

PROSPECTUS



## 80,000,000 Units consisting of shares of common stock and warrants

We are offering 80,000,000 units, with each unit consisting of one share of our common stock, par value \$0.001 per share, and one warrant to purchase one share of our common stock. Each share of our common stock is being sold together with a warrant to purchase one share of our common stock. The warrants will have an exercise price per share of \$0.10 (100% of the offering price), will be exercisable commencing on the effective date of an increase in our authorized shares of common stock or a reverse split in an amount sufficient to permit the exercise in full of the warrants and will expire on the fifth anniversary of the initial exercise date. The units will not be certificated and the shares of common stock and warrants comprising the units are immediately separable and will be issued separately in this offering.

Our common stock is listed on The Nasdaq Capital Market under the symbol “TTNP”. On October 27, 2020, the last reported sale price of our common stock on The Nasdaq Capital Market was \$0.128 per share. We do not intend to apply for the listing of the warrants on any national securities exchange or other trading market. See “Risk Related to Our Common Stock — Our failure to meet the continued listing requirements of Nasdaq could result in a de-listing of our common stock” for important information about the listing of our common stock.

The price of our common stock on The Nasdaq Capital Market during recent periods was only one of many factors in determining the public offering price. Other factors considered in determining the public offering price include our history, our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers, the general condition of the securities markets at the time of this offering and discussions between the underwriters and prospective investors.

**An investment in our securities involves a high degree of risk. See “Risk Factors” beginning on page 6 of this prospectus for a discussion of information that should be considered before making any investment in our securities.**

|   | <u>Per Unit</u> | <u>Total</u> |
|---|-----------------|--------------|
| Public offering                                       | \$ 0.10         | \$8,000,000  |
| Underwriting discounts and commissions <sup>(1)</sup> | \$0.006         | \$ 480,000   |
| Proceeds to us, before expenses                       | \$0.094         | \$7,520,000  |

(1) The underwriters will receive compensation in addition to the underwriting discount and commissions. See “Underwriting” beginning on page 21 of this prospectus for a description of compensation payable to the underwriters.

**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.**

We anticipate that delivery of the shares and warrants comprising the units will be made on or about October 30, 2020.

*Book-Running Manager*

**MAXIM GROUP LLC**

The date of this prospectus is October 28, 2020

## SUMMARY

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

### Company Overview

We are a pharmaceutical company developing therapeutics utilizing our proprietary long-term drug delivery platform, ProNeura™, for the treatment of select chronic diseases for which steady state delivery of a drug provides an efficacy and/or safety benefit. ProNeura consists of a small, solid implant made from a mixture of EVA (ethylene-vinyl acetate) and a drug substance. The resulting product is a solid matrix that is administered subdermally, normally in the inner upper arm, in a brief, outpatient procedure and is removed in a similar manner at the end of the treatment period. These procedures may be performed by trained health care providers, or HCPs, including licensed and surgically qualified physicians, nurse practitioners, and physician's assistants in a HCP's office or other clinical setting.

Probuphine® is the first product based on our ProNeura technology approved in the U.S., Canada and the European Union, or EU, for the maintenance treatment of opioid use disorder in clinically stable patients taking 8 mg or less a day of oral buprenorphine. On October 15, 2020, we issued a press release announcing our decision to discontinue selling Probuphine® (buprenorphine) implant and wind down our commercialization activities, and to pursue a plan that will enable us to focus on our ProNeura-based product development programs. We based this decision on several factors, most notably that commercializing Probuphine with the requirements of the current product label and the Risk Evaluation and Mitigation Strategy, or REMS, program has proven to be onerous, leading to minimal utilization despite our significant efforts to overcome these obstacles. Other factors that have negatively impacted Titan's ability to effectively commercialize Probuphine include the financial constraints that have limited our sales and marketing capabilities; suboptimal reimbursement rates; and the complexity of the distribution channel. The continually changing environment due to the COVID-19 pandemic has further exacerbated these issues. As a result, sales of Probuphine have been, and would likely continue for the foreseeable future to be, extremely limited. After careful review of the recent sales and marketing results, the hurdles that Titan has and will continue to face, and the substantial additional expenditures and resources that would be required, our board of directors made a determination to advise the U.S. Food and Drug Administration ("FDA") of its decision to cease commercialization of Probuphine. A wind-down plan taking into considerations FDA and state regulatory requirements, as well as business considerations is underway.

On October 25, 2020, we entered into a Debt Settlement and Release Agreement with L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A., or Molteni, and Horizon Credit II LLC, or Horizon, the holders of our approximately \$5.2 million of outstanding secured debt (\$4.0 million principal amount and \$1.2 million in payoff amounts) to settle such obligations for \$1.6 million in cash, the transfer of certain Probuphine assets to Molteni, including all of our manufacturing equipment, and the termination of our rights to future payments under the asset purchase and supply agreement with Molteni. The settlement agreement will provide for the release to us of the remaining collateral, which will enable us to continue operating as a research and development company. The consummation of such agreement is contingent on the completion of this offering. See "Use of Proceeds."

