

The registrant is submitting this draft Registration Statement confidentially as an "emerging growth company" pursuant to Section 6(e) of the Securities Act of 1933.

As submitted confidentially to the Securities and Exchange Commission on May 14, 2015

Registration No. 333-

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM S-1  
REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933**

**vTv Therapeutics Inc.**  
*(Exact Name of Registrant as Specified in Its Charter)*

**Delaware**  
*(State or other jurisdiction of  
incorporation or organization)*

**2834**  
*(Primary Standard Industrial  
Classification Code Number)*

**47-3916571**  
*(IRS Employer  
Identification Number)*

**4170 Mendenhall Oaks Pkwy  
High Point, NC 27265  
(336) 841-0300**

*(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)*

**Stephen L. Holcombe  
President and Chief Executive Officer  
4170 Mendenhall Oaks Pkwy  
High Point, NC 27265  
(336) 841-0300**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

**With copies to:**

**Lawrence G. Wee, Esq.  
Paul, Weiss, Rifkind, Wharton & Garrison LLP  
1285 Avenue of the Americas  
New York, NY 10019-6064  
(212) 373-3000**

**Marc D. Jaffe, Esq.  
Senet S. Bischoff, Esq.  
Latham & Watkins LLP  
885 Third Avenue  
New York, NY 10022  
(212) 906-1200**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, please check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer  Accelerated filer  Non-accelerated filer  Smaller reporting company   
(Do not check if a smaller reporting company)

**CALCULATION OF REGISTRATION FEE**

Title of each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)(2)</sup>	Amount of Registration Fee
Class A Common Stock, par value \$0.01 per share	\$	\$

<sup>(1)</sup>Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

<sup>(2)</sup>Includes offering price of any additional shares that the underwriters have the option to purchase to cover over-allotments, if any.

The registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion  
Preliminary Prospectus Dated \_\_\_\_\_, 2015

PRELIMINARY PROSPECTUS



Shares  
**vTv Therapeutics Inc.**  
Class A Common Stock

This is the initial public offering of shares of our Class A common stock. We are offering \_\_\_\_\_ shares of our Class A common stock. We expect the initial public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per ordinary share. Prior to this offering, there has been no public market for our Class A common stock. We intend to apply to list our Class A common stock on The NASDAQ Global Market under the symbol "VTVT." The listing is subject to approval of our application.

We are an "emerging growth company" as defined under the federal securities laws and are eligible for reduced public company reporting requirements. Please see "Prospectus Summary—Implications of being an Emerging Growth Company." We will also be a "controlled company" under the corporate governance rules for NASDAQ-listed companies and will be exempt from certain corporate governance requirements of the rules. See "Risk Factors—Risks Relating to this Offering and Ownership of Our Class A Common Stock."

**Our business and an investment in our Class A common stock involve significant risks. These risks are described under the caption "Risk Factors" beginning on page 14 of this prospectus.**

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share	Total
Public offering price	\$ _____	\$ _____
Underwriting discount <sup>(1)</sup>	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____

<sup>(1)</sup>We refer you to "Underwriting" beginning on page 127 of this prospectus for additional information regarding total underwriter compensation.

The underwriters may also purchase up to an additional \_\_\_\_\_ shares of our Class A common stock from us at the public offering price, less the underwriting discount, within 30 days from the date of this prospectus to cover over-allotments, if any.

The underwriters expect to deliver the shares against payment in New York, New York on \_\_\_\_\_, 2015.

**Piper Jaffray**

**Stifel**

\_\_\_\_\_  
\_\_\_\_\_, 2015

[TABLE OF CONTENTS](#)

For investors outside the United States: neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus or any free writing prospectus we may provide to you in connection with this offering in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions relating to this offering and the distribution of this prospectus and any such free writing prospectus outside of the United States.

TABLE OF CONTENTS

	Page
<a href="#">Prospectus Summary</a>	<a href="#">1</a>
<a href="#">Risk Factors</a>	<a href="#">14</a>
<a href="#">Cautionary Note Regarding Forward-Looking Statements</a>	<a href="#">50</a>
<a href="#">Use of Proceeds</a>	<a href="#">52</a>
<a href="#">Dividend Policy</a>	<a href="#">53</a>
<a href="#">Capitalization</a>	<a href="#">54</a>
<a href="#">Dilution</a>	<a href="#">56</a>
<a href="#">Unaudited Pro Forma Condensed Combined Consolidated Financial Information</a>	<a href="#">58</a>
<a href="#">Selected Financial Data</a>	<a href="#">64</a>
<a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	<a href="#">65</a>
<a href="#">Business</a>	<a href="#">77</a>
<a href="#">Management</a>	<a href="#">109</a>
<a href="#">Certain Relationships and Related Party Transactions</a>	<a href="#">113</a>
<a href="#">Principal Stockholders</a>	<a href="#">117</a>
<a href="#">Description of Capital Stock</a>	<a href="#">118</a>
<a href="#">Shares Eligible for Future Sale</a>	<a href="#">121</a>
<a href="#">Certain U.S. Federal Income Tax Considerations</a>	<a href="#">123</a>
<a href="#">Underwriting</a>	<a href="#">127</a>
<a href="#">Legal Matters</a>	<a href="#">129</a>
<a href="#">Experts</a>	<a href="#">129</a>
<a href="#">Where You Can Find More Information</a>	<a href="#">129</a>
<a href="#">Index to Financial Statements</a>	<a href="#">F-1</a>

You should rely only on the information contained in this prospectus and any related free writing prospectus that we may provide to you in connection with this offering. We have not, and the underwriters have not, authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus. Our business, financial condition, results of operations and prospects may have changed since that date.

The financial information provided in this prospectus consists of the combined financial information of TransTech Pharma, LLC, which will be renamed vTvx Holdings I LLC ("vTvx Holdings I"), and High Point Pharmaceuticals, LLC, which will be renamed vTvx Holdings II LLC ("vTvx Holdings II"), which are referred to together in this prospectus as the "Predecessors." In the reorganization transactions described in "Prospectus Summary—The Reorganization Transactions" (the "Reorganization Transactions"), among other transactions, the Predecessors will directly or indirectly contribute substantially all of their assets, including all of their personnel and operations, to subsidiaries of vTv Therapeutics Inc. In this prospectus, unless otherwise indicated or the context otherwise requires, references to the "Company," "we," "us" and "our" refer to (1) subsequent to the completion of this offering and the Reorganization Transactions, vTv Therapeutics Inc. and its consolidated subsidiaries and (2) prior to the completion of this offering and the Reorganization Transactions, the Predecessors and their consolidated subsidiaries. Where we refer to measures or statistics on a "pro forma" basis, we are referring to such measures or statistics after giving

[TABLE OF CONTENTS](#)

effect to the Reorganization Transactions and this offering (including the sale by us of        shares of our Class A Common Stock at an initial public offering price equal to the midpoint of the range on the front cover of this prospectus) and the application of net proceeds from this offering.

We have proprietary rights to or are exclusively licensed to use a number of registered and unregistered trademarks that we believe are important to our business, including, without limitation, TTP Translational Technology, TTPredict, TTPSpace and TTPScreen. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

**PROSPECTUS SUMMARY**

*This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our Class A common stock. You should read this entire prospectus carefully, especially the “Risk Factors” section and our financial statements and the related notes appearing elsewhere in this prospectus, before making an investment decision.*

**Overview**

**Our Company**

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates to fill significant unmet medical needs. We have a powerful pipeline of clinical drug candidates, led by our programs for the treatment of Alzheimer’s disease (“AD”) and type 2 diabetes. Our drug candidate for the treatment of AD, *azeliragon* (TTP488), is an orally administered, small molecule antagonist targeting the receptor for advanced glycation endproducts (“RAGE”), and we have commenced patient enrollment in a Phase 3 clinical trial (the “STEADFAST Study”) under an FDA-agreed Special Protocol Assessment (“SPA”). Our type 2 diabetes drug candidates include TTP399, an orally administered, liver-selective glucokinase activator (“GKA”), for which we are currently enrolling patients in a Phase 2b clinical trial (the “AGATA Study”), and TTP273, an orally administered, non-peptide agonist that targets the glucagon-like peptide-1 receptor (“GLP-1r”), which we anticipate will enter a Phase 2 clinical trial in early 2016. We have three additional programs in various stages of clinical development for the prevention of muscle weakness and the treatment of inflammatory disorders.

**Our Pipeline**

The following table summarizes key information about our drug candidates:

Program	Preclinical	Phase 1	Phase 2	Phase 3	Status	Milestones
<b>Alzheimer’s Disease</b>						
Azeliragon (TTP488): RAGE Antagonist					Phase 3 enrolling	Topline results expected mid 2018
<b>Type 2 Diabetes</b>						
TTP399: Glucokinase Activator					Phase 2b enrolling	Topline results expected mid 2016
TTP273: Oral GLP-1r Agonist					Initiation of Phase 2 trial expected early 2016	Topline results expected late 2016
<b>Prevention of Muscle Weakness Associated with PMV and Critical Injury</b>						
HPP593: PPAR-δ Agonist					Initiation of Phase 2 trial expected late 2015	Topline results expected late 2016
<b>Inflammatory Disorders</b>						
HPP737: PDE4 Inhibitor					Initiation of Phase 2 trial expected early 2016	Topline results expected late 2016
HPP971: Bach1 Inhibitor					Phase 1 ongoing	
<b>Cancer</b>						
Hexokinase II Inhibitor					Preclinical	Licensed to Calithera Biosciences, Inc. in 2015
vTv Therapeutics Inc. retains all rights to the programs in its pipeline, except for the Hexokinase II Inhibitor program, which is licensed to Calithera Biosciences, Inc.						

**Our Alzheimer’s Disease Program – Azeliragon**

Alzheimer’s disease is a progressive neurodegenerative disorder that slowly destroys memory and thinking skills, with a number of other behavioral and neuropsychiatric symptoms. While estimates of the prevalence of AD vary, the Alzheimer’s Association estimates that in 2015 there are 5.3 million people in the

United States suffering from AD. According to Decision Resources, in 2013, there were 8.3 million AD patients in the “G7 Pharmaceutical Markets,” including 3.1 million in the United States and 5.2 million in Western Europe (France, Germany, Italy, Spain and the United Kingdom) and Japan. Mild AD patients represent approximately 64% of the overall AD population. There are currently no disease-modifying therapies approved for the treatment of AD; however, according to Decision Resources, this segment of the market is expected to grow to \$7.7 billion by 2023, representing approximately 60% of expected 2023 revenues in the global AD market.

*Azeliragon* is an orally administered, small molecule drug candidate that has the potential to be among the first FDA approved disease-modifying AD therapeutics due to its novel mechanism of action of inhibiting RAGE. Because of that potential, *azeliragon* has been awarded Fast Track designation by the FDA. RAGE is a cell surface receptor that is implicated in many of the processes thought to play a primary role in the development and progression of AD, including amyloid-beta (“A $\beta$ ”) transport into the brain, the phosphorylation of tau protein, chronic inflammation, vascular dysfunction, metabolic dysregulation and neurotoxicity. By inhibiting RAGE, *azeliragon* has the potential to slow the progression of cognitive decline in mild and mild-to-moderate AD patients. We are not aware of any other clinical-stage drugs targeting RAGE. Unlike development stage disease-modifying treatments from other companies that target a singular cause of AD, *azeliragon* is designed to interact with multiple aspects of AD etiology.

We are currently enrolling the 800-patient STEADFAST Study, a Phase 3 clinical trial, under an FDA-agreed SPA. The STEADFAST Study includes two sub-studies under one protocol. Each sub-study will enroll 400 patients with mild AD, randomized to receive a 5 mg/day dose of *azeliragon* or placebo on a one-to-one basis, and is powered to achieve statistical significance on the co-primary endpoints—change from baseline in ADAS-COG<sub>11</sub> and CDR-SB scores, which are standard measures of cognitive impairment and global function in AD patients. Our Phase 2b study of *azeliragon* in 399 mild-to-moderate AD patients demonstrated a statistically significant benefit at the 5 mg/day dose versus placebo at 18 months with respect to ADAS-COG<sub>11</sub> and a statistically significant lower frequency of psychiatric adverse events. At the same dose, we identified an even more pronounced benefit in ADAS-COG<sub>11</sub> and CDR-SB scores in an analysis of the sub-population of patients with mild AD. In all of our Phase 1 and 2 clinical trials, *azeliragon* has been shown to be generally safe and well tolerated at a dose of 5 mg/day. We expect to report topline data from the STEADFAST Study by mid-2018, at which time, with successful study results, we plan on preparing and submitting a new drug application (“NDA”) for *azeliragon* to the FDA by year-end 2018.

***Our Diabetes Programs – Glucokinase Activator (TTP399) and GLP-1r Agonist (TTP273)***

Diabetes is characterized by the body’s inability to properly use or produce insulin, the hormone necessary for the uptake of sugar from the bloodstream so that it may be converted into energy. Type 2 diabetes is an inability to properly use insulin to control sugar in the bloodstream, and 90 to 95% of diabetes patients have type 2 diabetes. According to Decision Resources, in 2013, 62.2 million adults in the G7 Pharmaceutical Markets suffered from type 2 diabetes, including 29.8 million adults in the United States aged 20 and over. There are multiple drug classes approved for the treatment of type 2 diabetes, including insulin replacement, metformin, sulfonylureas, thiazolidinedione, SGLT-2 inhibitors, DPP-4 inhibitors and injectable GLP-1r agonists. We expect our type 2 diabetes drug candidates to compete in the non-insulin segment of the market, which, according to Decision Resources, totaled sales of \$13.4 billion in the G7 Pharmaceutical Markets for 2013 and is expected to grow to \$27.0 billion by 2023. Despite the availability of these drugs, a substantial portion of type 2 diabetes patients are unable to maintain adequate control of blood glucose levels and eventually progress to insulin therapy, demonstrating the need for additional therapies with novel mechanisms of action and routes of administration to improve efficacy and patient compliance.

