessed by third parties;

- our ability to adequately support future growth;

- our ability to maintain our Nasdaq listing; and

- potential product liability or intellectual property infringement claims.

These forward-looking statements are only predictions and we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, so you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have based these forward-looking statements largely on our current expectations and projections about future events and

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trends that we believe may affect our business, financial condition and operating results. We have included important factors in the cautionary statements included in this prospectus, and in the documents incorporated by reference, particularly in the ‘Risk Factors’ section, that could cause actual future results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

The forward-looking statements included in this prospectus, and documents incorporated by reference in this prospectus, represent our views as of the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this prospectus.

This prospectus contains estimates made, and other statistical data published, by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this prospectus from our own research as well as from industry and general publications, surveys and studies conducted by third parties. This data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

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USE OF PROCEEDS

We estimate that the net proceeds from sale of Units offered by us will be approximately $8.5 million, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us, at the public offering price of $0.25 per Class A Unit and $1,000 per Class B Unit. If the underwriters' option to purchase additional securities is exercised in full, we estimate that our net proceeds will be approximately $9.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, at the public offering price of $0.25 per Class A Unit and $1,000 per Class B Unit.

We anticipate that we will use the net proceeds from this offering for our operations and for other general corporate purposes, including, but not limited to, building our infrastructure, including a small sales and marketing team, to commercialize Probuphine and start-up costs for two of the Phase IV trials required by the FDA.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. 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.

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CAPITALIZATION

The following table sets forth our cash and cash equivalents and capitalization, as of June 30, 2018:

- on an actual basis; and
- on an as adjusted basis after giving effect to the sale of 5,100,000 Class A Units, at the public offering price of $0.25 per Class A Unit and 8,225 Class B Units, at the public offering price of $1,000 per Class B Unit, after deducting underwriting discounts and commissions and other estimated offering expenses payable by us.

You should consider this table in conjunction with “Use of Proceeds,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included elsewhere in this prospectus and our financial statements and unaudited as adjusted financial information and related notes thereto, which are incorporated by reference in this prospectus.

	As of June 30, 2018 (unaudited)	
	Actual	As Adjusted
Cash and cash equivalents	$ 1,613,564	$ 10,118,889
Total liabilities	$ 5,930,277	$ 5,930,277
Total stockholders’ equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized, 0 shares issued and outstanding, actual; 8,500 shares issued and outstanding, as adjusted	—	8
Common Stock, $0.001 par value, 125,000,000 shares authorized, 21,203,744 shares issued and outstanding, actual; 23,835,323 shares issued and outstanding, as adjusted	21,204	26,304
Additional paid in capital	325,411,154	333,911,371
Accumulated deficit	(326,745,543)	(326,745,543)
Total stockholders’ equity	(1,313,185)	7,192,140

The number of shares of our common stock that will be outstanding immediately after this offering is based on 21,203,744 shares of common stock outstanding as of June 30, 2018, and excludes as of such date:

- 3,647,863 shares of common stock issuable upon exercise of outstanding options, at a weighted average exercise price of $3.42 per share, of which 2,795,862 shares are vested as of such date;
- 46,000 shares of common stock reserved for future issuance under the 2015 Plan;
- 1,708,181 shares of common stock issuable upon exercise of warrants at a weighted average exercise price of $2.37;
- 2,000,000 shares of common stock issuable upon conversion of $2.4 million principal amount of outstanding indebtedness;
- shares of our common stock issuable upon exercise of the warrants to be issued in this offering; and

- shares of our common stock issuable upon conversion of the Series A Preferred to be issued in this offering.

The number of shares of our common stock outstanding after this offering will fluctuate depending on how many Class B Units are sold in this offering and whether and to what extent holders of Series A Preferred shares convert their shares to common stock.

To the extent we sell any Class B Units in this offering, the same aggregate number of common stock equivalents resulting from this offering would be convertible under the Series A Preferred issued as part of the Class B Units.

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The foregoing information assumes no exercise by the underwriters of their option to purchase additional securities and excludes shares of our common stock issuable upon exercise of the representative's warrants (4% of the shares of common stock sold in this offering, including shares issuable upon conversion of the Series B Preferred but excluding any securities sold upon exercise of the underwriter's option to purchase additional securities or shares issuable upon exercise of the warrants).

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DILUTION

If you purchase shares of our securities in this offering, you will experience dilution to the extent of the difference between the public offering price per share in this offering and our as adjusted net tangible book value per share immediately after this offering. Net tangible book value per share is equal to the amount of our total tangible assets, less total liabilities, divided by the number of outstanding shares of our common stock. As of June 30, 2018, our net tangible book value was approximately $(1,313,185), or approximately $(0.06) per share.

After giving effect to the sale by us of 38,000,000 shares of our common stock in this offering at the public offering price of $0.25 per share, and the accompanying common warrants at a purchase price of $0.01 per common warrant and assuming no sale of any Series A Preferred shares in this offering and excluding the proceeds, if any, from the exercise of the common warrants and after deducting the estimated underwriting discount and estimated offering expenses payable by us, our pro forma net tangible book value as of June 30, 2018 would have been approximately $7.2 million, or approximately $0.12 per share. This represents an immediate increase in pro forma net tangible book value of $0.18 per share to existing stockholders and an immediate dilution of $0.13 per share to new investors purchasing securities in this offering. The following table illustrates this per share dilution:

Public offering price per share of common stock		$ 0.25
Historical net tangible book value per share as of June 30, 2018	$ (0.06)	
Increase in pro forma net tangible book value per share after this offering	$ 0.18	
Pro forma net tangible book value per share after giving effect to this offering		0.12
Dilution per share to new investors		$ (0.13)

The information above and below assumes that no Series A Preferred shares are issued in this offering. The information above assumes that the underwriters do not exercise their over-allotment option. If the underwriters exercise their over-allotment option in full, the pro forma net tangible book value will increase to $0.13 per share, representing an immediate increase to existing stockholders of $0.19 per share and an immediate dilution of $0.12 per share to new investors.

The foregoing discussion and table do not take into account further dilution to new investors that could occur upon the exercise of outstanding options or warrants and the common warrants offered hereby. In addition, 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. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

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MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock has been listed on The Nasdaq Capital Market since October 2015. The following table sets forth, for the periods indicated, our high and low sales prices on The Nasdaq Capital Market.

	High	Low
2018		
First Quarter	$ 1.45	$ 0.94
Second Quarter	$ 1.15	$ 0.60
Third Quarter (through September 20, 2018)	$ 1.10	$ 0.50
2017		
First Quarter	$ 4.80	$ 3.15
Second Quarter	$ 3.40	$ 1.80
Third Quarter	$ 2.15	$ 1.20
Fourth Quarter	$ 2.85	$ 1.13
2016		
First Quarter	$ 4.91	$ 2.98
Second Quarter	$ 7.41	$ 4.76
Third Quarter	$ 6.17	$ 4.80
Fourth Quarter	$ 6.10	$ 3.80

Holders

As of September 20, 2018, we had 119 registered holders of record of our common stock. A substantially greater number of holders of our common stock are “street name” or beneficial holders, whose shares of record are held by banks, brokers, other financial institutions, and registered clearing agencies.