### Development Programs

#### *Kappa Opioid Agonist Peptide Program*

On October 27, 2020, we entered into an Asset Purchase Agreement with JT Pharmaceuticals, Inc., or JT Pharma, for the acquisition and development of JT Pharma's kappa opioid agonist peptide, or JT 09, for use in combination with our ProNeura technology. James McNab, a member of our board of directors, is a principal of JT Pharma. Several years ago, we began limited laboratory work in in collaboration with

JT Pharma to assess the feasibility of delivering JT 09 through peptide-infused ProNeura rods in animal models. Our initial work focused on JT 09's ability to activate peripheral kappa opioid receptors, with the JT ProNeura rods potentially providing a non-addictive treatment for certain types of pain. Recently, our collaboration with JT Pharma has pivoted to explore the feasibility of also using JT ProNeura rods in the treatment of chronic pruritus, a debilitating condition defined as itching of the skin lasting longer than six weeks. In 2015, an estimated 23 – 44 million Americans suffered from chronic pruritus in the setting of both cutaneous and systemic conditions. Current treatments include anti-histamines, corticosteroids, and over-the-counter lotions, all of which are relatively ineffective and may have undesirable side-effect profiles. The antipruritic effect of kappa opioid agonists is thought to be related to their binding to kappa opioid receptors on keratinocytes, immune cells and peripheral itch neurons. We believe, based on our early animal data, that subcutaneous implantation of the JT ProNeura rods could potentially deliver therapeutic concentrations of JT 09 for six months or longer following a single in-office procedure. A portion of the proceeds of this offering are expected to be used to conduct the initial non-clinical studies designed to establish proof of concept in an animal model. See "Use of Proceeds." If successful, we will need to conduct Investigational New Drug, or IND, enabling safety and pharmacology studies.

The efficacy of a kappa opioid agonist was first demonstrated in humans by Toray Industries, Inc., or Toray, using a highly potent small molecule kappa agonist, nalfurafine. Toray's application for nalfurafine was approved in Japan for the treatment of pruritus in end stage kidney disease, or ESKD, and chronic liver disease. However, because it is a small molecule that penetrates into the central nervous system, or CNS, some CNS-related adverse events were observed. More recently, Cara Therapeutics Inc., or Cara, has demonstrated in phase 2 and phase 3 clinical trials the efficacy of a selective kappa opioid receptor agonist peptide, CR845, in the treatment of pruritus associated with ESKD in patients undergoing dialysis, and Cara has announced plans to submit a New Drug Application in the U.S. in the second half of 2020.

According to published reports, the prevalence of ESKD has been rising continuously, and reached approximately 750,000 in 2017. Pruritus affects approximately 40% of patients with ESKD and has been associated with poor quality of life, poor sleep, depression, and mortality. We believe a ProNeura rod containing JT 09 could potentially eliminate the need for multiple weekly injections by delivering low-dose, non-fluctuating medication levels for six months or longer following implant.

#### Nalmefene Development Program

In September 2019, the National Institute for Drug Addiction, or NIDA, awarded us an approximately \$8.7 million grant over two years for our nalmefene implant development program for the prevention of opioid relapse following detoxification. An injectable formulation of nalmefene was approved by the FDA in 1995 for the management and reversal of opioid overdose, including respiratory depression. Oral nalmefene was approved by the European Medicines Agency in 2013 for treating alcohol dependence.

The NIDA grant provides funds for the completion of implant formulation development, cGMP manufacturing and non-clinical studies required for filing an IND. During the first quarter of 2020 we met with the FDA to review our non-clinical development plans and obtain guidance regarding filing an IND. The FDA provided clear guidance on the type of development plan that we should follow, specifically that this product development should follow the 505(b)(i) regulatory pathway due to the lack of safety data on nalmefene for a long acting formulation, and the non-clinical studies that will be required to file an IND. Based on this input, collecting all the non-clinical chronic toxicology data will require an additional study as well as increasing the duration of an ongoing study that will delay filing of the IND to mid-2021. We have discussed the change in development plan with NIDA and they have accepted our plan to reallocate previously approved funds for conduct of the studies.

#### **Management Restructuring**

As previously disclosed, Sunil Bhonsle, our Chief Executive Officer, advised us of his desire to retire before the end of the year. Effective October 18, 2020, Kate DeVarney, our Executive Vice President and Chief Scientific Officer and a member of the board of directors, assumed the roles of President and Chief Operating Officer. Effective October 31, 2020, Mr. Bhonsle will step down from his executive role. Dr. Marc Rubin, our Executive Chairman, together with Dr. DeVarney, will oversee our product development activities.

### **Other Recent Developments**

*Stockholder Meeting:* At a special meeting of stockholders held on September 24, 2020, our stockholders approved an amendment to our certificate of incorporation to increase the authorized number of shares of common stock from 125,000,000 to 225,000,000. The amendment was filed with the Secretary of State of the State of Delaware the same day.

*Registered Direct Offering:* On September 28, 2020, we completed a registered direct offering pursuant to which we sold an aggregate of 19,440,000 shares of common stock at a purchase price of \$0.14 per share to a couple of institutional investors. We received net proceeds of approximately \$2.5 million, after payment of placement agent fees and other offering expenses.

*Nasdaq Listing:* On October 15, 2020, we provided a letter to The Nasdaq Capital Market, or Nasdaq, that set forth our plan to regain compliance with the \$2.5 million minimum stockholders' equity requirement for continued listing. The plan described the wind down of our commercial activities, the settlement of our debt obligations, the reduction in personnel and overhead costs and the anticipated proceeds of this offering. Nasdaq has requested additional financial information in support of our compliance plan, which we submitted on October 19, 2020. There is no assurance that Nasdaq will accept our plan or that we will not be delisted from Nasdaq for failure to meet the minimum stockholders' equity or other requirements. For additional information regarding our continued listing on Nasdaq, see "Risk Factors — Our failure to meet the continued listing requirements of Nasdaq could result in a delisting of our common stock.