We are developing two distinct drug candidates for the treatment of type 2 diabetes: a liver-selective GKA (*TTP399*), for which we are currently enrolling the AGATA Study, a Phase 2b clinical trial, and an oral GLP-1r agonist (*TTP273*), for which we anticipate we will begin enrolling a Phase 2 clinical trial in early 2016.

### *Glucokinase Activator*

*TTP399* is an orally administered, small molecule liver-selective GKA. Glucokinase (“GK”) activation represents a novel mechanism of action for the treatment of type 2 diabetes. Liver-selective activation of GK provides intensive glycemic control without inducing hypoglycemia. Treatment with *TTP399* is designed to avoid the safety and tolerability issues associated with other GKA candidate drugs in clinical development. We are currently enrolling patients in a 180-patient Phase 2b trial, the AGATA Study, to demonstrate *TTP399*’s ability to improve control of blood glucose levels over a six-month period. The primary endpoint of the AGATA Study will be the change from baseline in glycosylated hemoglobin (“HbA<sub>1c</sub>”) levels. We expect to report topline results from the AGATA Study in the first half of 2016. We previously completed a six-week Phase 2a clinical trial of *TTP399* in 120 type 2 diabetes patients whose glycemic parameters were not well-controlled on metformin in which patients treated with *TTP399* showed statistically significant reductions in HbA<sub>1c</sub> levels compared with placebo without induction of hypoglycemia or hyperlipidemia and with no induction of insulin secretion. We believe that *TTP399* has the potential to be a first-in-class oral anti-diabetic drug (“OAD”) due to its liver-selectivity and novel mechanism of action.

### *GLP-1r Agonist*

*TTP273* is an orally administered, small molecule, non-peptide GLP-1r agonist. Currently available GLP-1r agonists (which are injectable peptides) are well established in terms of efficacy, including the ability to lower blood glucose, decrease HbA<sub>1c</sub> levels and induce weight loss, but their use has been limited due to their subcutaneous administration and gastrointestinal side effects, including nausea and vomiting. We believe that an orally administered GLP-1r agonist that has the metabolic effects of currently available GLP-1r agonists, without the gastrointestinal side effects typical of this class of compounds, would offer a competitive advantage compared to GLP-1r targeted treatment options currently available. We plan to initiate a 180-patient Phase 2 proof-of-concept trial for *TTP273* in early 2016 to demonstrate the efficacy of *TTP273* versus placebo in reducing HbA<sub>1c</sub> and body weight. We have previously conducted several Phase 1 trials in healthy volunteers and type 2 diabetics that showed that *TTP273* was safe and well-tolerated. Our trials have indicated that *TTP273* may have superior tolerability compared to competing products and no risk of antibody formation because *TTP273* is a small molecule. For these reasons, we believe *TTP273* has the potential to expand the market of GLP-1r agonist therapies and replace a number of current GLP-1-related therapies, including DPP-4 inhibitors and injectable GLP-1 analogues. We expect to report topline results from our Phase 2 proof-of-concept trial in late 2016. We believe that *TTP273* has the potential to become accepted as a best-in-class GLP-1r agonist due to enhanced safety and ease of administration.

### **Our Additional Product Candidates**

We have three additional programs in various stages of clinical development for the prevention of muscle weakness and the treatment of inflammatory disorders. *HPP593* is a functionally selective peroxisome proliferator-activated receptor delta (“PPAR- $\delta$ ”) agonist being developed for the prevention of muscle weakness associated with prolonged mechanical ventilation (“PMV”) and critical injury that has achieved proof-of-concept in a Phase 1b clinical trial. We plan to initiate a Phase 2 clinical trial in late 2015 and expect to report topline data in late 2016. *HPP737* is an orally administered phosphodiesterase-4 (“PDE4”) inhibitor that is being developed for the treatment of chronic obstructive pulmonary disease (“COPD”), psoriasis and other inflammatory diseases. *HPP737* was shown to be safe and well tolerated in a Phase 1 clinical trial and we plan to commence a Phase 2 trial in patients with either psoriasis or COPD in early 2016, with topline data anticipated in late 2016. *HPP971*, a Bach1 inhibitor, is being developed for the treatment of inflammation, autoimmune diseases and diseases associated with oxidative stress, and is currently in Phase 1 development.

### **Our Drug Discovery Technology Platform – TTP Translational Technology**

We developed a proprietary drug discovery platform called TTP Translational Technology, which we use to discover novel small molecule therapeutics for major diseases and to validate biological pathways and targets. All of the drug candidates in our pipeline (other than *HPP593*) were discovered using TTP Translational Technology. Our technology platform is a fully integrated drug discovery process, amenable to automation, which works to translate genomic and proteomic data into safe and effective small molecule

therapeutics in a high-throughput fashion, bypassing most of the classical requirements and bottlenecks in drug discovery. We have used this technology to discover drugs for our internal pipeline and in research collaborations with pharmaceutical and biotechnology companies.

### **Our Strategy**

Our goal is to leverage our powerful pipeline of orally administered small molecule drug candidates to deliver novel, differentiated therapies to fill significant unmet medical needs. As key components of our strategy, we intend to:

- Continue Phase 3 enrollment and seek regulatory approval of *azeliragon* as a disease-modifying treatment for patients with mild AD;
- Complete Phase 2 development of our type 2 diabetes programs;
- Evaluate strategic collaborations for the commercialization of *azeliragon*;
- Seek strategic collaborations for Phase 3 development and commercialization of our type 2 diabetes programs;
- Continue development of additional pipeline programs and seek strategic development partners for those programs; and
- Evaluate opportunities to leverage our TTP Translational Technology to discover additional drug candidates for internal or external development.

### **Our Intellectual Property**

Each of our most advanced drug candidates is the subject of patent and patent applications for composition of matter and method of use in major markets worldwide. Our patents are expected to provide us with intellectual property protection through 2029 for *azeliragon*, 2030 for *TTP399* and 2034 for *TTP273*, in each case, assuming we obtain the maximum applicable extensions in the United States.

### **Our Risks**

An investment in our Class A common stock involves a high degree of risk. You should carefully consider the risks summarized in the "Risk Factors" section of this prospectus immediately following this prospectus summary.

### **The Reorganization Transactions**

Prior to this offering and the reorganization transactions described below (collectively, the "Reorganization Transactions"), the programs, personnel, operations and other assets that will comprise our business are held by our Predecessors, vTv Holdings I and vTv Holdings II.

In the Reorganization Transactions:

- vTv Holdings I and vTv Holdings II will contribute substantially all of their assets, including all of their personnel and operations (the "Contributed Assets"), to a newly-formed holding company, vTv Therapeutics Holdings LLC ("vTv Therapeutics Holdings"), in return for interests of vTv Therapeutics Holdings. Assets that will not be contributed include restricted cash, certain receivables unrelated to our operations and land included in property and equipment, net, and liabilities that will not be assumed include debt, a contingent distribution payable and other related party liabilities. All assets and liabilities that will not be contributed or assumed will remain with vTv Holdings I and vTv Holdings II;
- vTv Therapeutics Holdings will contribute the Contributed Assets to vTv Therapeutics LLC, a newly formed Delaware limited liability company in return for non-voting units of LLC interest ("vTv Therapeutics LLC Units") in vTv Therapeutics LLC;
- vTv Therapeutics Inc. (the "Issuer") will amend and restate its certificate of incorporation and bylaws to provide that it will have two classes of common stock:
  - Class A common stock, par value \$0.01 per share, which will have economic rights and one vote per share, and



- Class B common stock, par value \$0.01 per share, which will have no economic rights and one vote per share;
- vTv Therapeutics LLC will issue a voting managing member interest (which has no economic rights) to the Issuer; and
- the Issuer will issue one share of Class B common stock, par value \$0.01 per share (which has no economic rights in the Issuer but has the right to cast one vote per share), to vTv Therapeutics Holdings for each vTv Therapeutics LLC Unit.

In this offering, the Issuer will issue \_\_\_\_\_ shares of its Class A common stock to investors for cash (or \_\_\_\_\_ shares if the underwriters exercise their over-allotment option in full). The Issuer will then use the net proceeds from this offering to purchase voting vTv Therapeutics LLC Units.

Immediately following the consummation of the Reorganization Transactions and this offering, the members of vTv Therapeutics LLC will consist of the Issuer and vTv Therapeutics Holdings, which will hold \_\_\_\_\_ vTv Therapeutics LLC Units and the same number of shares of vTv Therapeutics Inc. Class B common stock, which will represent \_\_\_\_\_ % of the combined voting power of our outstanding common stock (or \_\_\_\_\_ % if the underwriters exercise their over-allotment option in full). Entities affiliated with MacAndrews & Forbes Incorporated (“MacAndrews”) will initially bear certain costs and expenses of this offering, including the fees of attorneys, consultants, financial printers and auditors incurred by us. We will reimburse such MacAndrews affiliates using a portion of the gross proceeds of this offering. See “Certain Relationships and Related Party Transactions—Reimbursement of Expenses.”

In connection with this offering, vTv Therapeutics Holdings will enter into an Exchange Agreement, under which, from time to time, vTv Therapeutics Holdings will have the right, subject to the terms of the Exchange Agreement and the vTv Therapeutics LLC Operating Agreement, to exchange its vTv Therapeutics LLC Units (along with a corresponding number of shares of the Issuer’s Class B common stock) with vTv Therapeutics LLC for (i) shares of the Issuer’s Class A common stock on a one-for-one basis or (ii) cash (based on the market price of the shares of Class A common stock), at our option (as the managing member of vTv Therapeutics LLC), subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications. Any decision to require an exchange for cash rather than shares of Class A common stock will ultimately be determined by the entire board of directors of vTv Therapeutics Inc. (the “Board of Directors”). See “Certain Relationships and Related Party Transactions—Exchange Agreement.”

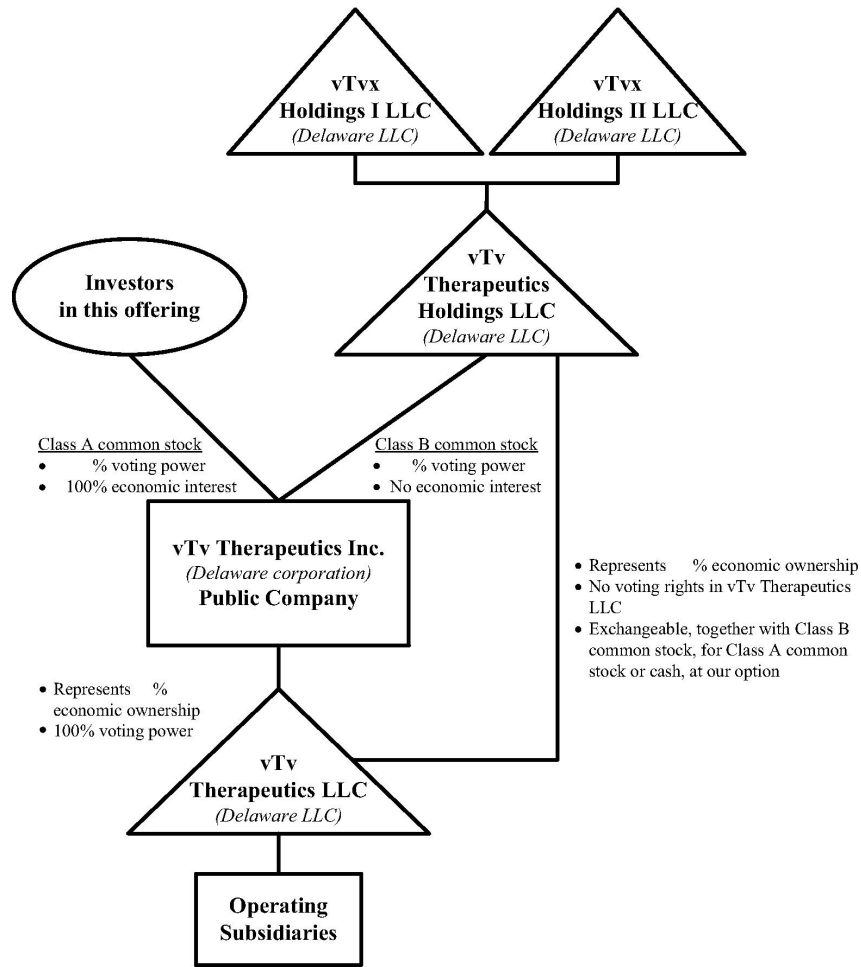
We intend to enter into a Tax Receivable Agreement with vTv Therapeutics Holdings that will provide for the payment by us to vTv Therapeutics Holdings (or its transferees or other assignees) of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that we actually realize (or, in some circumstances, we are deemed to realize) as a result of (a) the exchange of Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, for shares of our Class A common stock (or for cash), (b) tax benefits related to imputed interest deemed to be paid by us as a result of the Tax Receivable Agreement and (c) certain tax benefits attributable to payments under the Tax Receivable Agreement. See “Certain Relationships and Related Party Transactions—Tax Receivable Agreement.”

Immediately after the consummation of the Reorganization Transactions and this offering, the only asset of the Issuer will be its direct interest in vTv Therapeutics LLC and its indirect interests in the subsidiaries of vTv Therapeutics LLC. Each share of Class A common stock of the Issuer will correspond to an economic interest held by the Issuer in vTv Therapeutics LLC, whereas the shares of Class B common stock of the Issuer will have voting rights only in the Issuer and will have no economic rights of any kind. Shares of Class B common stock of the Issuer will be initially owned solely by vTv Therapeutics Holdings and cannot be transferred except in connection with an exchange or transfer of a corresponding vTv Therapeutics LLC Unit. We do not intend to list the Class B common stock on any stock exchange.