Dividend Policy

We do not anticipate paying dividends on our common stock. We currently intend to retain all of our future earnings, as applicable, to finance the growth and development of our business. Our Loan Agreement prohibits the payment of dividends while the debt remains outstanding. Any future determination as to the payment of cash dividends on our common stock, if otherwise permissible at the time, will be at our board of directors’ discretion and will depend on our financial condition, operating results, capital requirements and other factors that our board of directors considers to be relevant.

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BUSINESS

The following information relates primarily to our Probuphine business, activities and prospects. For additional information regarding our business, we refer you to the documents that are incorporated by reference herein. See "Incorporation Of Certain Documents By Reference."

Overview

We are a pharmaceutical company developing proprietary 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 are currently transitioning to a commercial stage enterprise having recently re-acquired Probuphine, a product approved in the U.S. for management of opiate dependence. ProNeura is a continuous drug delivery system consisting of a small, solid rod made from a mixture of ethylene-vinyl acetate, or EVA, and a drug substance. The resulting product is a solid matrix that is placed subdermally, normally in the inside part of the upper arm in a simple physician office based procedure, and is removed in a similar manner at the end of the treatment period. The drug substance is released continuously through the process of dissolution resulting in a steady rate of release generally similar to intravenous administration avoiding the fluctuating peak and trough levels of oral dosing that pose problems in many disease settings.

Probuphine

Overview

Probuphine, our first marketed product based on our ProNeura drug delivery technology, is a six-month buprenorphine implant for the maintenance treatment of opioid addiction in patients who have achieved and sustained prolonged clinical stability on a dose of up to 8 mg per day of oral buprenorphine, which represents approximately twenty-five percent of oral buprenorphine prescriptions. Treatment with Probuphine requires a healthcare provider to be trained and certified under the Probuphine REMS program to insert a set of four implants, each smaller than a one-inch matchstick, sub-dermally in the patient's upper arm under local anesthetic during a short in-office procedure lasting about 15 minutes. After insertion, Probuphine delivers buprenorphine continuously for six months. Thereafter, the implants are removed and can be replaced with a new set of implants in the opposite arm.

The development and commercialization rights to Probuphine for the U.S. and Canada were licensed to Braeburn in December 2012 and following FDA approval in May 2016, Braeburn commenced a full commercial launch during the first quarter of 2017. Progress was slow and we received royalty revenues of only $215,000 for the year ended December 31, 2017. In early 2018, Braeburn substantially reduced its field sales force and medical liaison personnel following its receipt of a complete response letter from the FDA for its weekly and monthly depot injection products. Anticipating a negative impact on Probuphine sales in the U.S., we began discussing with Braeburn terms for the return of the Probuphine U.S. commercialization rights to Titan and on May 25, 2018, we entered into an agreement under which we received a $1 million payment from Braeburn and Braeburn's undertaking to provided transition services through 2018.

Based on feedback from key opinion leaders, we believe that access to care for patients with Probuphine has been negatively impacted by issues related to the complexity, timing and amount of reimbursement to patients and their doctors from insurance providers, as well as the requirements of the REMS program. Although the opioid addiction epidemic continues to be a major concern for our country, the hurdles to penetrating the market and growing sales of Probuphine have been considerable. We believe that a more focused commercialization strategy is necessary for success. These include re-segmenting target customer markets and focusing on high Probuphine-prescribing physicians with long-term recovery oriented treatment programs, residential treatment facilities that utilize MAT, academic institutions with addiction residency and fellowships programs, and the criminal justice system. We also plan to expand the specialty pharmacy network in order to better utilize the third party payor system. Additionally, we believe Probuphine can benefit from the trend of opioid addiction treatment's move towards extended release formulations, such as one month depot injections, the first of which was approved by the FDA at the end of 2017. These products will enable clinicians and patients to become accustomed to longer duration procedure-oriented treatment, which may encourage the potential use of Probuphine during the maintenance treatment stage.

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In March 2017, we received confirmation from the EMA that Probuphine is eligible for a centralized review and approval process. While the preparation of the MAA was in progress, we met with the review teams of the two EMA member countries appointed as rapporteur (Ireland) and co-rapporteur (United Kingdom) to familiarize them with the development of Probuphine and the safety and efficacy data set, as well as receive their advice on the MAA preparation and presentation. The MAA was submitted to the EMA on November 6, 2017. We were also granted Small Manufacturing Entity, or SME, status in Europe, which provides for some monetary benefits during the application process and commercialization. On March 21, 2018, we entered into the Purchase Agreement pursuant to which Molteni acquired the European intellectual property related to Probuphine, including the MAA, and will have the exclusive right to commercialize the Titan supplied Probuphine product in Europe, as well as certain countries of the Commonwealth of Independent States, the Middle East and North Africa. We have continued to assist Molteni in the MAA review process and during the second quarter we had meetings with the rapporteur and co-rapporteur regulatory review teams to present our strategy to address specific questions asked by these regulatory agencies as part of the review process. Together with Molteni, we are now preparing the full response to all questions that were asked, and we expect to submit these to the EMA no later than mid-September 2018. Based on the overall review process timeline the final recommendation and potential approval would occur during the first half of 2019.

Agreements

Braeburn

In December 2012, we entered into a license agreement, or the Braeburn Agreement with Braeburn pursuant to which we granted Braeburn an exclusive right and license to commercialize Probuphine in the United States of America and its territories, including Puerto Rico, and Canada. Under the Braeburn Agreement, as subsequently amended, Braeburn made a non-refundable up-front license fee payment of $15.75 million in 2012 and a milestone payment of $15 million upon FDA approval of the NDA in May 2016. The agreement also entitled us to royalties on net sales of Probuphine ranging in percentage from the mid-teens to the low twenties. In February 2016, Braeburn entered into a Distribution and Sublicense Agreement, or the Knight Agreement, with Knight Therapeutics Inc., or Knight, in which it appointed Knight as the exclusive distributor of Probuphine in Canada and granted Knight an exclusive license to commercialize Probuphine in Canada.

On May 25, 2018, we entered into a Termination and Transition Services Agreement, or the Transition Agreement, with Braeburn pursuant to which we regained all rights to the commercialization and clinical development of Probuphine granted under the Braeburn Agreement and Braeburn agreed to provide assistance to Titan through December 28, 2018 to help ensure that patients and their doctors continue to have support and access to this treatment. As part of the Transition Agreement, we assumed a significant number of Braeburn’s commercial contracts relating to the commercialization of Probuphine, including the Knight Agreement.

Knight

Under the Knight Agreement, as amended in August 2018, we granted Knight an exclusive license to commercialize Probuphine in Canada as well as a right of first negotiation in the event we intend to license our right to commercialize any of our other products in Canada. During the term of the Knight Agreement, we may not commercialize any product containing buprenorphine that is intended for a treatment duration of six months or more in Canada.

Pursuant to the Knight Agreement, Knight must use commercially reasonable efforts to commercialize Probuphine in Canada. We are entitled to receive royalty payments from Knight on net sales of Probuphine in Canada ranging in percentage from the low-teens to the mid-thirties. In addition, we will be the exclusive supplier of Probuphine to Knight subject to a supply agreement between us and Knight.