### **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](http://www.titanpharm.com). We make our periodic and current reports that are filed with the SEC available, free of charge, on our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained in, and that can be accessed through, our website is not incorporated into and is not a part of this prospectus.

## THE OFFERING

|  |   |
|--|---|
| <b>Units offered</b>                                 | 80,000,000 units. Each unit consists of one share of common stock and a warrant to purchase one share of our common stock.  |
| <b>Offering price</b>                                | \$0.10 per unit.  |
| <b>Description of warrants</b>                       | The warrants will be exercisable beginning on the effective date of our stockholders' approval of an increase in our authorized shares of common stock or a reverse stock split in an amount sufficient to permit the exercise in full of the warrants, and will expire on the five year anniversary of the original exercise date. We do not have a sufficient number of authorized shares to permit exercise of the warrants. In the event that we are unable to effect an increase in our authorized shares of common stock or a reverse split in an amount sufficient to permit the exercise in full of the warrants, the warrants will not be exercisable and therefore have no value. In no event will the warrants have any cash value other than in connection with a fundamental transaction as described therein.   |
| <b>Common stock outstanding before this offering</b> | 116,763,180 shares  |
| <b>Common stock outstanding after this offering</b>  | 196,763,180 shares (or 276,763,180 shares if the warrants sold in this offering are exercised in full).   |
| <b>Use of proceeds</b>                               | We currently intend to use the net proceeds from this offering to make the cash payments pursuant to the debt settlement agreement, to fund ongoing product development activities, and to pay expenses associated with the winding down of commercial operations. See "Use of Proceeds" herein.  |
| <b>Risk Factors</b>                                  | Investing in our securities involves a high degree of risk. You should carefully review and consider the "Risk Factors" section of this prospectus for a discussion of factors to consider before deciding to invest in shares of our common stock.   |
| <b>Lock-up and Voting Agreement</b>                  | Certain investors in this offering agreed with the representative to enter into a lock-up and voting agreement whereby each such investor will be subject to a lock-up period through the closing of this offering. This means that, during the applicable lock-up period, such persons may not offer for sale, contract to sell, sell, distribute, grant any option, right or warrant to purchase, pledge, hypothecate or otherwise dispose of, directly or indirectly, any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock. Certain limited transfers are permitted during the lock-up period if the transferee agrees to these lock-up restrictions. Additionally, such investors will agree to vote all shares of common stock they beneficially own on the closing date of this offering, including the shares purchased in the offering, with respect to any proposals presented to the stockholders of the Company at the Company's next stockholders meeting. |
| <b>Market Symbol and trading</b>                     | Our common stock is listed on The Nasdaq Capital Market under the symbol "TTNP." There is no established trading market for the warrants and we do not expect a market to develop. In addition, we do not intend to apply for the listing of the warrants on any  |

national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited.

The number of shares of our common stock that will be outstanding immediately after this offering as shown above is based on 116,763,180 shares outstanding as of October 28, 2020 and excludes:

- 897,426 shares of our common stock issuable upon the exercise of outstanding options with a weighted average exercise price of \$7.58 per share;
- 25,932,114 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$0.42 per share (subject to adjustment of the exercise price of 9,031,614 warrants from \$0.14 to \$0.10 upon consummation of this offering);
- 3,422,777 shares issuable upon conversion of a portion of our outstanding debt; and
- 862,172 additional shares of our common stock reserved for future issuance under our 2015 equity incentive plan.

## 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**

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

To date, other than our work on Probuphine in OUD, and our work on nalmefene, we have conducted only limited research and development activities assessing our ProNeura delivery system's applicability in other potential indications. While the nalmefene program is being funded in large part by NIDA, we expect that the proceeds of this offering will only be sufficient to complete the proof of concept work on JT-09 and we will require substantial additional funds to support further research and development activities, including the anticipated costs of nonclinical studies and clinical trials, regulatory approvals and eventual commercialization of any therapeutic based on our ProNeura platform technology. If we are unable to obtain substantial government grants or enter into third party collaborations to fund our ProNeura programs, we will need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in obtaining the requisite funding for our ProNeura programs, we could be forced to discontinue product development. Furthermore, funding arrangements with collaborative partners or others may require us to relinquish rights to technologies, product candidates or products that we would otherwise seek to develop or commercialize ourselves or license rights to technologies, product candidates or products on terms that are less favorable to us than might otherwise be available.

Our ability to successfully develop any future product candidates based on our ProNeura drug delivery technology is subject to the risks of failure and delay inherent in the development of new pharmaceutical products, including: delays in product development, clinical testing, or manufacturing; unplanned expenditures in product development, clinical testing, or manufacturing; failure to receive regulatory approvals; emergence of superior or equivalent products; inability to manufacture on our own, or through any others, product candidates on a commercial scale; and failure to achieve market acceptance. Importantly, if the JT-09 initial proof of concept efforts are unsuccessful and we discontinue this program, our future prospects could be materially adversely impacted. Because of these risks, our research and development efforts may not result in any commercially viable products and our business, financial condition, and results of operations could be materially harmed.

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

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 cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials could materially harm our business, financial condition, and results of operations.

***The winding down of our commercial operations may be more costly and time-consuming than we anticipate.***

The cessation of our Probuphine related commercial activities requires us to comply with FDA and state regulatory requirements, including those related to notifications to various stakeholders and the continuation of adverse event reporting, as well as to address a number of business considerations, such as termination of third-party agreements and transfer of manufacturing equipment. The costs and timing associated with the wind down of our commercial operations may exceed our current estimates, requiring a reallocation of proceeds that may limit what we can accomplish in our product development programs unless additional financing is procured sooner than we currently anticipate.