In addition, as a part of the Reorganization Transactions, vTv Therapeutics Inc. will enter into an investor rights agreement with vTv Therapeutics Holdings and certain members of our management and our board providing for various governance matters and registration rights. The investor rights agreement will contain provisions related to the composition of the Board of Directors, the committees of the Board of

Directors and certain registration rights. Under the investor rights agreement, vTv Therapeutics Holdings will be initially entitled to nominate a majority of the members of our Board of Directors. See “Management—Board Composition” and “Certain Relationships and Related Party Transactions—Investor Rights Agreement.”

The following diagram shows our corporate structure after completion of the Reorganization Transactions and this offering (assuming an initial public offering price at the midpoint of the estimated price range set forth on the cover page of this prospectus and no exercise of the underwriters’ over-allotment option):



**Our Principal Equityholder**

Following the Reorganization Transactions and this offering, MacAndrews will indirectly control shares of Class B common stock held by vTv Therapeutics Holdings and will therefore control approximately % of the combined voting power of our outstanding common stock (or % if the underwriters exercise their over-allotment option in full). As a result, MacAndrews will control any action requiring the general approval of our stockholders, including the election of our board of directors, the adoption of amendments to our certificate of incorporation and by-laws and the approval of any merger or sale of substantially all of our assets.

MacAndrews is a company that acquires and manages a diversified portfolio of public and private companies. Wholly owned by Chairman and Chief Executive Officer Ronald O. Perelman, MacAndrews' core strategy is based on investing in companies with strong market positions, high quality management with vertical expertise, recognized growth potential and ability to increase productivity. Current investments include leading participants across a wide range of industries, from biotechnology and military equipment to cosmetics and entertainment.

#### **Implications of being an Emerging Growth Company**

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or "JOBS Act." As an emerging growth company, we may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include, among other things:

- the ability to present only two years of audited financial statements, in addition to any required unaudited interim financial statements, and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- exemption from the auditor attestation requirement in the assessment of our internal controls over financial reporting;
- exemption from new or revised financial accounting standards applicable to public companies until such standards are also applicable to private companies;
- exemption from compliance with any new requirements adopted by the Public Company Accounting Oversight Board (the "PCAOB"), requiring mandatory audit firm rotation or a supplement to our auditor's report in which the auditor would be required to provide additional information about the audit and our financial statements;
- an exemption from the requirement to seek non-binding advisory votes on executive compensation and golden parachute arrangements; and
- reduced disclosure about executive compensation arrangements.

We may take advantage of these provisions until the end of the fiscal year following the fifth anniversary of our initial public offering or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have \$1.0 billion or more in "total annual gross revenues" during our most recently completed fiscal year, if we become a "large accelerated filer" with market capitalization of \$700 million or more, or as of any date on which we have issued more than \$1.0 billion in non-convertible debt over the three-year period to such date. We may choose to take advantage of some, but not all, of these reduced burdens. For example, we have taken advantage of the reduced reporting requirement with respect to disclosure regarding our executive compensation arrangements, have presented only two years of audited financial statements and only two years of related "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus and expect to take advantage of the exemption from auditor attestation on the effectiveness of our internal control over financial reporting. For as long as we take advantage of the reduced reporting obligations, the information that we provide shareholders may be different from information provided by other public companies. We are irrevocably electing to "opt out" of the extended transition period relating to the exemption from new or revised financial accounting standards and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies.

In addition, upon the closing of this offering, we will be a "controlled company" within the meaning of the NASDAQ corporate governance standards because more than 50% of our voting common stock will be indirectly owned by MacAndrews. For further information on the implications of this distinction, see "Risk Factors—Risks Relating to this Offering and Ownership of Our Class A Common Stock" and "Management—Board Committees."

**Corporate Information**

We were incorporated in Delaware under the name vTv Therapeutics Inc. in April 2015. Our principal executive offices are located at 4170 Mendenhall Oaks Pkwy, High Point, North Carolina 27265, and our telephone number is (336) 841-0300. Our website address is [www.vtvtherapeutics.com](http://www.vtvtherapeutics.com). Our website and the information contained on, or that can be accessed through, our website will not be deemed to be incorporated by reference in, and are not considered part of, this prospectus. You should not rely on our website or any such information in making your decision whether to purchase our Class A common stock.

<b>The Offering</b>	
Issuer	vTv Therapeutics Inc.
Class A common stock offered	shares.
Class A common stock to be outstanding after this offering and the use of proceeds therefrom	shares ( shares if the underwriters exercise their over-allotment option in full).
Class B common stock to be outstanding after this offering and the use of proceeds therefrom	shares. Each share of our Class B common stock will have one vote on all matters submitted to a vote of stockholders but will have no economic rights (including no rights to dividends or distributions upon liquidation). Shares of our Class B common stock will be issued to vTv Therapeutics Holdings. The aggregate voting power of the outstanding Class B common stock will be equal to the aggregate percentage of vTv Therapeutics LLC Units held by vTv Therapeutics Holdings. See “Description of Capital Stock.”
Voting rights	One vote per share; Class A common stock and Class B common stock vote together as a single class on all matters submitted to a vote of stockholders. See “Description of Capital Stock.”
Exchange	Subject to the terms and conditions of the vTv Therapeutics LLC Operating Agreement, vTv Therapeutics LLC Units (along with a corresponding number of shares of our Class B common stock) held by vTv Therapeutics Holdings may, subject to the terms of the Exchange Agreement, be exchanged with vTv Therapeutics LLC at any time for (i) shares of our Class A common stock on a one-for-one basis or (ii) cash (based on the market price of the shares of Class A common stock), at our option (as the managing member of vTv Therapeutics LLC), subject to customary exchange rate adjustments for stock splits, stock dividends and reclassifications. Any decision to require an exchange for cash rather than shares of Class A common stock will ultimately be determined by our entire Board of Directors. When a vTv Therapeutics LLC Unit and the corresponding share of our Class B common stock are exchanged by a holder of vTv Therapeutics LLC Units for a share of Class A common stock or for cash, the corresponding share of our Class B common stock will be canceled.
Controlled company	Because, on a pro forma basis, vTv Therapeutics Holdings is expected to beneficially own more than 50% of the voting power of our outstanding voting stock, we expect to avail ourselves of the “controlled company” exemptions under the rules of the NASDAQ, including exemptions from the requirement to have a majority of independent directors, the requirement to have a fully independent nominating and corporate governance committee and the requirement to have a fully independent compensation committee.

Over-allotment option	We have granted to the underwriters an option to purchase up to additional shares of Class A common stock from us at the initial public offering price (less underwriting discounts and commissions) to cover over-allotments, if any, for a period of 30 days from the date of this prospectus.
Use of proceeds	We estimate that the net proceeds from the sale of our Class A common stock in this offering before the payment of expenses will be approximately \$ million (\$ million if the underwriters exercise their over-allotment option in full) based on an assumed initial public offering price of \$ per share (the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus). vTv Therapeutics Inc. will use the net proceeds of this offering to acquire vTv Therapeutics LLC Units from vTv Therapeutics LLC. We intend to use such proceeds to fund the STEADFAST Study, further clinical development of our drug candidates and for working capital and other general corporate purposes. Entities affiliated with MacAndrews will initially bear certain costs and expenses of this offering, including the fees of attorneys, consultants, financial printers and auditors incurred by us. We will reimburse such MacAndrews affiliates using a portion of the gross proceeds of this offering. For additional information, see “Use of Proceeds.”
Dividend policy	We do not intend to pay dividends on our common stock or to make distributions from vTv Therapeutics LLC to its members (other than to vTv Therapeutics Inc. to fund its operations). We plan to retain any earnings for use in the operation of our business and to fund future growth.
Listing	We have applied to list our Class A common stock on NASDAQ under the symbol “VTVT.”
Tax Receivable Agreement	We intend to enter into a Tax Receivable Agreement with vTv Therapeutics Holdings that will provide for the payment by us to vTv Therapeutics Holdings (or its transferees or other assignees) of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that we actually realize (or, in some circumstances, we are deemed to realize) as a result of (a) the exchange of Class B common stock, together with the corresponding number of vTv Therapeutics Holdings LLC Units, for shares of our Class A common stock (or for cash), (b) tax benefits related to imputed interest deemed to be paid by us as a result of the Tax Receivable Agreement and (c) certain tax benefits attributable to payments under the Tax Receivable Agreement. See “Certain Relationships and Related Party Transactions—Tax Receivable Agreement.”
Risk factors	Investing in our Class A common stock involves a high degree of risk. Please read “Risk Factors” beginning on page 14 of this prospectus for a discussion of factors you should carefully consider before deciding to purchase shares of our Class A common stock.
<p>Except as otherwise indicated, all information in this prospectus:</p>	
<ul style="list-style-type: none"> <li>assumes no exercise of the underwriters’ option to purchase additional shares of Class A common stock to cover over-allotments;</li> </ul>	

[TABLE OF CONTENTS](#)

- assumes        shares are issuable under options to purchase shares of Class A common stock, restricted stock units or other similar awards, including those that may be granted in connection with this offering under the vTv Therapeutics Inc. 2015 Omnibus Equity Incentive Plan (the “2015 Plan”);
- assumes        shares of Class A common stock are reserved for issuance upon the exchange of vTv Therapeutics LLC Units (along with the corresponding number of shares of our Class B common stock); and
- assumes an initial public offering price of \$        per share (the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus).

## SUMMARY HISTORICAL AND PRO FORMA FINANCIAL DATA

vTv Therapeutics Inc. was formed in April 2015 and does not have historical financial data. The historical financial data presented in this prospectus are the historical combined financial data of our Predecessors, vTv Holdings I and vTv Holdings II. The summary statement of operations data for the years ended December 31, 2014 and 2013 are derived from the audited combined consolidated statements of operations of the Predecessors for such periods, which are included in this prospectus. The summary balance sheet data as of December 31, 2014 are derived from the audited combined balance sheets of the Predecessors as of such date, which is included in this prospectus. The summary unaudited pro forma condensed combined consolidated statement of operations data for the year ended December 31, 2014 gives pro forma effect to the Reorganization Transactions, this offering and the application of the net proceeds from this offering as if they had been completed as of January 1, 2014, and the summary unaudited pro forma condensed combined consolidated balance sheet data as of December 31, 2014 gives pro forma effect to the Reorganization Transactions, this offering and the application of the net proceeds from this offering as if they had been completed as of December 31, 2014, in each case, as described in "Unaudited Pro Forma Condensed Combined Consolidated Financial Information." The summary unaudited pro forma condensed combined consolidated financial data are presented for information purposes only and should not be considered indicative of actual results of operations that would have been achieved had the Reorganization Transactions and this offering been consummated on the dates indicated, and do not purport to be indicative of statements of financial position or results of operations as of any future date or for any future period.

You should read the Summary Historical and Pro Forma Financial Data together with the sections entitled "Capitalization," "Selected Financial Data," "Unaudited Pro Forma Condensed Combined Consolidated Financial Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

	Years Ended December 31,		Pro Forma Year Ended December 31,
	2013	2014	2014
	(Predecessor)		
<b>(dollars in thousands, except for per unit and per share data)</b>			
<b>Statement of operations data:</b>			
Revenue	\$ 976	\$ 1,549	\$ 1,549
Operating expenses:			
Research and development	25,434	18,729	18,729
General and administrative	11,375	11,717	11,717
Total operating expenses	36,809	30,446	30,446
Operating loss	(35,833)	(28,897)	(28,897)
Other income (expense), net	41	(503)	(503)
Other (expenses) – related party	(575)	(623)	—
Interest (expense)	(476)	(282)	—
Interest (expense), net – related party	(11,346)	(5,727)	—
Investment (loss) – related party	(14)	(69)	—
Combined net loss	\$ (48,203)	\$ (36,101)	\$ (29,400)
<b>vTv Holdings I:</b>			
Net loss per member unit, basic and diluted	\$ (12.82)	\$ (16.81)	
Units used to compute basic and diluted net loss per member unit <sup>(1)</sup>	13,288,327	13,263,676	
<b>vTv Holdings II:</b>			
Net earnings (loss) per member unit, basic and diluted	\$ 0.06	\$ (0.64)	
Units used to compute basic and diluted net earnings (loss) per member unit <sup>(1)</sup>	19,597,888	19,570,078	
Pro forma net loss per share, basic and diluted (unaudited) <sup>(2)</sup>	\$	\$	\$
Shares used to compute pro forma net loss per share, basic and diluted (unaudited) <sup>(2)</sup>			



<sup>(1)</sup>See Note 16 (for the periods ended December 31, 2013 and 2014) of our Notes to Combined Consolidated Financial Statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per common unit.

<sup>(2)</sup>The calculations for the unaudited pro forma net loss per common share, basic and diluted, assume the conversion of all outstanding vTv Therapeutics LLC Units (along with a corresponding number of shares of our Class B common stock) for shares of our Class A common stock on a one-for-one basis, as if the conversion had occurred at the beginning of the period presented.