Unless earlier terminated, the initial term of the Knight Agreement will expire on the 15th anniversary of the date of the first commercial sale of Probuphine for opioid addiction in Canada, which is expected to occur during the fourth quarter of 2018. If Probuphine is approved for another indication in Canada after the fifth anniversary of the first commercial sale of Probuphine for opioid addiction in Canada, we must

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negotiate in good faith whether to extend the initial term. After the initial term, the Knight Agreement will automatically renew for two-year periods until either party provides the other party with written notice of its intent not to renew at least 180 days prior to the expiration of the initial term or then-current term. We or Knight may terminate the Knight Agreement in the event that (i) either party determines in good faith that it is not advisable for Knight to continue to commercialize Probuphine in Canada as a result of a bona fide safety issue, (ii) the other party has filed for bankruptcy, reorganization, liquidation or receivership proceedings, or (iii) the other party materially breached the agreement and has not cured such breach within a specified time period. In addition, subject to certain exceptions and requirements, we may terminate the Knight Agreement (i) if Knight discontinues the commercial sale of Probuphine for a period of at least three months and fails to resume sales within the specified cure period, or (ii) in the event that Knight commences any legal proceedings seeking to challenge the validity or ownership of any of our patents related to Probuphine.

In the event of termination, among other things, Knight shall (i) cease commercialization of Probuphine in Canada, (ii) transfer title to all current and pending regulatory submissions and regulatory approvals for Probuphine to us and (iii) pay any royalty payments generated by Knight's sales of Probuphine in Canada due to us.

Molteni

On March 21, 2018, we entered into an Asset Purchase, Supply and Support Agreement with Molteni that was subsequently amended on August 3, 2018, or the Purchase Agreement, pursuant to which Molteni acquired the European intellectual property related to Probuphine, including the MAA under review by the EMA, and will have the exclusive right to commercialize the Titan supplied Probuphine product in Europe, as well as certain countries of the Commonwealth of Independent States, the Middle East and North Africa, or the Molteni Territory. We received an initial payment of €2.0 million ($2,448,000) for the purchased assets and an additional payment of €950,000 ($1,107,000) upon execution of the amendment. We will receive the following additional potential payments totaling up to €2.5 million (approximately $2,850,000) upon the achievement of certain regulatory and product label milestones, including: an aggregate of €1.0 million of milestone payments upon approval of the product reimbursement price in certain key countries, provided that the payments, which are subject to a 50% reduction if the EMA marketing authorization is not received on or prior to September 30, 2019, shall not be payable in the event such authorization is not received on or prior to March 31, 2020. Additionally, Titan is entitled to receive earn-out payments for up to 15 years on net sales of Probuphine in the Molteni Territory ranging in percentage from the low-teens to the mid-twenties.

The Purchase Agreement provides that Titan will supply Molteni with semi-finished product (i.e., the implant and the applicator) on an exclusive basis at a fixed price through December 31, 2019, with subsequent price increases not to exceed annual cost increases to Titan under its current manufacturing agreement and for the purchase of the active pharmaceutical ingredient.

Molteni will be prohibited from marketing a Competitor Product (as defined in the Purchase Agreement) in the Territory for the five year period following approval of the MAA. Thereafter, Molteni will be required to pay Titan a low single digit royalty on net sales by Molteni of any Competitor Product.

On March 21, 2018, we entered into the Loan Agreement, which amended and restated our prior loan agreement with Horizon. Under the Loan Agreement, Horizon assigned $2,400,000 of the $4,000,000 outstanding principal balance of the loan to Molteni and Molteni was appointed collateral agent and assumed majority and administrative control of the debt. Molteni has the right to convert its portion of the debt into shares of our common stock at a conversion price of $1.20 per share and is required to effect this conversion of debt to equity if we complete an equity financing resulting in gross proceeds of at least $10,000,000 at a price per share of common stock in excess of $1.20 and repay the $1,600,000 principal balance of Horizon's loan amount.

In consideration of Molteni's entry into the Purchase Agreement and the Loan Agreement, on March 21, 2018, we entered into an agreement with Molteni. or the Rights Agreement, pursuant to which, as amended, we agreed to (i) issue Molteni seven-year warrants to purchase 540,000 shares of our common stock at an exercise price of $1.20 per share, (ii) provide Molteni customary demand and piggy-back

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registration rights with respect to the shares of common stock issuable upon conversion of its loan and exercise of its warrants, (iii) appoint one member of Titan's board of directors if Mr. Seghi Recli is not then serving on the board and (iv) provide board observer rights to Molteni if it has not designated a board nominee as well as certain information rights. The board designation, observer and information rights will terminate at such time as Molteni ceases to beneficially own at least one percent of our outstanding capital stock (inclusive of the shares issuable upon conversion of its note and exercise of its warrants).

In connection with the August 2018 amendment to the Purchase Agreement, Molteni made a convertible loan to us of €550,000 (approximately $642,000) upon submission of the response to the 120-day letter from EMA on September 14, 2018 in accordance with the amendment. The convertible loan will convert automatically into shares of our common stock upon the issuance by the EMA of marketing approval for Probuphine at a conversion price per share equal to the lower of (i) $0.57 (the closing price on the loan funding date) and (ii) the closing price on the conversion date. In the event the EMA has not granted marketing approval by December 31, 2019, the loan will become due and payable, together with accrued interest at the rate of 9.5% plus the amount by which the one-month LIBOR exceeds 1.1%.

Sales and Marketing; Strategy for Probuphine Relaunch

Prior to Titan's reacquisition of Probuphine commercialization rights in May 2018, Braeburn had sole responsibility for sales and marketing of Probuphine within the United States and, through Knight, in Canada. Since reacquiring our rights, we have relied on Braeburn and a team of marketing, regulatory and addiction consultants to assist us as we transition to a commercial entity. We intend to allocate proceeds of this offering to establish a small commercial team of approximately 10 specialists with experience in product marketing and supply chain logistics, medical liaison and training functions, third party payer medical access and field sales.

We believe that patient access to Probuphine has been negatively impacted by issues related to the complexity, timing and amount of reimbursement to patients and their doctors from insurance providers, as well as the requirements of the REMS program. See "REMS Program" below. We also believe that the broad marketing strategy that was initially undertaken reflected an incomplete understanding of the market and did not provide the requisite systems to support the reimbursement process and patient and physician education.

While our overall market strategy for the relaunch of Probuphine targets four market segments, the proceeds from this offering we will enable us to focus initially on physicians who are already prescribing Probuphine, while in the longer term, assuming we can obtain the requisite funding, our plan is to expand our efforts to address three additional market segments.

High Probuphine-prescribing physicians with long-term recovery oriented treatment programs

While there are currently approximately 52,000 buprenorphine certified healthcare providers in the U.S., approximately 90% of prescriptions for treating the 600,000 – 700,000 patients treated with oral buprenorphine are written by approximately 6,000 providers. Moreover, while over 2,500 healthcare providers are trained and certified to administer Probuphine, to date less than 200 have prescribed the treatment.

Our plan is to initially focus on the top tier of prescribers to facilitate the growth of their businesses through increased utilization of Probuphine. Utilizing some of the successful Probuphine practices, in the medium to longer term, we will establish centers of excellence that will provide sites for referrals from other health care providers. In addition, our medical access specialists will provide resources to help lessen the complexity of the supply chain and reimbursement process. In the longer term, some top tier Probuphine providers will also engage in investigator sponsored research which can generate new and clinically meaningful data, some of which will help us assess the potential for label expansion. We will also seek to partner with buprenorphine advocacy groups that can facilitate patient-healthcare provider location matching and broaden patient outreach.