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

We depend on third-party laboratories and medical institutions to conduct preclinical studies and clinical trials for our products and other third-party organizations to perform data collection and analysis, all of which must maintain both good laboratory and good clinical practices. We also depend upon third party manufacturers for the production of any products we may successfully develop to comply with cGMP of the FDA, which are similarly outside our direct control. If third party laboratories and medical institutions conducting studies of our products fail to maintain both good laboratory and clinical practices, the studies could be delayed or have to be repeated.

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

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

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

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

- obtain and keep patent protection for our products, methods and technologies on a domestic and international basis;
- enforce our patents to prevent others from using our inventions;
- maintain and prevent others from using our trade secrets; and

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

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

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

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

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

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

***We must comply with extensive government regulations.***

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

***We face intense competition.***

With respect to our product development programs, we 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 which 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.

***We depend on a small number of employees and consultants.***

We are highly dependent on the services of a limited number of personnel and the loss of one or more of such individuals could substantially impair our ongoing commercialization efforts. We compete in our hiring efforts with other pharmaceutical and biotechnology companies and it may be difficult and could take an extended period of time because of the limited number of individuals in our industry with the range of skills and experience required and because of our limited resources.

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

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

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

***We face risks related to health epidemics, such as the current COVID-19 global pandemic, that could adversely affect our operations or financial results.***

The spread of COVID-19, the novel coronavirus, including restrictions on travel, “shelter in place” orders, and quarantine policies put into place by businesses and state and local governments to mitigate its transmission, may have a material adverse effect on our business. While the duration of the pandemic and its potential economic impact are difficult to predict, it already has caused significant disruption in the healthcare industry and is likely to have continuing impacts as it continues. The travel restrictions, “shelter in place” orders, quarantine policies, and general concerns about the spread of COVID-19 was a significant factor in our decision to wind down our commercial operations because of the resulting disruptions in the delivery of healthcare to patients, our sales and marketing efforts and REMS training activities, as well as the operations of the various parts of our supply and distribution chain. The ultimate impact of the COVID-19 pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential impacts on our business, healthcare systems or the global economy as a whole. As the pandemic continues, it may result in a sustained economic downturn that could affect our ability to access capital on reasonable terms, or at all.

**Risks Related to Our Financial Condition and Need for Additional Capital**

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

We have incurred net losses in almost every year since our inception. Our financial statements have been prepared assuming that we will continue as a going concern. For the years ended December 31, 2019

and 2018, we had net losses of approximately \$16.5 million and \$9.3 million, respectively, and had net cash used in operating activities of approximately \$15.4 million and \$8.4 million, respectively. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We expect to continue to incur net losses and negative operating cash flow for the foreseeable future as we wind down our commercial activities and focus on development of ProNeura based products. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to obtain government or third party funding for our development programs. There can be no assurance that we will ever achieve profitability.

***We will require additional proceeds to fund our product development programs.***

We currently estimate that our available cash and cash equivalents, including the approximately \$2.5 million received from our September 2020 financing, will be sufficient to fund our operations into November 2020. We believe that the proceeds of this offering will be sufficient to meet our obligations under the debt settlement agreement, wind down our commercial operations and fund our working capital needs and product development efforts for more than nine months. We will require additional funds to advance JT-09 beyond the proof of concept stage, if successful, for which we expect to have the results of the initial studies during the second quarter of 2021, and to fund any of our ProNeura development programs into the clinic 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. There can be no assurance that any source of capital will be available to us on acceptable terms.

***We have a limited number of authorized shares of common stock available for issuance and will need to seek stockholder approval to amend our charter to either effect an increase in our authorized shares of common stock or a reverse split. The issuance of additional securities if we obtain the required amendment approval will cause investors to experience dilution***

Following this offering, there will only be minimal authorized but unissued or reserved shares of our common stock. We do not have a sufficient number of authorized shares to permit exercise of the warrants or to undertake the additional equity financing that we will need to fund our product development programs. We have agreed to seek stockholder approval of an amendment to our certificate of incorporation to effect an increase in our authorized shares of common stock or a reverse split in an amount sufficient to permit the exercise in full of the warrants offered hereby, which if approved will provide us with additional available shares. If we do not receive the requisite stockholder approval to enable us to issue equity in the future, our operations will likely be materially adversely impacted. There are risks associated with effecting a reverse split, including a decline in the market price of our common stock and the possibility of certain stockholders owning "odd lots" of less than 100 shares, which may be more difficult to sell, or require greater transaction costs per share to sell, than shares in "round lots" of even multiples of 100 shares. In addition, because holders of our common stock have no preemptive rights to purchase or subscribe for any unissued stock of our company, the availability of a greater number of authorized shares, whether as a result of a reverse split or an increase in the authorized number, could result in additional dilution to our existing stockholders. 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.

***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, 2019, we had federal net operating loss and tax credit carryforwards of approximately \$268.3 million and approximately \$8.5 million, respectively, and state net operating loss and tax credit carryforwards of approximately \$108.2 million and approximately \$9.1 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.