	<u>As of December 31, 2014</u>	
	<u>Predecessor</u>	<u>Pro Forma</u>
<b>(dollars in thousands)</b>		
<b>Balance sheet data:</b>		
Cash and cash equivalents	\$ 1,384	\$
Working capital deficiency	(5,253)	
Total assets	12,951	
Current liabilities	6,864	
Long-term debt, net of current portion	29,420	
Other liabilities	37,387	
vTv Holdings I and vTv Holdings II redeemable convertible preferred units	438,086	
Total members' deficit	(498,806)	

## RISK FACTORS

*An investment in shares of our Class A common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, before deciding to invest in our Class A common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our Class A common stock could decline, and you may lose all or part of your investment.*

### **Risks Relating to Our Financial Position and Need for Additional Capital**

***We have incurred significant losses since inception and anticipate that we will incur continued losses for the foreseeable future. We may never achieve or maintain profitability.***

We are a clinical-stage biopharmaceutical company with limited operating history. We have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since beginning to develop our drug candidates, including net losses of approximately \$36.1 million and \$48.2 million for 2014 and 2013, respectively. As of December 31, 2014, we had a total members' deficit of approximately \$498.8 million. In addition, we have not commercialized any products and have never generated any revenue from the commercialization of any product. We have devoted most of our financial resources to research and development, including our preclinical development activities and clinical trials. We expect to incur significant additional operating losses for the next several years, at least, as we conduct our research and development activities, advance drug candidates through clinical development, complete clinical trials, seek regulatory approval and, if we receive FDA approval, commercialize our products. Furthermore, the costs of advancing drugs into each succeeding clinical phase tend to increase substantially over time. The total costs to advance any of our drug candidates to marketing approval in even a single jurisdiction would be substantial. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to begin generating revenue from the commercialization of products or achieve or maintain profitability. We expect to incur increased expenses as we continue our parallel group 18-month 800-patient Phase 3 trial of *azeliragon*, or the STEADFAST Study, begin outsourcing of the commercial manufacturing of *azeliragon* for any indications for which we receive regulatory approval, advance our other drug candidates and expand our research and development programs. Furthermore, our ability to successfully develop, commercialize and license our products and generate product revenue is subject to substantial additional risks and uncertainties, as described under “—Risks Relating to the Development and Regulatory Approval of Our Drug Candidates” and “—Risks Relating to the Commercialization of Our Drug Candidates.” As a result, we expect to continue to incur net losses and negative cash flows for the foreseeable future. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. The amount of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues. In addition, we may not be able to enter into any collaborations that will generate significant cash. If we are unable to develop and commercialize one or more of our drug candidates either alone or with collaborators, or if revenues from any drug candidate that receives marketing approval are insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. If we are unable to achieve and then maintain profitability, the value of our equity securities will be materially and adversely affected.

***Currently, we have no products approved for commercial sale, and to date we have not generated any revenue from product sales. As a result, our ability to generate revenue from products, curtail our losses and reach profitability is unproven, and we may never generate substantial product revenue.***

We have no products approved for commercialization and have never generated any revenue from the commercialization of any product. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of, and obtain the regulatory and marketing approvals necessary to commercialize one or more of our product candidates. We do not anticipate generating revenue from product sales for a number of years. Our ability

to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and nonclinical and clinical development of our product candidates;
- obtaining regulatory and marketing approvals for product candidates for which we complete clinical studies;
- establishing collaborations for the development of certain of our drug candidates;
- establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain regulatory and marketing approval, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting and expanding our portfolio of intellectual property rights; and
- attracting, hiring and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory authorities to perform clinical and other studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

***We will need additional capital to complete the STEADFAST Study and to complete the development and commercialization of azeliragon and our other drug candidates. Even if this offering is successful, if we are unable to raise sufficient capital, we would be forced to delay, reduce or eliminate our product development programs.***

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue the STEADFAST Study, undertake additional clinical trials of our other drug candidates and continue to work on our other research programs. The expected net proceeds of this offering will not be sufficient for us to complete the STEADFAST Study, and we expect that we will need to raise substantial additional capital to complete the development and commercialization of *azeliragon*. We expect to fund a portion of the STEADFAST Study through licensing or other monetization of our other drug candidates, including *TTP399* and *TTP273*. If we are unable to successfully license our other drug candidates, we will need to raise additional capital to finance the completion of the STEADFAST Study through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements.

If the FDA or other regulators require that we perform additional studies beyond those we currently expect, or if there are any delays in completing our clinical trials or the development of any of our drug candidates, our expenses could increase beyond what we currently anticipate and the timing of any potential product approval may be delayed. We have no commitments or arrangements for any additional financing to fund our research and development programs. We also will need to raise substantial additional capital in the future to complete the development and commercialization of *azeliragon* for additional indications and for developing our other drug candidates. Because successful development of our drug candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize and license our products under development.

Until we can generate a sufficient amount of revenue from our drug candidates, if ever, we expect to finance future cash needs through equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our research or development programs. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time. If worldwide economic conditions and the international equity and credit markets deteriorate and return to depressed states, it will be more difficult for us to obtain additional equity or credit financing, when needed.

Our future capital requirements will depend on many factors, including:

- the progress, costs, results and timing of the STEADFAST Study, and the clinical development of *azeliragon*;
- the willingness of the FDA to accept the STEADFAST Study, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and approval of *azeliragon*;
- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue, including our drug candidates in preclinical development;
- the ability of our drug candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing, establishing and maintaining commercialization capabilities;
- the costs of acquiring, licensing or investing in businesses, products, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems; and
- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future.

***Raising additional capital may cause dilution to our stockholders, including purchasers of Class A common stock in this offering, restrict our operations or require us to relinquish rights to our technologies or drug candidates.***

Until such time, if ever, as we can generate substantial revenue, we may finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our

technologies, future revenue streams or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market drug candidates that we would otherwise prefer to develop and market ourselves.

***We have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.***

We are a clinical stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to developing our technology and undertaking preclinical studies and clinical trials of *azeliragon* and our other drug candidates. We have not yet obtained regulatory approvals for *azeliragon* or any of our other drug candidates. Consequently, any statements about our future success or viability are not based on any substantial operating history or commercialized products. Our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter or year-to-year due to a variety of factors, many of which are beyond our control. As a result, we may never successfully develop and commercialize a product, which could lead to a material adverse effect on the value of any investment in our securities.

#### **Risks Relating to the Development and Regulatory Approval of Our Drug Candidates**

***Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any drug candidate we advance through various stages of clinical trials or development may not have favorable results in later stages of clinical trials or development or receive regulatory approval.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical trials. In addition, data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For example, although treatment in our Phase 2b clinical trial in mild-to-moderate AD patients was discontinued early due to the findings of an interim futility analysis conducted approximately 12 months after all subjects were randomized, subsequent statistical analyses conducted in accordance with the protocol-specified statistical analysis plan found a statistically significant improvement, as described further under “Business—Our Alzheimer’s Program – *Azeliragon*—Completed Phase 2b Trial (TTP488-203).” Furthermore, an analysis of *azeliragon* in the subgroup of AD patients with MMSE scores of 21-26 (which are the mild AD patients that are the subjects of our Phase 3 STEADFAST Study) found that *azeliragon* had more pronounced efficacy in that subgroup. While we have reached an agreement with the FDA for our Phase 3 trial of *azeliragon* under a special protocol assessment, or SPA, there can be no assurance that the results of this Phase 3 trial will be consistent with the findings of our analyses. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a drug candidate. Frequently, drug candidates that have shown promising results in early clinical trials have subsequently suffered significant setbacks in later clinical trials. In addition, the design of a clinical trial can determine whether its results will support approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. While members of our management team have experience in designing clinical trials, our company has limited experience in designing clinical trials, and we may be unable to design and execute a clinical trial to support regulatory approval. Further, clinical trials of potential products often reveal that it is not practical or feasible to continue development efforts. For example, if the results of the STEADFAST Study do not achieve the primary efficacy endpoints or demonstrate safety, the prospects for approval of *azeliragon* would be materially and adversely affected. If *azeliragon* or our other drug candidates are found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for them and our business would be harmed.

***While we have negotiated a special protocol assessment, or SPA, agreement with the FDA relating to the STEADFAST Study, this agreement does not guarantee approval of azeliragon or any other particular outcome from regulatory review of the study or the drug candidate.***

We have reached agreement with the FDA to conduct the STEADFAST Study, our Phase 3 trial of *azeliragon* pursuant to an SPA agreement. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial design and data analysis plans, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the drug candidate with respect to its effectiveness against the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA. Nevertheless, an SPA agreement does not guarantee approval of a drug candidate, and even if the FDA agrees to the design, execution and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, an SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after an SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

In addition to the risk that the FDA may decide it is not bound by the terms of the SPA, our Phase 3 trial may not be completed in material accordance with the SPA agreement and the data generated may not meet the endpoints that have been agreed in the SPA to represent adequate evidence of effectiveness, and, for those or other reasons, may not result in any FDA approval for *azeliragon*. We expect that the FDA will review our compliance with the protocol under our SPA agreement and that it will conduct inspections of some of the approximately 100 sites where the clinical trial will be conducted. Each of the clinical trial sites may not pass such FDA inspections, and negative inspection results could significantly delay or prevent any potential approval for *azeliragon*. Even if we believe that the data collected from the Phase 3 trial demonstrate adequate evidence of efficacy in accordance with the SPA, if the FDA revokes or alters its agreement under the SPA, or if the FDA interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations.

***We cannot be certain that azeliragon or any of our other drug candidates will receive regulatory approval, and without regulatory approval we will not be able to market our drug candidates and generate revenue from products. Any delay in the regulatory review or approval of azeliragon or any of our other drug candidates will materially or adversely harm our business.***

We have invested a significant portion of our efforts and financial resources in the development of *azeliragon*, our most advanced drug candidate. Our ability to generate revenue related to product sales, which we do not expect will occur for at least the next several years, if ever, will depend on the successful development and regulatory approval of our drug candidates. We commenced the STEADFAST Study in April 2015. We may conduct the STEADFAST Study only to learn that *azeliragon* is not a safe or effective treatment, in which case the STEADFAST Study may not lead to regulatory approval for *azeliragon*. Similarly, our clinical development programs for our other drug candidates may not lead to regulatory approval from the FDA and similar foreign regulatory agencies. This failure to obtain regulatory approvals would prevent our drug candidates from being marketed and would prevent us from generating revenue from our drug candidates, which would have a material and adverse effect on our business.

All of our drug candidates require regulatory review and approval prior to commercialization, and generally, only a small percentage of pharmaceutical products under development are ultimately approved

for commercial sale. Moreover, any delays in the regulatory review or approval of our drug candidates would delay market launch, increase our cash requirements and result in additional operating losses.

The process of obtaining FDA and other required regulatory approvals, including foreign approvals, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Furthermore, this approval process is extremely complex, expensive and uncertain, and failure to comply with applicable regulatory requirements can, among other things, result in the suspension of regulatory approval as well as possible civil and criminal sanctions. We may be unable to submit any new drug application, or an NDA, in the United States or any marketing approval application in foreign jurisdictions for any of our products. If we submit an NDA including any amended NDA or supplemental NDA, to the FDA seeking marketing approval for any of our drug candidates, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any of these submissions will be accepted for filing and reviewed by the FDA, or that the marketing approval application submissions to any other regulatory authorities will be accepted for filing and review by those authorities. We cannot be certain that we will be able to respond to any regulatory requests during the review period in a timely manner, or at all, without delaying potential regulatory action. We also cannot be certain that any of our drug candidates will receive favorable recommendations from any FDA advisory committee or foreign regulatory bodies or be approved for marketing by the FDA or foreign regulatory authorities. In addition, delays in approvals or rejections of marketing applications may be based upon many factors, including regulatory requests for additional analyses, reports, data and studies, regulatory questions regarding data and results, changes in regulatory policy during the period of product development and the emergence of new information regarding *azeliragon* or our other drug candidates.

Data obtained from preclinical studies and clinical trials are subject to different interpretations, which could delay, limit or prevent regulatory review or approval of any of our drug candidates. Furthermore, regulatory attitudes towards the data and results required to demonstrate safety and efficacy can change over time and can be affected by many factors, such as the emergence of new information, including on other products, policy changes and agency funding, staffing and leadership. We do not know whether future changes to the regulatory environment will be favorable or unfavorable to our business prospects.

In addition, the environment in which our regulatory submissions may be reviewed changes over time. For example, average review times at the FDA for NDAs have fluctuated over the last ten years, and we cannot predict the review time for any of our submissions with any regulatory authorities. Review times can be affected by a variety of factors, including budget and funding levels and statutory, regulatory and policy changes. Moreover, in light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of the U.S. Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of Risk Evaluation and Mitigation Strategy, or "REMS," measures that may, for instance, place restrictions on the distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to delay or terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or may result in approval for a more limited indication than originally sought.

In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a drug candidate's clinical development and may vary among jurisdictions, and approval in one jurisdiction does not guarantee approval in any other jurisdiction. Our drug candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;

## TABLE OF CONTENTS

- we may be unable to demonstrate that a drug candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our drug candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our drug candidates, which would significantly harm our business, results of operations and prospects.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our drug candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a drug candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. For example, even if *azeliragon* receives regulatory approval, it may not be approved by the FDA as a disease modifying treatment. To date, the FDA has not approved any drugs for the treatment of AD as disease modifying. Any of the foregoing scenarios could materially harm the commercial prospects for our drug candidates.

### ***Delays in the commencement, enrollment and completion of our clinical trials could result in increased costs to us and delay or limit our ability to obtain regulatory approval for azeliragon and our other drug candidates.***

Delays in the commencement, enrollment and completion of clinical trials could increase our product development costs or limit the regulatory approval of our drug candidates. We commenced the STEADFAST Study in April 2015; however, this clinical trial may not be completed on schedule, if at all. In addition, we do not know whether planned clinical trials of *azeliragon* in additional indications and of our other drug candidates will begin on time or will be completed on schedule or at all. The commencement, enrollment and completion of the STEADFAST Study or other clinical trials can be delayed for a variety of reasons, including:

- inability to reach agreements on acceptable terms with prospective CROs and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- regulatory objections to commencing a clinical trial;
- inability to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs, including some that may be for the same indication as our drug candidates;
- withdrawal of clinical trial sites from our clinical trials as a result of changing standards of care or the ineligibility of a site to participate in our clinical trials;
- inability to obtain institutional review board, or IRB, approval to conduct a clinical trial;



## TABLE OF CONTENTS

- difficulty recruiting and enrolling subjects to participate in clinical trials for a variety of reasons, including willingness of subjects to undergo required study procedures, meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our drug candidates;
- inability to retain subjects in clinical trials due to the treatment protocol, personal issues, side effects from the therapy or lack of efficacy; and
- difficulty in importing and exporting clinical trial materials and study samples.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- failure to pass inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities;
- failure of any contract manufacturing organizations, or CMOs, that we use to comply with current Good Manufacturing Practices, or cGMPs;
- unforeseen safety issues or any determination that a clinical trial presents unacceptable health risks;
- failure to demonstrate benefit from using the drug;
- changes in the regulatory requirement and guidance; or
- lack of adequate funding to continue the clinical trial due to unforeseen costs resulting from enrollment delays, requirements to conduct additional trials and studies, increased expenses associated with the services of our CROs and other third parties or other reasons.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our drug candidates, the commercial prospects of our drug candidates will be harmed, and our ability to generate product revenues from any of these drug candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our drug candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates.