Residential Treatment Facilities

There are currently numerous residential addiction treatment facilities in the U.S. reflecting a large potential patient population who can benefit from Probuphine. These facilities have mostly relied on 12 step

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programs with the goal of complete and sustained abstinence while avoiding any MAT. However, the success of such programs has not withstood scrutiny, as it has been increasingly recognized that a very high percentage patients with opiate addiction ultimately relapse. Consequently, the use of MAT as part of the management of OUD has been increasing, and is expected to rise substantially in the near term. Our plan is to establish alliances with a few large programs.

Academic institutions with addiction treatment and training programs

There are an increasing number of academic addiction medicine training programs that treat OUD patients. We plan to form alliances with institutions that already have the necessary trained personnel and equipment for doing small procedures, and facilitate the introduction and/or increased use of Probuphine for appropriate patients. This will also serve to introduce Probuphine to the next generation of addiction specialists. In the longer term, we expect that KOLs at some of these sites will initiate investigator sponsored studies which can generate clinically meaningful data while helping us assess the potential for label expansion.

Criminal Justice System

It is estimated that of the 2.3 million people currently confined in U.S. correctional facilities, approximately 25% suffer from OUD. Currently, less than 1% of U.S. prisons and jails allow access to medication for OUD due largely to the risk of misuse and diversion of sublingual formulations (pills, film), However, new research published by JAMA Psychiatry has demonstrated benefits of buprenorphine during incarceration and upon release. In Rhode Island, a recent study found that opioid overdose deaths dropped by nearly 2/3 when MAT was provided to all state inmates. A few criminal justice programs have begun to utilize medications in order to address jail overcrowding and recidivism related to OUD.

Our goal is to initially establish pilot projects with a few select criminal justice programs, with the goal of generating meaningful data that potentially supports the use of Probphine in this setting. The first pilot program will be conducted within the Nevada criminal justice system.

REMS Program

As a condition to the FDA’s approval of Probuphine, we were required to maintain the Probuphine REMS program, to mitigate the risk of complications of migration, protrusion, expulsion and nerve damage potentially associated with the improper insertion and removal of Probuphine, and the risks of accidental overdose, misuse and abuse. The REMS requires training for healthcare providers who prescribe and insert Probuphine implants and patient counseling, and Probuphine distribution is restricted to those healthcare providers who have completed training and received certification under the Probuphine REMS. Accordingly, our sales and marketing team will include trained clinical educators who will be responsible for training, certification and on-going in-market technical support to assist doctors in developing expertise with the Probuphine insertion and removal procedures. The field force will also need to work closely with the reimbursement support personnel to help ensure that all information required to place Probuphine orders and to complete benefits investigations is provided on a timely basis.

Manufacturing

The manufacturing of Probuphine has primarily been conducted at DPT Laboratories, Inc., or DPT. We have entered into a commercial manufacturing agreement with DPT that governs the terms of the production and supply of Probuphine. Pursuant to the Purchase Agreement, we are responsible for the manufacture and supply of Probuphine as needed for the Molteni Territory.

To date, we have obtained the supply of bupenorphine from Teva Pharmaceuticals, Inc. under a commercial supply agreement similar to the one with DPT.

Intellectual Property

In June 2010, the United States Patent and Trademark Office, or USPTO, issued a patent covering methods of using Probuphine for the treatment of opiate addiction. Titan is the owner of this patent which claims a method for treating opiate addiction with a subcutaneously implanted device comprising

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buprenorphine and EVA, a biocompatible copolymer that releases buprenorphine continuously for extended periods of time. This patent will expire in June 2024. A U.S. continuation application is currently pending which includes claims related to Probuphine for the treatment of pain. Related patents covering use of Probuphine with the continuous delivery technology for the treatment of opiate addiction have also been issued in Australia, Canada, Europe, India, Japan, Mexico and New Zealand. A further Probuphine application is pending in Hong Kong. On February 28, 2018, the European Patent Office issued us a patent covering composition for use claims for treating opioid dependence with a subdermal implant containing buprenorphine through June 2023. On March 21, 2018 we executed the Purchase Agreement with Molteni whereby the European intellectual property covering Probuphine, including the European patent, was acquired by Molteni.

Competition

The pharmaceutical and biotechnology industries are characterized by rapidly evolving technology and intense competition. Many companies of all sizes, including major pharmaceutical companies and specialized biotechnology companies, are engaged in the development and commercialization of therapeutic agents designed for the treatment of the same diseases and disorders that we target. Many of our competitors have substantially greater financial and other resources, larger research and development staff and more experience in the regulatory approval process. Moreover, potential competitors have or may have patents or other rights that conflict with patents covering our technologies. With respect to Probuphine, there are no six-month implant formulations of buprenorphine on the market or in development, and the primary competition it faces comes from Indivior, PLC (formerly the pharmaceutical business of Reckitt Benckiser Group, PLC), which markets globally a sublingual buprenorphine product (tablet and film formulations trade name Subutex and Suboxone) for the treatment of opioid dependence that currently holds the dominant market share of global sales, and recently received FDA approval for a one month depot injection (tradename Sublocade) that became commercially available in the first quarter of 2018. Probuphine also faces competition from two additional proprietary daily dose formulations that have been approved by the FDA; the first is a sublingual tablet called Zubsolv marketed by Orexo and the second is a buccal patch called Bunavail marketed by Bio Delivery Sciences International. Also, during 2013 and 2014, several generic sublingual tablet formulations of buprenorphine similar to Suboxone and Subutex were approved by the FDA that are expected to compete in the opioid addiction treatment market. Other forms of buprenorphine are also in development by other companies, including intramuscular and intradermal one week and one month depot injections which, if approved, will also compete with our product. Braeburn has licensed rights to certain of such potential products and Titan is entitled to a low single digit royalty on net sales of competing products, if commercialized. However, Braeburn received a complete response letter, or CRL, to the depot formulations of buprenorphine (Camurus 2038) and the approval is likely delayed by several months. Alkermes, Inc. also markets Vivitrol®, a one-month depot injection of naltrexone as a maintenance treatment for opioid dependent patients who have successfully gone through a detoxification process and achieved abstinence.

Regulatory Matters

FDA

As a condition of the marketing approval for Probuphine, the FDA is requiring the conduct of three post-approval Phase IV clinical trials to assess potential safety risks associated with the insertion and removal of Probuphine, potential prolongation of the QT interval and to assess the potential for repeat administration of Probuphine into the same insertion site or insertion into an alternate site. The FDA established a schedule for carrying out the required studies. Prior to our reacquisition of Probuphine rights in May 2018, Braeburn had been in negotiations with the FDA regarding various design and protocol matters but had never commenced any of the mandated trials. We have begun interactions with the FDA regarding the timing, study design and conduct of the Phase IV trials and will allocate a portion of the proceeds of this offering to initiate such trials.

We will also request a meeting with FDA with the ultimate goal of exploring the potential for future expansion of the product label to cover a broader group of OUD patients and the possible pathways to accomplish that.

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European Medicines Agency

In early March 2017, we received confirmation from the EMA that Probuphine is eligible for a centralized review and approval process. We were also granted Small Manufacturing Entity, or SME, status in Europe, which provides for some monetary benefits during the application process and commercialization. While the preparation of the MAA was in progress, we met with the review teams of the two EMA member countries appointed as rapporteur (Ireland) and co-rapporteur (United Kingdom) to familiarize them with the development of Probuphine and the safety and efficacy data set, as well as receive their advice on the MAA preparation and presentation. The MAA was submitted to the EMA on November 6, 2017.