***We received a loan under the Paycheck Protection Program of the CARES Act, and all or a portion of the loan may not be forgivable.***

On April 20, 2020, we received an approximately \$0.7 million PPP Loan pursuant to the Paycheck Protection Program of the CARES Act. The PPP Loan matures in April 2022 with an annual interest rate of 1.0%. The PPP Loan has a six month deferral of payments period and may be prepaid at any time without penalty. The proceeds of the PPP Loan are to be used to retain workers and maintain payroll and make mortgage interest, lease and utility payments. Under the CARES Act, we will be eligible to apply for forgiveness of all loan proceeds used to pay payroll costs, rent, utilities and other qualifying expenses during the 24-week period following receipt of the loan, provided that we maintain our number of employees and compensation within certain parameters during such period. Not more than 40% of the forgiven amount may be for non-payroll costs. If the conditions outlined in the PPP loan program are adhered to by us, all or part of such loan could be forgiven. However, we cannot provide any assurance that we will be eligible for loan forgiveness or that any amount of the PPP loan will ultimately be forgiven by the SBA. Any forgiven amounts will not be included in our taxable income.

#### **Risks Related to Our Common Stock**

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

On August 18, 2020, we received a notice from the Nasdaq Capital Market, or Nasdaq, that because our stockholders' equity is less than \$2,500,000, we are no longer in compliance with the minimum stockholders' equity requirement for continued listing pursuant to Nasdaq Listing Rule 5550(b)(1). The proceeds of this offering, together with the wind down of our commercial operations and settlement of our debt obligations, will enable us to regain compliance with the minimum stockholders' equity requirement; however, we may not be able to maintain compliance with the minimum stockholders' equity requirement for a sufficient period of time to satisfy Nasdaq. If we are unable to demonstrate to Nasdaq's satisfaction that we will be able to sustain compliance with this requirement, Nasdaq may delist our common stock. In addition, even if we regain technical compliance with the stockholders' equity requirement, we will have to continue to meet other objective and subjective listing requirements to continue to be listed on the Nasdaq Capital Market. There can be no assurance that we will be able to maintain compliance and meet Nasdaq's minimum stockholders' equity requirements.

In addition, on September 19, 2019, we received a letter from Nasdaq notifying us that the market price of our common stock has been below the \$1.00 minimum bid price requirement for continued listing and requiring us to regain compliance with the minimum bid price requirement within 180 days. On April 17, 2020, Nasdaq notified us that the 180-day period to regain compliance with the minimum bid price requirement had been extended due to the global market impact caused by COVID-19. More specifically, Nasdaq has stated that the compliance periods for any company previously notified about non-compliance are suspended effective April 16, 2020, until June 30, 2020. On July 1, 2020, companies received the balance of any pending compliance period exception to regain compliance as a result of which we now have until November 30, 2020 to regain compliance with the minimum bid price rule. Our prior efforts to obtain stockholder approval of a reverse stock split of our outstanding shares of common stock that would increase the closing bid price of our common stock to above \$1.00 were not successful. We intend to seek stockholder approval of a reverse split in the range of one-for-15 and one-for-30 that we would have the effect of regaining compliance with the minimum bid price requirement in addition to providing sufficient authorized shares for the exercise of the warrants offered hereby. There can be no assurance that stockholders will approve such reverse split proposal in a timely manner or at all.

If our common stock is delisted, our common stock would likely then trade only in the over-the-counter market. If our common stock were to trade on the over-the-counter market, selling our common stock could be more difficult because smaller quantities of shares would likely be bought and sold, transactions could be delayed, and we could face significant material adverse consequences, including: a limited availability of market quotations for our securities; reduced liquidity with respect to our securities; a determination that our shares are a "penny stock," which will require brokers trading in our securities to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading

market for our securities; a reduced amount of news and analyst coverage for our Company; and a decreased ability to issue additional securities or obtain additional financing in the future. These factors could result in lower prices and larger spreads in the bid and ask prices for our common stock and would substantially impair our ability to raise additional funds and could result in a loss of institutional investor interest and fewer development opportunities for us.

In addition to the foregoing, if our common stock is delisted from Nasdaq and it trades on the over-the-counter market, the application of the “penny stock” rules could adversely affect the market price of our common stock and increase the transaction costs to sell those shares. The SEC has adopted regulations which generally define a “penny stock” as an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. If our common stock is delisted from Nasdaq and it trades on the over-the-counter market at a price of less than \$5.00 per share, our common stock would be considered a penny stock. The SEC’s penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document that provides information about penny stocks and the risks in the penny stock market. The broker-dealer must also provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker-dealer and the salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer’s account. In addition, the penny stock rules generally require that before a transaction in a penny stock occurs, the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser’s agreement to the transaction. If applicable in the future, these rules may restrict the ability of brokers-dealers to sell our common stock and may affect the ability of investors to sell their shares, until our common stock no longer is considered a penny stock.

***We have used almost all of our unreserved, authorized shares.***

After giving effect to this offering, we will have used almost all of our unreserved authorized shares and will need stockholder approval to implement an increase in our authorized shares of common stock or a reverse stock split. Our certificate of incorporation and the Delaware General Corporation Law, or the DGCL, currently require the approval of stockholders holding not less than a majority of all outstanding shares of capital stock entitled to vote in order to approve an increase in our authorized shares of common stock or a reverse stock split. There are no assurances that stockholder approval will be obtained, in which event will be unable to raise additional capital through the issuance of shares of common stock to fund our future operations.