***We have never completed a Phase 3 clinical trial or submitted an NDA before, and may be unable to do so for azeliragon and other drug candidates we are developing.***

We commenced the STEADFAST Study in April 2015. The conduct of Phase 3 clinical trials and the submission of a successful NDA is a complicated process. We have never conducted a Phase 3 clinical trial before, have limited experience in preparing, submitting and prosecuting regulatory filings, and have not submitted an NDA before. Consequently, we may be unable to successfully and efficiently execute and complete these planned clinical trials in a way that leads to NDA submission and approval of *azeliragon* and other drug candidates we are developing. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of drug candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials would prevent or delay commercialization of *azeliragon* and other drug candidates we are developing.

***Our drug candidates may cause serious adverse events or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales.***

Serious adverse events or undesirable side effects from *azeliragon* or any of our other drug candidates could arise either during clinical development or, if approved, after the approved product has been marketed. The results of future clinical trials, including the STEADFAST Study, may show that our drug candidates cause serious adverse events or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other regulatory authorities or could result in a more restrictive label if our drug candidates are approved. To date, patients treated with *azeliragon* at a dose of 20 mg/day experienced a higher level of adverse events including confusion and falls, but such elevated levels of adverse events were not observed at the 5 mg/day dose.

If *azeliragon* or any of our other drug candidates cause serious adverse events or undesirable side effects either during clinical development, or after marketing approval, if obtained:

- regulatory authorities, IRBs, or the DSMB may impose a clinical hold, or we may decide on our own to suspend or terminate a study, which could result in substantial delays and adversely impact our ability to continue development of the product;
- regulatory authorities may require the addition of labeling statements, specific warnings, contraindications or field alerts to study subjects, investigators, physicians or pharmacies;
- we may be required to change the product design or the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be required to implement a REMS, which could result in substantial cost increases or signification limitations on distribution or have a negative impact on our ability to successfully commercialize the product;
- we may be required to limit the patients who can receive the product;
- we may be subject to limitations on how we promote the product;
- sales of the product may decrease significantly;
- regulatory authorities may require us to take our approved product off the market;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from obtaining approval, or achieving or maintaining market acceptance of the affected product, if approved, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products.

***Azeliragon and our other drug candidates employ novel mechanisms of action and may never be approved or accepted by their intended markets.***

*Azeliragon* and a number of our other drug candidates have novel mechanisms of action. *Azeliragon* targets RAGE, a novel mechanism of action for the treatment of AD. We are not aware of any other products under development that target RAGE. Our future success depends on our ability to complete the STEADFAST Study of *azeliragon* successfully, obtain market approval for and successfully commercialize *azeliragon*, as well as our ability to develop and market other drug candidates. The scientific discoveries that form the basis of our drug candidates are relatively new. We are not aware of any other drugs for the treatment of AD that have the same mechanism of action as *azeliragon* and even if *azeliragon* is approved, physicians may not be willing to use it. If we do not successfully develop and commercialize drug candidates based upon our technological approach, we may not become profitable and the value of our common stock may decline.

Evidence of the effectiveness of *azeliragon* in humans is limited to data generated in a single Phase 2b study and to the group of patients in that study receiving the lower, 5 mg/day, dose of the drug. Patients in that study who received the higher, 20 mg/day, dose of the drug tended to experience adverse events. The FDA has granted Fast Track designation to our *azeliragon* development program based on our pre-clinical (animal) studies and not based on our Phase 2b study. The results of the Phase 2b study may not be replicated in our Phase 3 STEADFAST Study, and the FDA may not approve *azeliragon* for commercial use.

In addition, regulatory approval of novel drug candidates such as *azeliragon* and our other drug candidates using novel mechanisms of action can be more expensive and take longer than other, more well-known or extensively studied pharmaceutical or biopharmaceutical products, due to our and regulatory agencies' lack of experience with them. We are not aware of the FDA reviewing any other products targeting RAGE as a mechanism of action to date. This lack of experience may lengthen the regulatory review process, require us to conduct additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these drug candidates or lead to significant post-approval limitations or restrictions.

**Risks Relating to the Commercialization of Our Drug Candidates**

***If any of our drug candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that are generated from their sales will be limited.***

The commercial success of *azeliragon* and our other drug candidates, if approved, will depend upon the acceptance of these products among physicians, healthcare payors, patients and others in the medical community. The degree of market acceptance of our drug candidates will depend on a number of factors, including:

- limitations or warnings contained in a product's FDA-approved labeling;
- changes in the standard of care or the availability of alternative therapies for the targeted indications for any of our drug candidates;
- limitations in the approved indications for our drug candidates;
- demonstrated clinical safety and efficacy compared to other products;
- lack of significant adverse side effects;
- education, sales, marketing and distribution support;
- availability and degree of coverage and reimbursement from third-party payors;
- timing of market introduction and perceived effectiveness of competitive products;
- cost-effectiveness;
- availability of alternative therapies at similar or lower cost, including generics, biosimilar and over-the-counter products;
- adverse publicity about our drug candidates or favorable publicity about competitive products;

## TABLE OF CONTENTS

- convenience and ease of administration of our products;
- potential product liability claims; and
- government-imposed pricing restrictions.

If our drug candidates are approved, but do not achieve an adequate level of acceptance by physicians, healthcare payors, patients and others in the medical community, sufficient revenue may not be generated from these products, and we may not become or remain profitable. In addition, efforts to educate the medical community and third-party payors on the benefits of our drug candidates may require significant resources and may never be successful.

***We do not have the capability to sell, distribute and market our drug candidates. If we are unable to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements, we may not be able to commercialize our drug candidates successfully.***

We do not have the capability to sell, distribute and market our drug candidates. We will need to build a commercial organization or secure a strategic partner to commercialize *azeliragon* and our other drug candidates. If we are unable to build a commercial infrastructure or secure a strategic collaboration, our business and results of operations will be materially and adversely affected. Development of an internal commercial organization will require substantial resources and will be time consuming. These costs may be incurred in advance of any approval of our drug candidates. In addition, we may not be able to hire a sales force in the United States that is sufficient in size or has adequate expertise in the markets that we intend to target. If we are unable to establish a sales and marketing capability, our operating results may be adversely affected. If we seek to enter into sales and marketing or licensing arrangements with third parties for the marketing and sale of any approved products, we may be unable to enter into any such arrangements on acceptable terms, or at all.

***Even if our drug candidates receive regulatory approval, we will still be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense, and we may still face future development and regulatory difficulties.***

Even if regulatory approval is obtained for any of our drug candidates, regulatory authorities may still impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. Given the number of high profile adverse safety events with certain drug products, regulatory authorities may require, as a condition of approval, costly REMS, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, expedited reporting of certain adverse events, pre-approval of promotional materials and restrictions on direct-to-consumer advertising. For example, any labeling approved for any of our drug candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications or patient populations. Furthermore, any new legislation addressing drug safety issues could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements.

Our drug candidates will also be subject to ongoing regulatory requirements for the labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information. In addition, sellers of approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMP. As such, we and our CMOs are subject to continual review and periodic inspections to assess compliance with cGMP and the terms and conditions of approvals. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. We will also be required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. As such, we may not promote our products for indications or uses for which they do not have approval.

## TABLE OF CONTENTS

If a regulatory agency discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or objects to the promotion, marketing or labeling of a product, it may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our drug candidates fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters;
- mandate modifications to promotional materials or require us to disseminate corrective information to healthcare practitioners or other parties;
- require us to enter into a consent decree or permanent injunction, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

The FDA's policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our drug candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***We expect that our existing and future drug candidates will face competition, and most of our competitors have significantly greater resources than we do.***

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies, generic or biosimilar drug companies, universities and other research institutions. Our drug candidates, if successfully developed and approved, will compete in crowded and competitive markets. In order to compete with approved products, our drug candidates will need to demonstrate compelling advantages. We believe the key competitive factors that will affect the development and commercial success of our drug candidates are efficacy, safety and tolerability profile, mechanism of action, control and predictability, convenience of dosing and price and reimbursement. Our most advanced drug candidate, *azeliagon*, is being developed for use in the treatment of patients with mild AD receiving a standard of care with an acetylcholinesterase inhibitor and/or memantine. If approved for this indication, new competitors may emerge and *azeliagon* may face competition from several therapies currently in clinical development that address different mechanisms of action than *azeliagon*. Potential competitors with products in late stage clinical development are Eli Lilly and Company, with its drug candidates solanezumab and gantenerumab, and Merck & Co., with its drug candidate MK-8931. Our drug candidates *TTP399* and *TTP273*, compounds for treating type 2 diabetes, would compete with both currently available non-insulin medication products and marketed non-insulin anti-diabetic agents that are in clinical development. Competition is high among novel drug classes for the treatment of type 2 diabetes. Products that are currently available that may compete with *TTP399* and *TTP273* include DPP-4 inhibitors, such as sitagliptin or saxagliptin, and SGLT-2 inhibitors, such as dapagliflozin and canagliflozin. Companies with GKAs in early clinical development that may compete with *TTP399* include Advinus Therapeutics Ltd., Eli Lilly and Company, Pfizer Inc., Hua Medicine Ltd. and Teijin Pharma Limited. *TTP273* would face competition from GLP-1r agonists that are being developed and are currently available, including Trulicity, which is marketed by Eli Lilly and Company, Tanzeum, which is marketed by GlaxoSmithKline plc, Bydureon, which is marketed by AstraZeneca plc, and Victoza, which is marketed by Novo Nordisk A/S.

Many of our potential competitors have substantially greater:

- resources, including capital, personnel and technology;
- research and development capability;
- clinical trial expertise;
- regulatory expertise;
- intellectual property rights, including patent rights;
- expertise in obtaining, maintaining, defending and enforcing intellectual property rights, including patent rights;
- manufacturing and distribution expertise; and
- sales and marketing expertise.

In addition, academic and government institutions are increasingly likely to enter into exclusive licensing agreements with commercial enterprises, including our competitors, to market commercial products based on technology developed at such institutions. Many of these competitors have significant products approved or in development that could be competitive with our products.

Accordingly, our competitors may be more successful than us in obtaining regulatory approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, less costly, or more effectively marketed and sold, than any drug candidate we may commercialize and may render our drug candidates obsolete or non-competitive before we can recover the expenses of their development and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our drug candidates non-competitive or obsolete.

***Healthcare cost containment initiatives and the growth of managed care may limit our revenues and profitability.***

Our ability to commercialize our products successfully may be negatively affected by the ongoing efforts of governmental and third-party payors to contain the cost of health care. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, was passed, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These automatic reductions include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers

and cancer treatment centers. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

Both governmental and third-party payers are challenging the cost of healthcare products and services, denying or limiting coverage and reimbursement amounts for new therapeutic products, for FDA-approved products considered experimental or investigational or used for disease indications without FDA marketing approval. Any restrictions in coverage or reductions in reimbursement rates under government programs often result in reductions in reimbursement rates by insurance companies and other third-party payors.

Even if we succeed in bringing *azeliragon* or any of our other drug candidates to the market, we may not be considered cost-effective, and governmental or third-party payor coverage and reimbursement might not be available or sufficient. If adequate governmental or third-party coverage or reimbursement is not available, we may not be able to maintain price levels sufficient to realize an appropriate return on our investment in research and product development. In addition, legislation and regulations affecting the pricing of pharmaceuticals may change in ways adverse to us before or after any of our proposed products are approved for marketing.

Therefore, adverse changes in third-party payor coverage and reimbursement and/or new state and federal healthcare reform measures that may be adopted in the future could have a material adverse effect on our businesses, financial conditions and results of operations.

***Our current and future relationships with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable healthcare laws and regulations.***

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers (actual and potential) and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- federal civil and criminal false claims laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or

under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act and its implementing regulations, which imposed annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for payments and “transfers of value” provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business activities, including our relationships with physician consultants, some of whom may prescribe our product candidates, if approved, in the future, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business.

***If we try to obtain approval to commercialize any products outside the United States, many of the same risks that apply to obtaining approvals in the United States will likely apply to such a process, and even if we obtain approval to commercialize any such products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business.***

If we try to obtain approval to commercialize any of our products outside the United States, many of the same risks with respect to obtaining such approvals in the United States will apply to that process. If *azeliagon* or any of our other drug candidates are approved for commercialization outside of the United States, we intend to enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. In that event, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals;
- reduced protection for intellectual property rights, including trade secret and patent rights;



## TABLE OF CONTENTS

- existing tariffs, trade barriers and regulatory requirements and expected or unexpected changes;
- economic weakness, including inflation, or political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more or less common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, hurricanes, floods and fires; and
- difficulty in importing and exporting clinical trial materials and study samples.

### ***Our business and operations would suffer in the event of computer system failures, cyber-attacks or a deficiency in our cyber-security.***

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Also, confidential patient and other information may be compromised in a cyber-attack or cyber-intrusion. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, damage to our reputation, and the further development of our drug candidates could be delayed.