In connection with the Purchase Agreement, all rights in the MAA were sold to Molteni and since then we have been working collaboratively with Molteni on the EMA regulatory approval process. On March 22, 2018, the EMA delivered its “120 Day Consolidated List of Questions” which addressed clinical, manufacturing and quality control areas. We have met with the rapporteur and co-rapporteur regulatory review teams to review key questions and provide our planned responses, and we have received constructive guidance from these teams.. We submitted, on behalf of Molteni, the response to the EMA’s questions on September 14, 2018.

Health Canada

In April 2018, Knight announced that it had received regulatory approval from Health Canada to commercialize Probuphine in Canada.

Additional Products in Development

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

ProNeura-Ropinirole for Parkinson’s Disease

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

Based on these principles we designed an implant to deliver the drug ropinirole and conducted appropriate non-clinical studies, including a non-clinical study in an MPTP Parkinsonian primate model and demonstrated that a sustained non-fluctuating plasma level of ropinirole could be delivered safely for several months following implantation and could control PD symptoms without triggering dyskinesias in

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severely lesioned primates. Following further optimization of the implant and completion of the IND enabling non-clinical studies, we submitted the IND application to the FDA in early 2017 and it was cleared in August 2017 for commencement of the proposed Phase 1/2 clinical study. The trial is an open-label, sequential, dose escalation study that will enroll approximately 20 subjects with idiopathic Parkinson's disease. The primary objectives are to characterize the pharmacokinetic profile of the ropinirole implants, to evaluate their safety and tolerability, and to explore potential signals of efficacy using established disease-specific assessment scales. The first patient was treated in October 2017 and initial data from the early patients in the study was obtained in early 2018. In July 2018, we announced that the independent Data Safety Monitoring Board had completed a review of the data from the first cohort of patients and recommended that the trial continue with enrollment of the second cohort of patients. However, due to limited resources and our need to focus on our Probuphine relaunch, we decided to temporarily postpone patient enrollment until such time, if ever, as resources allow.

Other Feasibility Programs

Our goal is to expand our product pipeline using the ProNeura implant platform, and we have been opportunistically evaluating other drugs and disease settings for use with the ProNeura platform in potential treatment applications where conventional treatment is limited by variability in blood drug levels and poor patient compliance. The proceeds of this offering will not be sufficient to fund any external expenses associated with these early stage programs.

We have conducted a feasibility assessment of a subcutaneous implant using our proprietary ProNeura sustained release technology to administer an opioid antagonist. A product that may deliver non-fluctuating, therapeutic levels of an opioid antagonist continuously for up to six months may be ideally suited for the prevention of opioid relapse and overdose. On September 6, 2018, we were awarded a grant by the National Institutes of Health National Institute for Drug Addiction in support of this program. The grant provides for approximately $2.67 million in funding during the first year and $4.05 million during the second year subject to the terms and conditions specified in the grant, including our fund matching obligation in the amount of approximately $1.33 million during the first year and $2.03 million during the second year. Funding during the second year is also subject to satisfactory progress of the project and the availability of funds. We will need to obtain additional funds to meet our matching obligations.

We are collaborating with the Walter Reed Army Institute of Research, or WRAIR, and the Southwest Research Institute in the early non-clinical evaluation of the ProNeura platform in malaria prophylaxis. The early data from this collaboration is encouraging and has been presented by the WRAIR staff at several conferences, and WRAIR is now seeking additional funding from the Department of Defense to continue the program with additional non-clinical testing of the implant formulations in large animal studies.

Early non-clinical testing is being conducted for the development of a kappa opioid receptor agonist implant for the treatment of chronic pain. If successfully developed and approved, this would offer a potential non-addictive opioid analgesic for the treatment of chronic pain. Formulation studies and early in vitro testing is being conducted for the potential development of an implant with a currently approved peptide for the treatment of adult type 2 diabetes mellitus. Also, in 2017 we completed early non-clinical development focused on formulation optimization of an implantable triiodothyronine (T3) product for the treatment of hypothyroidism. Any further development will depend on availability of resources and interest from partners.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information regarding the beneficial ownership of our common stock as of September 20, 2018 by:

- our named executive officers;
- each of our directors;
- all of our current directors and executive officers as a group; and
- each stockholder known by us to own beneficially more than five percent of our common stock.

Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to the securities. Shares of Common Stock that may be acquired by an individual or group within 60 days of September 20, 2018, pursuant to the exercise of options are deemed to be outstanding for the purpose of computing the percentage ownership of such individual or group, but are not deemed to be outstanding for the purpose of computing the percentage ownership of any other person shown in the table. The percentage of beneficial ownership of our Common Stock is calculated based on an aggregate of 21,203,744 shares outstanding as of September 20, 2018. Unless otherwise indicated, the stockholders listed in the table have sole voting and investment power with respect to the shares indicated.

Name and Address of Beneficial Owner(1)	Shares Beneficially Owned	Percent of Shares Beneficially Owned
Joseph A. Akers(2)	49,819	*%
Sunil Bhonsle(3)	849,584	3.9
Rajinder Kumar(4)	15,000	*
M. David MacFarlane, Ph.D.(5)	79,552	*
James R. McNab, Jr.(6)	136,819	*
Marc Rubin, M.D.(7)	826,889	3.8
Federico Seghi Recli(8)	2,500	*
Scott A. Smith(9)	15,000	*
All executive officers and directors as a group (8) persons	1,975,163	8.7

*
Less than one percent.

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

(2)
Includes 36,819 shares issuable upon exercise of outstanding options.

(3)
Includes (i) 659,322 shares issuable upon exercise of outstanding options and (ii) 54,684 shares held in a family trust for which he serves as trustee.

(4)
Includes 15,000 shares issuable upon exercise of outstanding options.

(5)
Includes 57,277 shares issuable upon exercise of outstanding options.

(6)
Includes 36,819 shares issuable upon exercise of outstanding options.

(7)
Includes 670,572 shares issuable upon exercise of outstanding options.

(8)
Represents shares issuable upon exercise of outstanding options. Does not include 3,666,316 shares issuable upon conversion of notes and exercise of warrants held by Molteni. Mr. Seghi Recli does not have voting or dispositive power over, and disclaims beneficial ownership of, such underlying shares, except to the extent of his direct pecuniary interest therein. The shares attributed to Molteni are subject to a 4.99% exercise limitation.

(9)
Includes 15,000 shares issuable upon exercise of outstanding options

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CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

In March 2018, we entered into the Loan Agreement, the Purchase Agreement and the Rights Agreement with Molteni. We received and an initial payment of €2.0 million ($2,448,000) for the purchased assets under the Purchase Agreement and granted Molteni seven-year warrants to purchase 540,000 shares of our common stock at an exercise price of $1.20 per share under the Rights Agreement. There is currently $2.4 million owed to Molteni under the Loan Agreement. On May 14, 2018, Federico Seghi Recli joined our board as lead director. Molteni is indirectly owned by Mr. Recli's immediate family.

On August 3, 2018, we entered into an amendment to the Purchase Agreement pursuant to which we received an additional payment of €950,000 ($1,107,000).