***The price of our common stock may fluctuate significantly, and this may make it difficult for you to resell the common stock you want or at prices you find attractive.***

The price of our common stock constantly changes. The price of our common stock could fluctuate significantly for many reasons, including the following:

- results of our product development programs;
- future announcements concerning us, including our clinical and product development strategy, or our competitors;
- regulatory developments;
- reports and recommendations of analysts and whether or not we meet the milestones and metrics set forth in such reports;
- introduction of new products;
- fluctuations of investor interest in the pharmaceutical and healthcare sectors; and
- fluctuations in the economy, world political events or general market conditions.

The stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions,

interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our common stock and could subject us to securities class action litigation.

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

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

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

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

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

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the 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.

### **Risks Related to this Offering**

***If you purchase our securities in this offering, you may incur immediate and substantial dilution in the book value of your shares.***

The public offering price per unit may be substantially higher than the net tangible book value per share of our common stock immediately prior to the offering. After giving effect to the sale of 80,000,000 units in this offering, at a public offering price of \$0.10 per unit and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and attributing no value to the warrants sold in this offering, purchasers of our common stock in this offering will incur immediate dilution of \$(0.059) per share in the net tangible book value of the common stock they acquire. In the event that you exercise your warrants, you may experience additional dilution to the extent that the exercise price of the warrants is higher than the tangible book value per share of our common stock. For a further description of the dilution that investors in this offering may experience, see "Dilution." In addition, to the extent that outstanding stock options or warrants have been or may be exercised or other shares issued, you may experience further dilution.

***You will be unable to exercise the warrants and they may have no value under certain circumstances.***

We currently do not have authorized shares available to permit exercise of the warrants. Therefore, the warrants will not be exercisable until we obtain stockholder approval to effect an increase in our authorized shares of common stock or a reverse stock split in an amount sufficient to permit exercise in full of the warrants. If we are unable to obtain such stockholder approval, the warrants will have no value and will expire. In no event may the warrants be net cash settled. Our prior efforts to obtain stockholder approval of a reverse split were not successful. Certain investors in this offering will enter into a lock-up and voting agreement whereby each such investor will be subject to a lock-up period through the closing of this offering and will vote all shares of common stock they beneficially own on the closing date of this offering with respect to any proposals presented to the stockholders of the Company at the Company's next meeting of its stockholders, including the contemplated reverse split proposal. However, existing holders of common stock may have an incentive to vote against the proposal for an increase in our authorized shares of common stock or a reverse stock split to prevent dilution in their interests by the shares underlying the warrants. Furthermore, in the event that the price of a share of our common stock does not exceed the exercise price of the warrants during their exercise period, the warrants may not have any value.

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

Our management will have significant discretion and flexibility in applying the net proceeds of this offering that are not allocated to payment of outstanding debt and other financial obligations. You will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the net proceeds are being used appropriately. It is possible that the net proceeds will be invested in a way that does not yield a favorable, or any, return for us. The failure of our management to use such funds effectively could have a material adverse effect on our business, financial condition, operating results and cash flow.

***There is no public market for the warrants to purchase shares of our common stock being offered in this offering.***

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

***The warrants purchased in this offering do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock.***

Until you acquire shares of our common stock upon exercise of your warrants purchased in this offering, such warrants will not provide you any rights as a common stockholder, except as set forth therein. Upon exercise of your warrants purchased in this offering, you will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

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

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

## USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the securities offered by this prospectus in this offering will be approximately \$7.4 million after deducting commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering for general corporate purposes, including the costs associated with winding down our commercial operations and funding our product development programs, as well as for the settlement of our outstanding indebtedness to Horizon and Molteni, for which we have allocated \$1.6 million of proceeds. We may use a portion of the net proceeds for the acquisitions of businesses, products, technologies or licenses that are complementary to our business, although we have no present commitments or agreements to do so other than the possible acquisition of certain intellectual property rights from JT Pharma described elsewhere in this prospectus.

The allocation of the net proceeds of the offering set forth above represents our estimates based upon our current plans and assumptions regarding industry and general economic conditions, our future revenues and expenditures. The amounts and timing of our actual expenditures may vary significantly and will depend on numerous factors, regulatory requirements, cash used by our operations, the extent to which we receive project funding from government grants and other third party collaborators and other business developments and opportunities that may arise. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

We believe that the net proceeds of this offering, together with cash on hand, will be sufficient to fund our operations for more than nine months, although we will need to raise additional capital to fund JT-09 beyond the proof of concept activities, which we expect to complete in the second quarter of 2021. Additional capital may not be available on terms favorable to us, or at all. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Debt financing, if available, may involve restrictive covenants or additional security interests in our assets. Any additional debt or equity financing that we complete may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or products or grant licenses on terms that are not favorable to us. If we are unable to raise adequate funds, we may have to delay, reduce the scope of, or eliminate some or all of, our development programs or liquidate some or all of our assets.

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

## DILUTION

Purchasers of units in this offering will experience an immediate dilution of the net tangible book value per share of our common stock. Our net tangible book value as of June 30, 2020 was approximately \$1.6 million, or approximately \$0.0160 per share of our common stock. Net tangible book value per share is equal to our total tangible assets less our total liabilities, divided by the number of shares of our outstanding common stock. Dilution per share of common stock equals the difference between the amount paid by purchasers of common stock in this offering (ascribing no value to the warrants) and the net tangible book value per share of our common stock immediately after this offering.