### **Risks Relating to Our Dependence on Third Parties**

#### ***We may not succeed in establishing and maintaining collaborative relationships, which may significantly limit our ability to develop and commercialize our drug candidates successfully, if at all.***

We intend to seek collaborative relationships for the development and commercialization of our drug candidates, including *azeliragon*. Failure to obtain a collaborative relationship for *azeliragon*, particularly in the European Union and for other markets requiring extensive sales efforts, may significantly impair the potential for this drug candidate. We also will need to enter into collaborative relationships to provide funding to support our other research and development programs. The process of establishing and maintaining collaborative relationships is difficult, time-consuming and involves significant uncertainty, including:

- a collaboration partner may shift its priorities and resources away from our drug candidates due to a change in business strategies, or a merger, acquisition, sale or downsizing;
- a collaboration partner may seek to renegotiate or terminate their relationships with us due to unsatisfactory clinical results, manufacturing issues, a change in business strategy, a change of control or other reasons;
- a collaboration partner may cease development in therapeutic areas which are the subject of our strategic collaboration;

## TABLE OF CONTENTS

- a collaboration partner may not devote sufficient capital or resources towards our drug candidates;
- a collaboration partner may change the success criteria for a drug candidate thereby delaying or ceasing development of such candidate;
- a significant delay in initiation of certain development activities by a collaboration partner will also delay payment of milestones tied to such activities, thereby impacting our ability to fund our own activities;
- a collaboration partner could develop a product that competes, either directly or indirectly, with our drug candidate;
- a collaboration partner with commercialization obligations may not commit sufficient financial or human resources to the marketing, distribution or sale of a product;
- a collaboration partner with manufacturing responsibilities may encounter regulatory, resource or quality issues and be unable to meet demand requirements;
- a partner may exercise a contractual right to terminate a strategic alliance;
- a dispute may arise between us and a partner concerning the research, development or commercialization of a drug candidate resulting in a delay in milestones, royalty payments or termination of an alliance and possibly resulting in costly litigation or arbitration which may divert management attention and resources; and
- a partner may use our products or technology in such a way as to invite litigation from a third party.

For example, we previously licensed the development of *azeliragon* to Pfizer Inc. in 2006, before Pfizer determined not to pursue the development of the program and we reacquired *azeliragon* in 2011, and Forest Laboratories had previously licensed our GKA programs, including *TTP399*, but decided to return the GKA programs to us in 2013, shortly before its acquisition by Actavis plc. Any collaborative partners we enter into agreements with in the future may also shift their priorities and resources away from our drug candidates or seek to renegotiate or terminate their relationships with us.

If any collaborator fails to fulfill its responsibilities in a timely manner, or at all, our research, clinical development, manufacturing or commercialization efforts related to that collaboration could be delayed or terminated, or it may be necessary for us to assume responsibility for expenses or activities that would otherwise have been the responsibility of our collaborator. If we are unable to establish and maintain collaborative relationships on acceptable terms or to successfully transition terminated collaborative agreements, we may have to delay or discontinue further development of one or more of our drug candidates, undertake development and commercialization activities at our own expense or find alternative sources of capital.

***We rely on third parties to conduct, supervise and monitor certain of our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.***

We rely on contract research organizations, or “CROs,” and clinical trial sites to ensure the proper and timely conduct of certain of our clinical trials, including the STEADFAST Study. While we have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs’ activities. Nevertheless, we will be responsible for ensuring that our clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the FDA’s good clinical practices requirements, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA enforces these GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA may determine that our clinical trials did not comply with GCPs. In addition, our clinical trials conducted by third parties will

require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a drug candidate. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, our clinical trials may be delayed or we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical trials. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our drug candidates. As a result, our financial results and the commercial prospects for such drug candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We also rely on other third parties to store and distribute drug products for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our drug candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

***We do not have multiple sources of supply for the components used in azeliragon and our other drug candidates. If we were to lose a supplier, it could have a material adverse effect on our ability to complete the development of azeliragon or our other drug candidates. If we obtain regulatory approval for azeliragon or our other drug candidates we would need to expand the supply of its components in order to commercialize them.***

We do not have multiple sources of supply for the components used in *azeliragon* and our other drug candidates. We also do not have long-term supply agreements with any of our suppliers. We expect that we would need to significantly expand our supply for the components used in our drug candidates to meet potential demand if any of our drug candidates are approved and we commercialize them. If for any reason we are unable to obtain drug compounds from a supplier, we would have to seek to obtain it from another manufacturer. We may not be able to establish additional sources of supply for our drug candidates, or may be unable to do so on acceptable terms. Such suppliers are subject to regulatory requirements, covering manufacturing, testing, quality control and record keeping relating to our drug candidates and subject to ongoing inspections by the regulatory agencies. Failure by any of our suppliers to comply with applicable regulations may result in long delays and interruptions.

The number of suppliers of the raw material components of our drug candidates is limited. In the event it is necessary or desirable to acquire supplies from an alternative supplier, we might not be able to obtain them on commercially reasonable terms, if at all. It could also require significant time and expense to redesign our manufacturing processes to work with another company.

As part of any marketing approval, a manufacturer and its processes are required to be qualified by the FDA prior to commercialization. If supply from the approved supplier is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA amendment or supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

If we are unable to obtain the supplies we need at a reasonable price or on a timely basis, it could have a material adverse effect on our ability to complete the development of *azeliragon* and our other drug candidates or, if we obtain regulatory approval for *azeliragon* or our other drug candidates, to commercialize them.

***We intend to rely on third-party manufacturers to produce our drug candidates. If we experience problems with any of these suppliers, the manufacturing of our drug candidates or products could be delayed.***

We do not have the capability to manufacture our drug candidates and do not intend to develop that capability. In order to continue to develop our drug candidates, apply for regulatory approvals and

ultimately commercialize products, we need to develop, contract for or otherwise arrange for the necessary manufacturing capabilities. The facilities used by our CMOs to manufacture our drug candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products. If our CMOs cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved.

In addition, there are a limited number of manufacturers that operate under the FDA's cGMP regulations capable of manufacturing our drug candidates. As a result, we may have difficulty finding manufacturers for our drug candidates with adequate capacity for our needs. If we are unable to arrange for third-party manufacturing of our drug candidates on a timely basis, or to do so on commercially reasonable terms, we may not be able to complete development of our drug candidates or market them.

Reliance on third-party manufacturers entails risks to which we might not be subject if we manufactured drug candidates ourselves, including:

- the limited number of manufacturers that could produce our drug candidates for us;
- the inability to meet our product specifications and quality requirements consistently;
- inability to access production facilities on a timely basis;
- inability or delay in increasing manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for commercial level activity;
- a failure to satisfy the FDA's cGMP requirements and similar foreign standards on a consistent basis;
- the inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a single sources of supply which, if unavailable, would delay our ability to complete our clinical trials or to sell any product for which we have received marketing approval;
- the lack of qualified backup suppliers for supplies that are currently purchased from a single source supplier;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver products under specified storage conditions and in a timely manner.

Any of these risks could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our products, cause us to incur higher costs and prevent us from commercializing our drug candidates successfully. Manufacturing of our drug candidates and any approved products could be disrupted or halted if our third-party manufacturers do not comply with cGMP or foreign manufacturing standards, even if the compliance failure does not relate to our drug candidates or approved products. Furthermore, if any of our drug candidates are approved and our third-party manufacturers fail to deliver the required commercial quantities of finished product on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a

substantially equivalent cost, in substantially equivalent volumes and quality and on a timely basis, we would likely be unable to meet demand for our products and could lose potential revenue. It may take several years to establish an alternative source of supply for our drug candidates and to have any such new source approved by the FDA or a foreign regulator.

### **Risks Relating to Our Intellectual Property**

***It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection.***

Our commercial success will depend in part on our ability to:

- apply for, obtain, maintain and enforce patents;
- protect trade secrets; and
- operate without infringing upon the proprietary rights of others.

We will be able to protect our proprietary technology from unauthorized use by third parties only to the extent that such proprietary rights are covered by valid and enforceable patents or are effectively maintained as trade secrets. Any non-confidential disclosure to or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

As of May 1, 2015, we were the owner of record of at least 35 issued U.S. patents and at least 150 issued non-U.S. patents, as well as the licensee of at least 11 issued U.S. patents and at least 55 issued non-U.S. patents. We are actively pursuing 16 U.S. patent applications, of which two are provisional and 14 are non-provisional, four international patent applications and at least 110 non-U.S. patent applications in twelve or more jurisdictions as the owner of record, in addition to at least one U.S. patent application and one non-U.S. patent application under license.

The patent application process, also known as patent prosecution, is expensive and time-consuming, and we and our current or future licensors and licensees may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current licensors, or any future licensors or licensees, will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, these and any of our patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims or inventorship. If we or our current licensors or licensees, or any future licensors or licensees, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our current licensors or licensees, or any future licensors or licensees, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Any of these outcomes could impair our ability to prevent competition from third parties, which may harm our business.

The patent applications that we own or license may fail to result in issued patents in the United States or in other countries. Even if patents do issue on such patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. For example, U.S. patents can be challenged by any person before the new USPTO Patent Trial and Appeals Board at any time within the one year period following that person's receipt of an allegation of infringement of the patents. Patents granted by the European Patent Office may be similarly opposed by any person within nine months from the publication of the grant. Similar proceedings are available in other jurisdictions, and in the United States, Europe and other jurisdictions third parties can raise questions of validity with a patent office even before a patent has granted. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is successfully challenged, then our ability to commercialize such product candidates could be negatively affected, and we

may face unexpected competition that could harm our business. Further, if we encounter delays in our clinical trials, the period of time during which we or our collaborators could market our product candidates under patent protection would be reduced.

The degree of future protection of our proprietary rights is uncertain. Patent protection may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we might not have been the first to invent or the first to file the inventions covered by each of our pending patent applications and issued patents;
- others may be able to make, use, sell, offer to sell or import products that are similar to our products or product candidates but that are not covered by the claims of our patents; others may independently develop similar or alternative technologies or duplicate any of our technologies;
- the proprietary rights of others may have an adverse effect on our business;
- any proprietary rights we do obtain may not encompass commercially viable products, may not provide us with any competitive advantages or may be challenged by third parties;
- any patents we obtain or our in-licensed issued patents may not be valid or enforceable; or
- we may not develop additional technologies or products that are patentable or suitable to maintain as trade secrets.

If we or our current licensors or licensees, or any future licensors or licensees, fail to prosecute, maintain and enforce patent protection for our product candidates, our ability to develop and commercialize our product candidates could be harmed and we might not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to our product candidates could harm our business, financial condition and operating results. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. If we or one of our collaborators were to initiate legal proceedings against a third party to enforce a patent covering the product candidate, the defendant could assert an affirmative defense or counterclaim that our patent is not infringed, invalid and/or unenforceable. In patent litigation in the United States, defendant defenses and counterclaims alleging noninfringement, invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, anticipation or obviousness, and lack of written description, definiteness or enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld material information from the USPTO, or made a misleading statement, during prosecution. The outcomes of proceedings involving assertions of invalidity and unenforceability are unpredictable. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which would render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of, but that we do not believe are relevant to our current or future patents, that could nevertheless be determined to render our patents invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability of our patents covering one of our product candidates, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would harm our business. Moreover, our competitors could counterclaim in any suit to enforce our patents that we infringe their intellectual property. Furthermore, some of our competitors have substantially greater intellectual property portfolios, and resources, than we do.

Our ability to stop third parties from using our technology or making, using, selling, offering to sell or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities. If any patent we currently or in the future may own or license is deemed not infringed, invalid or unenforceable, it could impact our commercial success. We cannot predict the breadth of claims that may be issued from any patent applications we currently or may in the future own or license from third parties.

To the extent that consultants or key employees apply technological information independently developed by them or by others to our product candidates, disputes may arise as to who has the proprietary rights to such information and product candidates, and certain of such disputes may not be resolved in our favor. Consultants and key employees that work with our confidential and proprietary technologies are required to assign all intellectual property rights in their inventions and discoveries created during the scope of their work to our company. However, these consultants or key employees may terminate their relationship with us, and we cannot preclude them indefinitely from dealing with our competitors.

***If we are unable to prevent disclosure of our trade secrets or other confidential information to third parties, our competitive position may be impaired.***

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. Our ability to stop third parties from obtaining the information or know-how necessary to make, use, sell, offer to sell or import our products or practice our technology is dependent in part upon the extent to which we prevent disclosure of the trade secrets that cover these activities. Trade secret rights can be lost through disclosure to third parties. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our trade secrets to third parties, resulting in loss of trade secret protection. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how, which would not constitute a violation of our trade secret rights. Enforcing a claim that a third party is engaged in the unlawful use of our trade secrets is expensive, difficult and time consuming, and the outcome is unpredictable. In addition, recognition of rights in trade secrets and a willingness to enforce trade secrets differs in certain jurisdictions.

***Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a “first to file” system. The first-to-file provisions, however, only became effective on March 16, 2013. Accordingly, it is not yet clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaborators’ patent applications and the enforcement or defense of our or our collaborators’ issued patents, all of which could harm our business, results of operations and financial condition.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation could harm our business.***

Our commercial success depends significantly on our ability to operate without infringing, violating or misappropriating the patents and other proprietary rights of third parties. Our own technologies may infringe, violate or misappropriate the patents or other proprietary rights of third parties, or we may be

subject to third-party claims of such infringement. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties, exist in the fields in which we are developing our product candidates. Because some patent applications may be maintained in secrecy until the patents are issued, because publication of patent applications is often delayed, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that we were the first to invent the technology or that others have not filed patent applications for technology covered by our pending applications. We may not be aware of patents that have already issued that a third party might assert are infringed by our product candidates. It is also possible that patents of which we are aware, but which we do not believe are relevant to our product candidates, could nevertheless be found to be infringed by our product candidates. Moreover, we may face patent infringement claims from non-practicing entities that have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect. In the future, we may agree to indemnify our manufacturing partners against certain intellectual property claims brought by third parties.