On September 18, 2018, we entered into an unsecured convertible loan agreement with Molteni pursuant to which Molteni made a convertible loan to Titan of €550,000 (approximately $642,000) following our submission of the response to the 120-day letter from the EMA. The terms of the convertible loan were in the amendment to the Purchase Agreement. In the event the EMA grants marketing approval for Probuphine by December 31, 2019, the loan, together with accrued interest at the rate equal to 9.50% plus the amount by which the one month LIBOR exceeds 1.10%, will convert automatically into shares of our common stock at a conversion price per share equal to the lower of (i) $0.57 (the closing price on the funding date) and (ii) the closing price on the conversion date. In the event the EMA has not granted marketing approval by December 31, 2019, the convertible loan, together with accrued interest, will become due and payable.

See "Business — Probuphine — Agreements" for a description of the Loan Agreement, the Purchase Agreement and the Ri Agreement.

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DESCRIPTION OF SECURITIES WE ARE OFFERING

The following description of our capital stock and the provisions of our certificate of incorporation and our bylaws are summaries and are qualified by reference to the certificate of incorporation and the bylaws that will be in effect upon the closing of this offering. We have filed copies of these documents with the SEC as exhibits to our registration statement of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur prior to and upon the closing of this offering.

General

We are authorized to issue 125,000,000 shares of common stock, par value $0.001 per share, of which 21,203,744 shares are outstanding as of September 20, 2018 (29,536,891 shares on a fully diluted basis assuming exercise of all outstanding options, warrants and convertible debt) and 5,000,000 shares of "blank check" preferred stock, par value $0.0001 per share, none of which are currently outstanding.

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 amended and restated certificate of incorporation and amended and restated 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."

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company. They are located at 1 State Street, 30th floor, New York, New York 10004. Their telephone number is (212) 509-4000.

Warrants

The following summary of certain terms and provisions of the common warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant agency agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part. Continental Stock Transfer & Trust Company will act as warrant agent with respect to the warrants issued to the investors in this offering. Prospective investors should carefully review the terms and provisions of the form of warrant agent agreement for a complete description of the terms and conditions of the common warrants.

Pursuant to a warrant agency agreement between us and Continental Stock Transfer & Trust Company, as warrant agent, the warrants will be issued in book-entry form and shall initially be represented only by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company, or DTC, and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Each Class A Unit includes a warrant to purchase one share of our common stock at an exercise price of $0.25 per share at any time for up to five years after the date of the closing of this offering. Each Class B Unit issued in this offering includes an equivalent number of warrants as would have been issued to such

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purchaser if they have purchased Class A Units based on the public offering price exercisable at any time for up to five years after the date of the closing of this offering. The warrants issued in this offering will be governed by the terms of a global warrant held in book-entry form. The holder of a warrant will not be deemed a holder of our underlying Common Stock until the warrant is exercised, except as set forth in the warrants.

Subject to limited exceptions, a holder of warrants will not have the right to exercise any portion of its warrants if the holder (together with such holder's affiliates, and any persons acting as a group together with such holder or any of such holder's affiliates) would beneficially own a number of shares of common stock in excess of 4.99% (or, at the election of the holder prior to the issuance date, 9.99%) of the shares of our common stock then outstanding after giving effect to such exercise (the "Beneficial Ownership Limitation"); provided, however, that upon notice to the Company, the holder may increase or decrease the Beneficial Ownership Limitation, provided that in no event shall the Beneficial Ownership Limitation exceed 9.99% and any increase in the Beneficial Ownership Limitation will not be effective until 61 days following notice of such increase from the holder to us.

The exercise price and the number of shares issuable upon exercise of the warrants is subject to appropriate adjustment in the event of a Dilutive Issuance (as defined in the common warrants) recapitalization events, stock dividends, stock splits, stock combinations, reclassifications, reorganizations or similar events affecting our common stock. The warrant holders must pay the exercise price in cash upon exercise of the warrants, unless such warrant holders are utilizing the cashless exercise provision of the warrants, which is only available in certain circumstances such as if the underlying shares are not registered with the SEC pursuant to an effective registration statement. We intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part, effective when the warrants are exercised.

In addition, in the event we consummate a merger or consolidation with or into another person or other reorganization event in which our common stock is converted or exchanged for securities, cash or other property, or we sell, lease, license, assign, transfer, convey or otherwise dispose of all or substantially all of our assets or we or another person acquire 50% or more of our outstanding shares of common stock (a "fundamental transaction"), then following such event, the holders of the warrants will be entitled to receive upon exercise of the warrants the same kind and amount of securities, cash or property which the holders would have received had they exercised the warrants immediately prior to such fundamental transaction. Any successor to us or surviving entity is required to assume the obligations under the warrants. Notwithstanding the foregoing, in the event of a fundamental transaction, the holders will have the option, which may be exercised within 30 days after the consummation of the fundamental transaction, to require the company or the successor entity purchase the warrant from the holder by paying to the holder an amount of cash equal to the Black Scholes value of the remaining unexercised portion of the warrant on the date of the consummation of the fundamental transaction. However, if the fundamental transaction is not within the company's control, including not approved by the company's Board of Directors, the holder will only be entitled to receive from the company or any successor entity, as of the date of consummation of such fundamental transaction, the same type or form of consideration (and in the same proportion), at the Black Scholes value of the unexercised portion of the warrant, that is being offered and paid to the holders of common stock of the company in connection with the fundamental transaction, whether that consideration be in the form of cash, stock or any combination thereof, or whether the holders of common stock are given the choice to receive from among alternative forms of consideration in connection with the fundamental transaction.

Upon the holder's exercise of a warrant, we will issue the shares of common stock issuable upon exercise of the warrant within two trading days following our receipt of a notice of exercise, provided that payment of the exercise price has been made (unless exercised via the "cashless" exercise provision).

Prior to the exercise of any warrants to purchase common stock, holders of the warrants will not have any of the rights of holders of the common stock purchasable upon exercise, including the right to vote, except as set forth therein.

Warrant holders may exercise warrants only if the issuance of the shares of common stock upon exercise of the warrants is covered by an effective registration statement, or an exemption from registration is available under the Securities Act and the securities laws of the state in which the holder resides. We

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intend to use commercially reasonable efforts to have the registration statement of which this prospectus forms a part effective when the warrants are exercised. The warrant holders must pay the exercise price in cash upon exercise of the warrants unless there is not an effective registration statement or, if required, there is not an effective state law registration or exemption covering the issuance of the shares underlying the warrants (in which case, the warrants may only be exercised via a “cashless” exercise provision). If a warrant is exercised via the “cashless” exercise provision, the holder will receive the number of shares equal to the quotient obtained by dividing (i) the difference between the VWAP (as determined pursuant to the terms of the warrants) and the exercise price of the warrant multiplied by the number of shares issuable under the warrant by (ii) the VWAP.

We do not intend to apply for listing of the warrants on any securities exchange or other trading system.

Preferred Stock

Our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. In addition, the preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock other than the Series A Preferred, we cannot assure you that we will not do so in the future.

Series A Convertible Preferred Stock

The following is a summary of the material terms of the Series A Preferred. This summary is not complete. The following summary of the terms and provisions of the Series A Preferred is qualified in its entirety by reference to the form of Certificate of Designation of the Series A Preferred, the form of which has been filed as an exhibit to the registration statement of which this prospectus is a part.

General. Our board of directors has designated up to 8,225 shares of the 5,000,000 authorized shares of preferred stock as Series A Convertible Preferred Stock. When issued, the shares of Series A Preferred will be validly issued, fully paid and non-assessable. Each share of Series A Preferred will have a stated value of $1,000 per share.

Rank. The Series A Preferred will rank on parity to our common stock.