After giving effect to the assumed sale by us of 80,000,000 units in this offering at a public offering price of \$0.10 per unit, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us and the allocation of \$1.6 million to settle outstanding indebtedness, our as adjusted net tangible book value as of June 30, 2020 would have been approximately \$7.3 million, or approximately \$0.041 per share. This represents an immediate increase in net tangible book value of approximately \$0.025 per share to existing stockholders and an immediate decrease in net tangible book value of approximately \$0.059 per share to new investors purchasing shares of our common stock and related warrants in this offering, attributing none of the assumed combined public offering price to the warrants offered hereby. The following table illustrates this per share dilution:

|   |                         |
|---|-------------------------|
| Combined public offering price per unit                           | \$ 0.10                 |
| Net tangible book value per share as of June 30, 2020             | \$0.016                 |
| Increase in net tangible book value per share after this offering | <u>0.025</u>            |
| As adjusted net tangible book value per share after this offering | <u>0.041</u>            |
| Dilution per share to new investors                               | <u><u>\$(0.059)</u></u> |

The above discussion and table is as of June 30, 2020 and excludes, as of that date:

- 917,544 shares of our common stock issuable upon exercise of outstanding options with a weighted average exercise price of \$7.44 per share;
- 26,173,376 shares of our common stock issuable upon exercise of outstanding warrants with a weighted average exercise price of \$0.56 per share (inclusive of 8,700,000 warrants for which the underlying shares had not yet been authorized);
- 3,422,777 shares issuable upon conversion of a portion of our outstanding debt; and
- 842,054 additional shares of our common stock reserved for future issuance under our 2015 equity incentive plan.

The above discussion also does not reflect the sale of 19,440,000 shares of our common stock in a registered direct offering completed in September 2020.

## DESCRIPTION OF SECURITIES WE ARE OFFERING

As of the date of this prospectus, our certificate of incorporation authorizes us to issue 225,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share. The following description of our capital stock is not complete and is subject to and qualified in its entirety by our certificate of incorporation, as amended, and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, and by the relevant provisions of the Delaware General Corporation Law.

### Units

We are offering 80,000,000 units, with each unit consisting of one share of our common stock and a warrant to purchase one share of our common stock at an assumed public offering price of \$0.10 per unit. The shares of common stock and warrants are being sold in this offering only as part of the units. However, the units will not be certificated and the common stock and warrants comprising such units are immediately separable. Upon issuance, the shares of common stock and warrants may be transferred independent of one another, subject to applicable law and transfer restrictions.

### Common Stock

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

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

### Warrants

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

*Exercisability.* The warrants are exercisable on the date we file an amendment to our certificate of incorporation to reflect our stockholders' approval of an increase in our authorized shares of common stock or a reverse stock split in an amount sufficient to permit the exercise in full of the warrants and will expire on the date that is five years after the warrants become exercisable. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice. In no event may the warrants be net cash settled.

*Stockholder Approval.* We have agreed to hold a stockholders meeting in order to seek stockholder approval for an amendment to our certificate of incorporation to effect an increase in our authorized shares of common stock or a reverse split of the common stock in an amount sufficient to permit the exercise in full of the warrants in accordance with their terms. In the event that we are unable to obtain stockholder approval and effect an increase in our authorized shares of common stock or effect a reverse split of our common stock, the warrants will not be exercisable and will have no value. In no event may the warrants be net cash settled.

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

*Exercise Price.* The warrants will have an exercise price of \$0.10 per share (100% of the per unit offering price). The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

*Cashless Exercise.* If, at the time a holder exercises its warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of the shares underlying the warrant to the holder, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the warrant.

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

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

*Fundamental Transactions.* If a fundamental transaction occurs, then the successor entity will succeed to, and be substituted for us, and may exercise every right and power that we may exercise and will assume all of our obligations under the warrants with the same effect as if such successor entity had been named in the warrant itself. If holders of our common stock are given a choice as to the securities, cash or property to be received in a fundamental transaction, then the holder shall be given the same choice as to the consideration it receives upon any exercise of the warrant following such fundamental transaction. Additionally, as more fully described in the warrant, in the event of certain fundamental transactions, the holders of the warrants will be entitled to receive consideration in an amount equal to the Black Scholes value of the warrants on the date of consummation of such transaction.

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

#### **Transfer Agent**

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

## UNDERWRITING

We have entered into an underwriting agreement with the underwriters named below with respect to the units described in this prospectus. Subject to certain conditions, we have agreed to sell to the underwriters, and the underwriters have agreed to purchase, the number of units set forth below opposite each underwriter's name. Maxim Group LLC is acting as the representatives of the underwriters.

| <b>Underwriter</b> | <b>Number of Units</b> |
|--------------------|------------------------|
| Maxim Group LLC    | 80,000,000             |
| <b>Total</b>       | <b>80,000,000</b>      |

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

### Underwriting Discounts and Expenses

The following table summarizes the underwriting discount and commission to be paid to the underwriters by us.

|  | <b>Per Unit<sup>(1)</sup></b> | <b>Total</b> |
|--|-------------------------------|--------------|
| Public offering price  | \$ 0.10                       | \$8,000,000  |
| Underwriting discount to be paid to the underwriters by us (6.0%) <sup>(1)</sup> | \$0.006                       | \$ 480,000   |
| Proceeds to us (before expenses)   | \$0.094                       | \$7,520,000  |

- (1) We have also agreed to reimburse the accountable expenses of the representative, including legal fees, in this offering, up to a maximum of \$50,000.

We have agreed to pay the underwriters an aggregate fee equal to 6.0% of the gross proceeds of this offering and expect the net proceeds from this offering to be approximately \$7.4 million after deducting \$480,000 in underwriting commissions and \$100,000 in our other estimated offering expenses. We have also agreed to pay the underwriters an accountable expense allowance for certain of the underwriters' expenses relating to the offering up to a maximum aggregate amount of \$55,000, including the underwriters' legal fees incurred in this offering.