Intellectual property litigation involves many risks and uncertainties, and there is no assurance that we will prevail in any lawsuit brought against us. Third parties making claims against us for infringement, violation or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. Defense of these claims, regardless of their merit, would cause us to incur substantial expenses and, would be a substantial diversion of resources from our business. In the event of a successful claim of any such infringement, violation or misappropriation, we may need to obtain licenses from such third parties and we and our partners may be prevented from pursuing product development or commercialization and/or may be required to pay damages. We cannot be certain that any licenses required under such patents or proprietary rights would be made available to us, or that any offer to license would be made available to us on commercially reasonable terms. If we cannot obtain such licenses, we and our collaborators may be restricted or prevented from manufacturing and selling products employing our technology. These adverse results, if they occur, could adversely affect our business, results of operations and prospects, and the value of our shares.

***We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.***

The biotechnology and pharmaceutical industries have been characterized by extensive litigation regarding patents and other intellectual property rights. The defense and prosecution of contractual or intellectual property lawsuits, USPTO interference or derivation proceedings, European Patent Office oppositions and related legal and administrative proceedings in the United States, Europe and other countries, involve complex legal and factual questions. As a result, such proceedings may be costly and time-consuming to pursue and their outcome is uncertain.

Litigation may be necessary to:

- protect and enforce our patents and any future patents issuing on our patent applications;
- enforce or clarify the terms of the licenses we have granted or may be granted in the future;
- protect and enforce trade secrets, know-how and other proprietary rights that we own or have licensed, or may license in the future; or
- determine the enforceability, scope and validity of the proprietary rights of third parties and defend against alleged patent infringement.

Competitors may infringe our intellectual property. As a result, we may be required to file infringement claims to stop third-party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patent claims do not cover its technology or that the factors necessary to grant an injunction against an infringer are not satisfied. An adverse determination of any litigation or other proceedings could put one or more of our patents at risk of being invalidated, interpreted



narrowly, or amended such that they do not cover our product candidates. Moreover, such adverse determinations could put our patent applications at risk of not issuing, or issuing with limited and potentially inadequate scope to cover our product candidates or to prevent others from marketing similar products.

Interference, derivation or other proceedings brought at the USPTO, may be necessary to determine the priority or patentability of inventions with respect to our patent applications or those of our licensors or potential collaborators. Litigation or USPTO proceedings brought by us may fail or may be invoked against us by third parties. Even if we are successful, domestic or foreign litigation or USPTO or foreign patent office proceedings may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed.

Some of our competitors may be able to sustain the costs of patent-related disputes, including patent litigation, more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

***We may not be able to enforce our intellectual property rights throughout the world.***

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States do not afford intellectual property protection to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

***If we do not obtain patent term extensions for our drug candidates, our business may be materially harmed.***

Depending upon the timing, duration and specifics of any FDA marketing approval of our drug candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act. The Hatch-Waxman Act permits a patent extension term of up to five years as compensation for patent term lost

during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. For example, patents providing intellectual property protection for *azeliagon* are scheduled to expire in 2023, but if we obtain the maximum possible extension in the United States, a period of patent extension for the approved *azeliagon* product could extend into 2029. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following the original expiration dates of our patents, and our business may be materially harmed.

#### **Risks Relating to Employee Matters and Managing Growth**

##### ***We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.***

As we advance our drug candidates through preclinical studies and clinical trials and develop new drug candidates, we will need to increase our product development, scientific and administrative headcount to manage these programs. If we commercialize our products, we will be required to expand our staff further, particularly in sales and marketing. See “—Risks Relating to the Commercialization of Our Drug Candidates.” We do not have the capability to sell, distribute and market our drug candidates. If we are unable to establish an effective sales force and marketing infrastructure, or enter into acceptable third-party sales and marketing or licensing arrangements, we may not be able to commercialize our drug candidates successfully. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees with the expertise and experience we will require;
- manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites;
- develop a marketing, distribution and sales infrastructure if we seek to market our products directly; and
- continue to improve our operational, manufacturing, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

##### ***We may not be able to manage our business effectively if we are unable to attract and retain key personnel.***

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of our executive officers and key employees identified in the “Management” section of this prospectus. If we lose one or more of our executive officers or key personnel, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees may terminate their employment at any time. Replacing executive officers and key employees may be difficult, will be costly and

may take an extended period of time because of the limited number of individuals in our industry with the mix of skills and experience required to develop, gain regulatory approval of and commercialize products successfully. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these additional key personnel. Our failure to attract and retain key personnel could materially harm our business.

***Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.***

As a public company, we will operate in an increasingly demanding regulatory environment, which requires us to comply with applicable provisions of the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

We will need to hire additional finance personnel and build our financial infrastructure as we transition to operating as a public company, including complying with the applicable requirements of Section 404 of the Sarbanes-Oxley Act. We may be unable to do so on a timely basis.

Until we are able to expand our finance and administrative capabilities and establish necessary financial reporting infrastructure, we may not be able to prepare and disclose, in a timely manner, our financial statements and other required disclosures or comply with the applicable provisions of the Sarbanes-Oxley Act or existing or new reporting requirements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed and investors could lose confidence in our reported financial information.

***Our employees, independent contractors, principal investigators, CROs, consultants and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants and collaborators may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate the regulations of the FDA and non-U.S. regulators, including those laws requiring the reporting of true, complete and accurate information to the FDA and non-U.S. regulators, healthcare fraud and abuse laws and regulations in the United States and abroad, or laws that require the reporting of true and accurate financial information and data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. These activities also include the improper use or disclosure of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations.

## Other Risks Relating to Our Business

***We may use our financial and human resources to pursue a particular research program or drug candidate and fail to capitalize on programs or drug candidates that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and human resources, we intend to focus primarily on the regulatory approval of *azeliragon*, including the completion of the STEADFAST Study. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on existing and future drug candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate, or we may allocate internal resources to a drug candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of any future products we develop.***

We face an inherent risk of product liability as a result of the clinical testing of our drug candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for *azeliragon* or any future drug candidates or products we develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or cancellation of clinical trials;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- the inability to commercialize any products we develop; and
- a decline in our share price.

Our inability to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims could prevent or inhibit the commercialization of *azeliragon* or any future products we develop. We currently carry clinical trial liability insurance in the amount of \$10,000,000 in the aggregate. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and

we may not have, or be able to obtain, sufficient capital to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing *azeliragon*, we intend to expand our insurance coverage to include the sale of *azeliragon*, however, we may be unable to obtain this liability insurance on commercially reasonable terms.

***Our operations involve hazardous materials, which could subject us to significant liabilities.***

Our research and development processes involve the controlled use of hazardous materials, including medical waste. Our operations produce hazardous waste products. We cannot eliminate the risk of accidental contamination or discharge or injury from these materials. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of these materials. We could be subject to civil damages in the event of exposure of individuals to hazardous materials. In addition, claimants may sue us for injury or contamination that results from our use of these materials and our liability may exceed our total assets. We have general liability and umbrella insurance of up to \$6 million per occurrence, with an annual aggregate limit of \$7 million, which excludes pollution liability. This coverage may not be adequate to cover all claims related to our hazardous materials. Furthermore, if we were to be held liable for a claim involving hazardous materials, this liability could exceed our insurance coverage, if any, and our other financial resources. Compliance with environmental and other laws and regulations may be expensive and current or future regulations may impair our research, development or production efforts.

***Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities.***

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include general liability, employment practices liability, property, auto, workers' compensation, umbrella, clinical trial and directors' and officers' insurance. We also expect that operating as a public company will make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our Board of Directors, our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.

***The market for our proposed products is rapidly changing and competitive, and new drugs and new treatments that may be developed by others could impair our ability to maintain and grow our businesses and remain competitive.***

The pharmaceutical and biotechnology industries are subject to rapid and substantial technological change. Developments by others may render proposed products noncompetitive or obsolete, or we may be unable to keep pace with technological developments or other market factors. Technological competition from pharmaceutical and biotechnology companies, universities, governmental entities and others diversifying into the field is intense and is expected to increase.

As a company with nominal revenues engaged in the development of drug technologies, our resources are limited, and we may experience technical challenges inherent in such technologies. Competitors have developed or are in the process of developing technologies that are, or in the future may be, the basis for competition. Some of these technologies may have an entirely different approach or means of accomplishing similar therapeutic effects compared to our proposed products. Our competitors may develop drugs that are safer, more effective or less costly than our proposed products and, therefore, present a serious competitive threat to us.

The potential widespread acceptance of therapies that are alternatives to those of ours may limit market acceptance of our drug candidates, even if commercialized. Some of our targeted diseases and conditions can also be treated by other medication. These treatments may be widely accepted in medical communities and have a longer history of use. The established use of these competitive drugs may limit the potential for our technologies, formulations and products to receive widespread acceptance if commercialized.

Therefore, changes in the market for our products and the availability of new or alternative treatments could have a material adverse effect on our businesses, financial conditions and results of operations.

### **Risks Relating to this Offering and Ownership of Our Class A Common Stock**

#### ***MacAndrews has substantial influence over our business, and their interests may differ from our interests or those of our other stockholders.***

Following this offering, MacAndrews will continue to hold a majority of our combined voting power. Due to its ownership and rights under our investor rights agreement, amended and restated certificate of incorporation and amended and restated bylaws, MacAndrews has the power to control us and our subsidiaries, including the power to:

- nominate a majority of our directors, elect a majority of our directors and appoint our executive officers, set our management policies and exercise overall control over our company and subsidiaries;
- agree to sell or otherwise transfer a controlling stake in our company; and
- determine the outcome of substantially all actions requiring stockholder approval, including transactions with related parties, corporate reorganizations, acquisitions and dispositions of assets and dividends.

The interests of MacAndrews may differ from our interests or those of our other stockholders and the concentration of control in MacAndrews will limit other stockholders' ability to influence corporate matters. The concentration of ownership and voting power with MacAndrews may also delay, defer or even prevent an acquisition by a third party or other change of control of our company and may make some transactions more difficult or impossible without the support of MacAndrews, even if such events are in the best interests of our other stockholders. The concentration of voting power with MacAndrews may have an adverse effect on the price of our Class A common stock. Our company may take actions that our other stockholders do not view as beneficial, which may adversely affect our results of operations and financial condition and cause the value of your investment to decline.

#### ***Our directors who have relationships with MacAndrews may have conflicts of interest with respect to matters involving our company.***

Following this offering, the majority of our directors will be affiliated with MacAndrews. These persons will have fiduciary duties to us and in addition will have duties to MacAndrews. In addition, our amended and restated certificate of incorporation will provide that no officer or director of MacAndrews who is also an officer, director, employee or other affiliate of MacAndrews or an officer, director or employee of an affiliate of MacAndrews will be liable to us or our stockholders for breach of any fiduciary duty by reason of the fact that any such individual directs a corporate opportunity to MacAndrews or their affiliates instead of us, or does not communicate information regarding a corporate opportunity to us that such person or affiliate has directed to MacAndrews or its affiliates. As a result, such circumstances may entail real or apparent conflicts of interest with respect to matters affecting both us and MacAndrews, whose interests, in some circumstances, may be adverse to ours. In addition, as a result of MacAndrews' indirect ownership interest, conflicts of interest could arise with respect to transactions involving business dealings between us and MacAndrews or their affiliates, including potential business transactions, potential acquisitions of businesses or properties, the issuance of additional securities, the payment of dividends by us and other matters.

#### ***We do not anticipate paying cash dividends on our Class A common stock, and accordingly, stockholders must rely on stock appreciation for any return on their investment.***

We have never declared or paid any cash dividend on our Class A common stock and do not anticipate paying cash dividends on our Class A common stock in the future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, the only return to stockholders will be appreciation in the price of our Class A common stock, which may never occur. Investors seeking cash dividends should not invest in our Class A common stock.

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

The initial public offering price for our shares will be determined by negotiations between us and the representative of the underwriters and may not be indicative of prices that will prevail in the trading market. The market price of shares of our Class A common stock could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- results and timing of our clinical trials;
- results of clinical trials of our competitors' products;
- failure or discontinuation of any of our research programs;
- delays in the development or commercialization of our potential products;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated fluctuations in our financial condition and operating results;
- actual or anticipated changes in our growth rate relative to our competitors;
- actual or anticipated fluctuations in our competitors' operating results or changes in their growth rate;
- competition from existing products or new products that may emerge;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or scientific personnel;
- disputes or other developments related to proprietary rights, including patents, litigation matters and our ability to obtain, maintain, defend or enforce proprietary rights relating to our products and technologies;
- announcement or expectation of additional financing efforts;
- sales of our Class A common stock by us, our insiders or our other stockholders;
- issues in manufacturing our potential products;
- market acceptance of our potential products;
- market conditions for biopharmaceutical stocks in general; and
- general economic and market conditions.

Furthermore, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively impact the market price of shares of our Class A common stock. In addition, such fluctuations could subject us to securities class action litigation, which could result in substantial costs and divert our management's attention from other business concerns, which could potentially harm our business. If the market price of shares of our Class A common stock after this offering does not exceed the initial public offering price, you may not realize any return on your investment in us and may lose some or all of your investment.