Conversion. Each share of Series A Preferred is convertible into shares of our common stock (subject to adjustment as provided in the related certificate of designation of preferences, rights and limitations) at any time at the option of the holder at a conversion price equal to the stated value of the Series A Preferred of $1,000 divided by the public offering price of the Class A Units in this offering. Holders of Series A Preferred will be prohibited from converting Series A Preferred into shares of our common stock if, as a result of such conversion, 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.

Liquidation Preference. In the event of our liquidation, dissolution or winding-up, holders of Series A Preferred will be entitled to receive the same amount that a holder of our common stock would receive if the Series A Preferred were fully converted into shares of our common stock at the conversion price (disregarding for such purposes any conversion limitations) which amounts shall be paid pari passu with all holders of common stock.

Voting Rights. Shares of Series A Preferred will generally have no voting rights, except as required by law and except that the affirmative vote of the holders of a majority of the then outstanding shares of Series A Preferred is required to, (a) alter or change adversely the powers, preferences or rights given to the Series A Preferred, (b) amend our certificate of incorporation or other charter documents in any manner that materially adversely affects any rights of the holders, (c) increase the number of authorized shares of Series A Preferred, or (d) enter into any agreement with respect to any of the foregoing.

Dividends. Shares of Series A Preferred will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. The holders of the Series A Preferred will participate, on an as-if-converted-to-common stock basis, in any dividends to the holders of common stock.

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Redemption. We are not obligated to redeem or repurchase any shares of Series A Preferred. Shares of Series A Preferred are not otherwise entitled to any redemption rights or mandatory sinking fund or analogous fund provisions.

Exchange Listing. We do not plan on making an application to list the Series A Preferred on any national securities exchange or other nationally recognized trading system.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Continental Stock Transfer & Trust Company.

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UNDERWRITING

Alliance Global Partners is acting as the representative of the underwriters and the sole book-running manager in this offering. We have entered into an underwriting agreement dated September 20, 2018 with the representative. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to each underwriter named below and each underwriter named below has severally and not jointly agreed to purchase from us, at the public offering price per share less the underwriting discounts and commissions set forth on the cover page of this prospectus, the number of Units listed next to its name in the following table:

Underwriters	Number of Class A Units	Number of Class B Units
Alliance Global Partners	4,462,500	7,197
CIM Securities, LLC	637,500	1,028

The underwriters are committed to purchase all the Units offered by us other than those covered by the option to purchase additional securities described below, if they purchase any Units. The obligations of the underwriters may be terminated upon the occurrence of certain events specified in the underwriting agreement. Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions and representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We have agreed to indemnify the underwriters against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect thereof.

The underwriters are offering the Units, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel and other conditions specified in the underwriting agreement. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Option to Purchase Additional Securities

We have granted the underwriters an option to purchase additional shares of common stock and/or warrants to purchase common stock. This option, which is exercisable for up to 45 days after the date of this prospectus, permits the underwriters to purchase a maximum of 5,700,000 additional shares of common stock (15% of the shares of common stock included in the Class A Units and the shares of common stock underlying the shares of Series A Preferred included in the Class B Units sold in this offering) and/or warrants to purchase a maximum of 5,700,000 shares of common stock from us. If the underwriters exercise all or part of this option, they will purchase such common stock covered by the option at the public offering price per Class A Unit, minus once cent and the warrants covered by the option at a price of one cent per warrant, in each case less the underwriting discounts and commissions. If this option is exercised in full, the total offering price to the public will be approximately $10.9 million and the total net proceeds, after expenses, to us will be approximately $9.8 million.

Discounts, Commissions and Expense Reimbursement

The following table shows the public offering price, underwriting discount and proceeds, before expenses, to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional securities.

	Per Class B Unit	Per Class A Unit(2)	Total Without Over-Allotment Option	Total With Over-Allotment Option
Public offering price	$ 1,000	$ 0.25	$ 9,500,000	$ 10,868,000
Underwriting discount(1)	$ 70	$ 0.0175	$ 654,675	$ 750,435
Proceeds, before expense, to us(2)	$ 930	$ 0.2325	$ 8,845,325	$ 10,117,565

(1)

We have agreed to pay the underwriters a commission of 4% of the gross proceeds of this offering attributable to participation by certain predetermined investors, 3.5% of the gross proceeds of this

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offering attributable to participation by members of our board of directors and 7% of the gross proceeds of this offering to the remaining investors.

(2)

An underwriting discount of $0.00875 per Class A Unit is applicable to 1,180,000 Class A Units and the proceeds to us, before expenses, on these units is $0.24125 per unit.

The underwriters propose to offer the Units offered by us to the public at the public offering price per respective Unit set forth on the cover of this prospectus. In addition, the underwriters may offer some of the Units to other securities dealers at such price less a concession of up to $0.00875 per Class A Unit and $35.00 per Class B Unit.

If all of the Units offered by us are not sold at the respective public offering prices per Unit, the underwriters may change the offering price per Unit and other selling terms by means of a supplement to this prospectus.

Several members of our board of directors have are purchasing an aggregate of $295,000 of Class A Units in this offering at the public offering price per unit.

We have also agreed to reimburse certain of the representative's out of pocket expenses not to exceed $120,000, including the fees of underwriters' counsel, which will not exceed $70,000, $15,000 for IPREO software related expenses, $6,000 for background check expenses, $2,000 for tombstones and up to $27,000 in marketing related expenses including roadshow expenses.

We estimate that the total expenses of the offering payable by us, excluding the total underwriting discounts, commissions and underwriter expense reimbursement will be approximately $0.2 million.

Representative's Warrants

We have agreed to issue to the representative warrants to purchase up to an aggregate of shares of our commo (4% of the shares of common stock included in the Class A Units and the shares of common stock underlying the shares of Series B Preferred included in the Class B Units sold in this offering, but excluding any shares of common stock underlying the warrants issued in this offering and any shares of common stock sold (and any shares of common stock underlying any warrants sold) upon exercise of the underwriters' option to purchase additional securities). The warrants will be exercisable at any time, and from time to time, in whole or in part, during the four-year period commencing one year from the effective date of the registration statement relating to this offering. The warrants are exercisable at a per share price equal to $0.28 per share, or 110% of the public offering price per Class A Unit in the offering. The warrants are deemed underwriter compensation by FINRA and are therefore subject to a 180-day lock-up pursuant to Rule 5110(g)(1) of FINRA. The underwriter (or permitted assignees under Rule 5110(g)(1)) will not sell, transfer, assign, pledge, or hypothecate these warrants or the securities underlying these warrants, nor will they engage in any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of the warrants or the underlying securities for a period of 180 days from the effective date of the registration statement relating to this offering. In addition, the warrants provide for registration rights upon request, in certain cases. The demand registration right provided will expire five years from the effective date of the registration statement relating to this offering in compliance with FINRA Rule 5110(f)(2)(G)(iv). The piggyback registration right provided will expire seven years from the effective date of the registration statement relating to this offering in compliance with FINRA Rule 5110(f)(2)(G)(v). We will bear all fees and expenses attendant to registering the common stock issuable on exercise of the warrants other than underwriting commissions incurred and payable by the holders. The exercise price and number of shares issuable upon exercise of the warrants may be proportionately adjusted in the event of a stock split, stock dividend, recapitalization, reorganization or similar event involving the company in compliance with FINRA Rule 5110(f)(2)(G)(vi).