### Right of First Refusal

We have also agreed that if the securities are sold in accordance with the terms of this prospectus, the representative of the underwriters shall have a preferential right for a period of twelve (12) months from the commencement of sales of the offering to act as sole lead managing underwriter and sole book runner, for any securities (whether public or private offerings of debt or equity or any combination thereof) we or any subsidiary or successor may seek to sell whether with or without or through an underwriter, placement agent or broker-dealer and whether pursuant to registration under the Securities Act or otherwise. The representative's failure to exercise its preferential right with respect to any particular proposal shall not affect its preferential rights relative to future proposals. The representative shall have the right to designate any other agents or underwriters in any such financing and the economics in connection with a financing that will be split with any additional agent(s) or underwriter(s) will be determined at the sole discretion of the Representative.

**Indemnification**

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

**Lock-up Agreements**

We have agreed, subject to limited exceptions, for a period of the later of 90 days after the closing of this offering or the date we file an amendment to our certificate of incorporation to reflect our stockholders' approval of an increase in our authorized shares of common stock or a reverse stock split in an amount sufficient to permit the exercise in full of the warrants and our officers and directors have agreed, subject to limited exceptions, for a period of 180 days after the closing of this offering, not to offer, sell, contract to sell, pledge, grant any option to purchase, make any short sale or otherwise dispose of, directly or indirectly any shares of common stock or any securities convertible into or exchangeable for our common stock either owned as of the date of the underwriting agreement or thereafter acquired without the prior written consent of Maxim Group LLC. Maxim Group LLC may, in its sole discretion and at any time or from time to time before the termination of the lock-up period, without notice, release all or any portion of the securities subject to lock-up agreements.

**Price Stabilization, Short Positions and Penalty Bids**

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

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- Over-allotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares over-allotted by the underwriters is not greater than the number of shares that they may purchase in the over-allotment option. In a naked short position, the number of shares involved is greater than the number of shares in the over-allotment option. The underwriters may close out any covered short position by either exercising their over-allotment option and/or purchasing shares in the open market.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the over-allotment option. A naked short position occurs if the underwriters sell more shares than could be covered by the over-allotment option. This position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

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

Neither we nor the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our shares of common stock.

In addition, neither we nor the underwriters make any representation that the underwriters will engage in these transactions or that any transaction, if commenced, will not be discontinued without notice.

#### **Electronic Distribution**

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

#### **Other**

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

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

In April 2020, we entered into an advisory agreement with Maxim Group LLC to provide general financial advisory and investment banking services. On September 28, 2020, we completed an offering of 19,440,000 shares of our common stock at a purchase price of \$0.14 per share. Maxim Group LLC acted as placement agent in connection with such transaction.

#### **Offers Outside the United States**

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction in which such an offer or a solicitation is unlawful.

## LEGAL MATTERS

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

## EXPERTS

The financial statements as of and for the years ended December 31, 2019 and 2018 incorporated by reference in this prospectus supplement constituting a part of the registration statement on Form S-3 have been so incorporated in reliance on the report of OUM & Co. LLP, an independent registered public accounting firm, incorporated herein by reference, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

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

You may read and copy all or any portion of the registration statement without charge at the public reference room of the Securities and Exchange Commission at 100 F Street, N.E., Washington, D.C. 20549. Copies of the registration statement may be obtained from the Securities and Exchange Commission at prescribed rates from the public reference room of the Securities and Exchange Commission at such address. You may obtain information regarding the operation of the public reference room by calling 1-800-SEC-0330. In addition, registration statements and certain other filings made with the Securities and Exchange Commission electronically are publicly available through the Securities and Exchange Commission's website at [www.sec.gov](http://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](http://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](http://www.titanpharm.com). Except for the specific incorporated reports and documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

## INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

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

- [our Annual Report on Form 10-K/A for the year ended December 31, 2019, filed with the SEC on March 30, 2020](#);
- our Quarterly Report on Form 10-Q for the period ended March 31, 2020, filed with the SEC on [May 15, 2020](#); our Quarterly Report on Form 10-Q for the period ended June 30, 2020, filed with the SEC on [August 14, 2020](#);
- our Current Reports on Form 8-K filed with the SEC on [April 24, 2020](#), [June 25, 2020](#), [June 29, 2020](#), [July 16, 2020](#), [August 5, 2020](#), [August 12, 2020](#), [August 13, 2020](#), [August 20, 2020](#), [September 1, 2020](#), [September 14, 2020](#), [September 18, 2020](#), [September 24, 2020](#), [October 15, 2020](#), [October 26, 2020](#) and [October 28, 2020](#);
- [our Definitive Proxy Statement, filed with the SEC on May 22, 2020](#)
- [our additional Definitive Proxy Materials filed with the SEC on June 19, 2020 and July 8, 2020](#)
- [our Preliminary Proxy Statement, filed with the SEC on October 23, 2020](#) and
- [the description of our common stock contained in our registration statement on Form 8-A \(FileNo. 001-13341\) filed under the Exchange Act on October 8, 2015, including any amendment or reports filed for the purpose of updating such descriptions.](#)

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

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

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

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

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**80,000,000 Units**

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**PROSPECTUS**

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**MAXIM GROUP LLC**

**October 28, 2020**

**Through and including November 15, 2020 (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.**

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