Lock-Up Agreements

We have agreed with the underwriter not to offer for sale, issue or sell, or register for offer or sale, any of our common stock or securities convertible into our common stock for a period of 90 days after the date of this prospectus, subject to certain exceptions. In addition, all of our directors and executive officers and one of our affiliated securityholders have entered into lock up agreements with the representative prior to

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the commencement of this offering pursuant to which each of these persons, for a period of 90 days from the closing date of this offering, without the prior written consent of the representative, agree not to (1) offer, pledge, sell, contract to sell, grant, lend, or otherwise transfer or dispose of, directly or indirectly, any of our shares of common stock or any securities convertible into or exercisable or exchangeable for shares our common stock owned or acquired on or prior to the closing date of this offering (including any common shares acquired after the closing date of this offering upon the conversion, exercise or exchange of such securities); (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of such securities, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of common shares or such other securities, in cash or otherwise, except for certain exceptions and limitations; (3) file or caused to be filed any registration statement relating to the offering of any shares of our capital shares; or (4) publicly disclose the intention to make any offer, sale, pledge or disposition, or to enter into any transaction, swap, hedge or other arrangement relating to such securities.

Right of First Refusal

For a period of nine months immediately following the effective date of the registration statement in connection with this offering, we will grant the representative an irrevocable right of first refusal to act as lead investment banker, lead book-runner and/or lead placement agent, at the representative's sole discretion, for each and every future public and private equity and debt offering, including all equity-linked financings, by us or any of our successors or subsidiaries during such nine month period on terms customary to the representative, and the representative shall have the sole right to determine whether or not any other broker dealer shall have the right to participate in any such offering and the economic terms of any such participation.

Electronic Offer, Sale and Distribution of Securities

A prospectus in electronic format may be made available on the websites maintained by one or more of the underwriters or selling group members, if any, participating in this offering and one or more of the underwriters participating in this offering may distribute prospectuses electronically. The representative may agree to allocate a number of either class of Unit to underwriters and selling group members for sale to their online brokerage account holders. Internet distributions will be allocated by the underwriters and selling group members that will make internet distributions on the same basis as other allocations. Other than the prospectus in electronic format, the information on these websites is not part of, nor incorporated by reference into, this prospectus or the registration statement of which this prospectus forms a part, has not been approved or endorsed by us or any underwriter in its capacity as underwriter, and should not be relied upon by investors.

The Nasdaq Capital Market Listing

Our common stock is listed on The Nasdaq Capital Market under the symbol "TTNP."

Stabilization

In connection with this offering, the underwriters may engage in stabilizing transactions, over-allotment transactions, syndicate-covering transactions, penalty bids and purchases to cover positions created by short sales. Stabilizing transactions permit bids to purchase shares so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the shares while the offering is in progress.

Over-allotment transactions involve sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase. This creates a syndicate short position that 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 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 short position by exercising their option to purchase additional shares of common stock and/or warrants to purchase common stock and/or purchasing shares in the open market.

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Syndicate covering transactions involve purchases of shares 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 with the price at which they may purchase shares through exercise of the over-allotment option. If the underwriters sell more shares than could be covered by exercise of the over-allotment option and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.

Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the shares originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions 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 shares or common stock or preventing or retarding a decline in the market price of our shares or common stock. As a result, the price of our common stock in the open market may be higher than it would otherwise be in the absence of these transactions. Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of our common stock. These transactions may be effected on The Nasdaq Capital Market, in the over-the-counter market or otherwise and, if commenced, may be discontinued at any time.

Passive market making

In connection with this offering, underwriters and selling group members may engage in passive market making transactions in our common stock on The Nasdaq Capital Market in accordance with Rule 103 of Regulation M under the Exchange Act, during a period before the commencement of offers or sales of the shares and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, then that bid must then be lowered when specified purchase limits are exceeded.

Certain Relationships

The underwriters and their affiliates have provided, or may in the future provide, various investment banking, commercial banking, financial advisory, brokerage, and other services to us and our affiliates for which services they have received, and may in the future receive, customary fees and expense reimbursement.

The underwriters and their affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of our company. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Offer Restrictions 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.

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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 Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

EXPERTS

The financial statements as of December 31, 2017 and 2016 and for each of the two years in the period ended December 31, 2017 incorporated by reference in this Prospectus and in the Registration Statement have been so incorporated in reliance on the report of OUM, LLP, an independent registered public accounting firm (the report on the financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern), incorporated by reference in this Prospectus and in the Registration Statement, 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

We "incorporate by reference" certain documents we have filed with the SEC, which means that we are disclosing important information to you by referring you to those documents. The information

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incorporated by reference is an important part of this prospectus, and any information contained in any document incorporated by reference in this prospectus will be deemed to be modified or superseded to the extent that a statement contained in this prospectus or free writing prospectus provided to you in connection with this offering modified or supersedes the original statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to be a part of this prospectus. The later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (Commission File No. 001-13341) after (i) the date of this initial registration statement and prior to effectiveness of this registration statement and (ii) the date of this prospectus and before the completion of the offering of the securities included in this prospectus, however, we will not incorporate by reference any documents or portions thereof that are not deemed “filed” with the SEC, or any information furnished pursuant to Items 2.02 or 7.01 of Form 8-K or related exhibits furnished pursuant to Item 9.01 of Form 8-K:

- Our Annual Report on Form 10-K for the year ended December 31, 2017 filed on April 2, 2018;
- Our Quarterly Report on Form 10-Q, filed on May 15, 2018;
- Our Quarterly Report on Form 10-Q, filed on August 14, 2018;
- Our Current Report on Form 8-K filed on January 22, 2018;
- Our Current Report on Form 8-K filed on February 7, 2018;
- Our Current Report on Form 8-K filed on March 26, 2018;
- Our Current Report on Form 8-K filed on April 13, 2018;
- Our Current Report on Form 8-K filed on May 16, 2018;
- Our Current Report on Form 8-K filed on May 30, 2018;
- Our Current Report on Form 8-K filed on June 1, 2018;
- Our Current Report on Form 8-K filed on July 31, 2018;
- Our Current Report on Form 8-K filed on August 3, 2018;
- Our Current Report on Form 8-K filed on August 8, 2018;

- Our Current Report on Form 8-K filed on August 17, 2018;

- Our Current Report on Form 8-K filed on September 4, 2018;

- Our Current Report on Form 8-K filed on September 10, 2018;

- Our Current Report on Form 8-K filed on September 20, 2018;

- Our Definitive Proxy Statement on Schedule 14A filed with the SEC on July 2, 2018; and

- The description of the our common stock set forth in the Registration Statement on Form 8-A12B filed on October 8, 2015.

We will provide to each person, including any beneficial owner, to whom a prospectus is delivered, a copy of any or all of the reports or documents that we incorporate by reference in this prospectus contained in the registration statement (except exhibits to the documents that are not specifically incorporated by reference) at no cost to you, by writing or calling us at the following address and telephone number:
Titan Pharmaceuticals, Inc.
400 Oyster Point Blvd., Suite 505
South San Francisco, California 94080
(650) 244-4990
Information about us is available at 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.

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5,100,000 Class A Units
Consisting of Common Stock and Warrants
and
8,225 Class B Units
Consisting of Series A Convertible Preferred Stock and Warrants

PROSPECTUS

A.G.P.
CIM Securities, LLC
September 20, 2018

Through and including October 15, 2018 (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.