**No public market for our Class A common stock currently exists and an active trading market may not develop or be sustained following this offering.**

Prior to this offering, there has been no public market for our Class A common stock. An active trading market may not develop following the completion of this offering or, if developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

**If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.**

The trading market for our Class A common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We do not currently have and may never obtain research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our Class A common stock after this offering, and such lack of research coverage may adversely affect the market price of our Class A common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

**A substantial portion of our total outstanding shares may be sold into the market at any time. This could cause the market price of our Class A common stock to drop significantly, even if our business is doing well.**

The market price of our Class A common stock could decline as a result of sales of a large number of shares of our Class A common stock or the perception that such sales could occur. These sales, or the possibility that these sales may occur, also might make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate. After the consummation of this offering, we will have \_\_\_\_\_ shares of outstanding Class A common stock on a fully diluted basis, assuming that all the vTv Therapeutics LLC Units outstanding (and the corresponding shares of Class B common stock) after giving effect to the Reorganization Transactions and this offering described under "Prospectus Summary—The Reorganization Transactions," excluding those held by us, are exchanged into shares of our Class A common stock and no exercise of the underwriters' over-allotment option.

Immediately following the consummation of the Reorganization Transactions and this offering, the members of vTv Therapeutics LLC will consist of the Issuer and vTv Therapeutics Holdings, which will hold \_\_\_\_\_ vTv Therapeutics LLC Units and the same number of shares of vTv Therapeutics Inc. Class B common stock, which will represent \_\_\_\_\_ % of the combined voting power of our outstanding common stock (or \_\_\_\_\_ % if the underwriters exercise their over-allotment option in full). Pursuant to the terms of the Exchange Agreement, vTv Therapeutics Holdings will be able to exchange its vTv Therapeutics LLC Units (along with the corresponding number of shares of our Class B common stock) for (i) shares of our Class A common stock on a one-for-one basis or (ii) cash (based on the market price of the shares of Class A common stock), at our option (as the managing member of vTv Therapeutics LLC). Shares of our Class A common stock issuable to vTv Therapeutics Holdings upon an exchange of vTv Therapeutics LLC Units as described above would be considered "restricted securities," as that term is defined in Rule 144 under the Securities Act, unless the exchange is registered under the Securities Act. We, our executive officers and directors and shareholders will also agree with the underwriters not to sell, otherwise dispose of or hedge any Class A common stock, Class B common stock or vTv Therapeutics LLC Units or securities convertible or exchangeable for shares of Class A common stock, subject to specified exceptions, during the period from the date of this prospectus continuing through the date that is 180 days after the date of this prospectus, except with the prior written consent of the representatives of the underwriters. After the expiration of the 180-day lock-up period, the shares of Class A common stock issuable upon exchange of vTv Therapeutics LLC Units will be eligible for resale from time to time, subject to certain contractual restrictions and the requirements of the Securities Act.



We intend to file a registration statement under the Securities Act registering \_\_\_\_\_ shares of our Class A common stock reserved for issuance under our 2015 Plan and we will enter into an investor rights agreement with vTv Therapeutics Holdings and certain members of our management and Board of Directors providing certain governance and registration rights. See the information under the heading “Shares Eligible for Future Sale” and “Certain Relationships and Related Party Transactions—Investor Rights Agreement” for a more detailed description of the shares of Class A common stock that will be available for future sale upon completion of this offering.

***Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.***

The initial public offering price of the shares offered by this prospectus will be substantially higher than the pro forma as adjusted net tangible book value per share of our Class A common stock based on the total value of our tangible assets less our total liabilities immediately following this offering. Therefore, if you purchase shares of our Class A common stock in this offering, you will experience immediate and substantial dilution of approximately \$ \_\_\_\_\_ per share (\$ \_\_\_\_\_ per share if the underwriters’ exercise their over-allotment option in full) in the price you pay for shares of our Class A common stock as compared to the pro forma as adjusted net tangible book value per share. To the extent outstanding options to purchase shares of Class A common stock are exercised, there may be further dilution. For further information on this calculation, see “Dilution” elsewhere in this prospectus.

***Future sales and issuances of our Class A common stock or rights to purchase Class A common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.***

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our stockholders may experience substantial dilution. We may sell Class A common stock, convertible securities or other equity securities. If we sell Class A common stock, convertible securities or other equity securities, your investment in our Class A common stock will be diluted. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

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

***We are an “emerging growth company,” and will be able take advantage of reduced disclosure requirements applicable to “emerging growth companies,” which could make our Class A common stock less attractive to investors.***

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and, for as long as we continue to be an “emerging growth company,” we intend to take advantage of certain exemptions from various reporting requirements applicable to other public companies but not to “emerging growth companies,” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an “emerging growth company” for up to five years, or until the earliest of (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1 billion, (ii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our Class A common stock

that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter, or (iii) the date on which we have issued more than \$1 billion in non-convertible debt during the preceding three year period. We cannot predict if investors will find our Class A common stock less attractive if we choose to rely on these exemptions. If some investors find our Class A common stock less attractive as a result of any choices to reduce future disclosure, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

***We will incur significantly increased costs and devote substantial management time as a result of operating as a public company particularly after we are no longer an “emerging growth company.”***

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. For example, we will be required to comply with certain of the requirements of the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act, as well as rules and regulations subsequently implemented by the Securities and Exchange Commission, and NASDAQ, our stock exchange, including the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. We expect that compliance with these requirements will increase our legal and financial compliance costs and will make some activities more time consuming and costly. In addition, we expect that our management and other personnel will need to divert attention from operational and other business matters to devote substantial time to these public company requirements. In particular, we expect to incur significant expenses and devote substantial management effort toward ensuring compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. In that regard, we currently do not have an internal audit function, and we will need to hire additional accounting and financial staff with appropriate public company experience and technical accounting knowledge.

However, for as long as we remain an “emerging growth company” as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We intend to take advantage of these reporting exemptions until we are no longer an “emerging growth company.”

Under the JOBS Act, “emerging growth companies” can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not “emerging growth companies.”

After we are no longer an “emerging growth company,” we expect to incur additional management time and cost to comply with the more stringent reporting requirements applicable to companies that are deemed accelerated filers or large accelerated filers, including complying with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

We cannot predict or estimate the amount of additional costs we may incur as a result of becoming a public company or the timing of such costs.

***We will be exempt from certain corporate governance requirements since we will be a “controlled company” within the meaning of the NASDAQ rules, and as a result our stockholders will not have the protections afforded by these corporate governance requirements.***

MacAndrews will continue to control more than 50% of our combined voting power upon the completion of this offering. As a result, we will be considered a “controlled company” for the purposes of NASDAQ rules and corporate governance standards, and therefore we will be permitted to, and we intend to, elect not to comply with certain NASDAQ corporate governance requirements, including those that would otherwise require our Board of Directors to have a majority of independent directors and require that we either establish a Compensation and Nominating and Corporate Governance Committees, each comprised entirely of independent directors, or otherwise ensure that the compensation of our executive

officers and nominees for directors are determined or recommended to the Board of Directors by the independent members of the Board of Directors. Accordingly, holders of our Class A common stock will not have the same protections afforded to stockholders of companies that are subject to all of the NASDAQ rules and corporate governance standards, and the ability of our independent directors to influence our business policies and affairs may be reduced. See “Management—Board Committees.”

***Provisions in our charter and bylaws and provisions of Delaware law may delay or prevent our acquisition by a third party, which might diminish the value of our common stock.***

Our amended and restated certificate of incorporation and amended and restated bylaws, which we intend to adopt prior to the completion of this offering, will contain several provisions that may make it more difficult or expensive for a third party to acquire control of us without the approval of the Board of Directors. These provisions also may delay, prevent or deter a merger, acquisition, tender offer, proxy contest or other transaction that might otherwise result in our stockholders receiving a premium over the market price for their common stock. The provisions include, among others:

- a prohibition on actions by written consent of the stockholders;
- removal of directors only for cause;
- vacancies on the Board of Directors may be filled only by the Board of Directors;
- no cumulative voting; and
- advance notice requirements for stockholder proposals and director nominations.

Section 203 of the Delaware General Corporation Law may affect the ability of an “interested stockholder” to engage in certain business combinations, including mergers, consolidations or acquisitions of additional shares, for a period of three years following the time that the stockholder becomes an “interested stockholder.” An “interested stockholder” is defined to include persons owning directly or indirectly 15% or more of the outstanding voting stock of a corporation. We have elected in our amended and restated certificate of incorporation not to be subject to Section 203 of the Delaware General Corporation Law. Nevertheless, the amended and restated certificate of incorporation will contain provisions that have the same effect as Section 203 of the Delaware General Corporation Law, except that they provide that MacAndrews, investment funds affiliated with MacAndrews and their respective successors and affiliates (and transferees of any of them) will not be deemed to be “interested stockholders,” regardless of the percentage of our stock owned by them, and accordingly will not be subject to such restrictions.

For more information, see “Description of Capital Stock.” The provisions of our amended and restated certificate of incorporation and amended and restated bylaws, the significant common stock ownership of MacAndrews and the ability of the Board of Directors to create and issue a new series of preferred stock or implement a stockholder rights plan could discourage potential takeover attempts and reduce the price that investors might be willing to pay for shares of our common stock in the future, which could reduce the market price of our common stock.

***We will be required to pay vTv Therapeutics Holdings for certain tax benefits we may claim that arise in connection with this offering and related transactions. In certain circumstances, payments under the Tax Receivable Agreement may be accelerated and/or significantly exceed the actual tax benefits we realize.***

As described under “Use of Proceeds” we intend to use the net proceeds from this offering to acquire equity interests in vTv Therapeutics LLC. In the future, Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, may be exchanged for shares of our Class A common stock, or for cash, at our option (as the managing member of vTv Therapeutics LLC). See “Certain Relationships and Related Party Transactions—Exchange Agreement.” These future exchanges of Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, may result in increases in the tax basis of the assets of vTv Therapeutics LLC that otherwise would not have been available. Such increases in tax basis are likely to increase (for tax purposes) depreciation and amortization

deductions and therefore reduce the amount of income tax we would otherwise be required to pay in the future and may also decrease gain (or increase loss) on future dispositions of certain assets to the extent the increased tax basis is allocated to those assets. The IRS may challenge all or part of these tax basis increases and a court could sustain such a challenge.

We intend to enter into a Tax Receivable Agreement with vTv Therapeutics Holdings that will provide for the payment by us to vTv Therapeutics Holdings (or its transferees or other assignees) of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that we actually realize (or, in some circumstances, we are deemed to realize) as a result of (a) the exchange of Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, for shares of our Class A common stock (or for cash), (b) tax benefits related to imputed interest deemed to be paid by us as a result of the Tax Receivable Agreement and (c) certain tax benefits attributable to payments under the Tax Receivable Agreement. Although the actual increase in tax basis and the amount and timing of any payments under the Tax Receivable Agreement will vary depending upon a number of factors, including the timing of exchanges, the price of shares of our Class A common stock at the time of the exchange, the nature of the assets, the extent to which such exchanges are taxable, the tax rates then applicable, and the amount and timing of our income, we expect that the payments that we may make to vTv Therapeutics Holdings could be substantial.

vTv Therapeutics Holdings generally will not reimburse us for any payments that may previously have been made under the Tax Receivable Agreement even if the IRS subsequently disallows the tax basis increase or any other relevant tax item. Instead, any excess cash payments made by us to vTv Therapeutics Holdings will be netted against any future cash payments that we might otherwise be required to make under the terms of the Tax Receivable Agreement. However, we might not determine that we have effectively made an excess cash payment to vTv Therapeutics Holdings for a number of years following the initial time of such payment. As a result, in certain circumstances we could make payments to vTv Therapeutics Holdings under the Tax Receivable Agreement in excess of our cash tax savings. Our ability to achieve benefits from any tax basis increase and the payments to be made under the Tax Receivable Agreement, will depend upon a number of factors, including the timing and amount of our future income and the nature of our assets.

To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid. In addition, the Tax Receivable Agreement provides that, upon a merger, asset sale or other form of business combination or certain other changes of control or if, at any time, we elect an early termination of the Tax Receivable Agreement, our (or our successor's) obligations under the Tax Receivable Agreement with respect to exchanged or acquired Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units (whether exchanged or acquired before or after such change of control or early termination), would be required to be paid significantly in advance of the actual realization, if any, of any future tax benefits and would be based on certain assumptions, including that we would have sufficient taxable income to fully utilize the deductions arising from the increased tax deductions and tax basis and other benefits related to entering into the Tax Receivable Agreement, and, in the case of certain early termination elections, that any Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, that have not been exchanged will be deemed exchanged for the market value of the Class A common stock at the time of termination. Consequently, it is possible that the actual cash tax savings realized by us may be significantly less than the corresponding Tax Receivable Agreement payments.

***The only asset of vTv Therapeutics Inc. after the completion of this offering will be its interest in vTv Therapeutics LLC, and accordingly it will depend on distributions from vTv Therapeutics LLC to pay taxes and expenses, including payments under the Tax Receivable Agreement. vTv Therapeutics LLC's ability to make such distributions may be subject to various limitations and restrictions.***

Upon consummation of this offering, vTv Therapeutics Inc. will be a holding company, will have no material assets other than its ownership of vTv Therapeutics LLC Units and will have no independent means of generating revenue or cash flow. vTv Therapeutics LLC will be treated as a partnership for U.S. federal income tax purposes and, as such, will not be subject to any entity-level U.S. federal income tax. Instead, taxable income will be allocated to holders of its common units, including us. As a result, we will incur U.S. federal, state and local income taxes on our allocable share of any net taxable income of vTv Therapeutics LLC. Under the terms of vTv Therapeutics LLC Operating Agreement, vTv Therapeutics LLC

will be obligated to make tax distributions to holders of its common units, including us. In addition to tax expenses, we will also incur expenses related to our operations, including expenses under the Tax Receivable Agreement, which could be significant. We intend, as its managing member, to cause vTv Therapeutics LLC to make distributions in an amount sufficient to allow us to pay our taxes and operating expenses, including any payments due under the Tax Receivable Agreement. However, vTv Therapeutics LLC's ability to make such distributions may be subject to various limitations and restrictions including, but not limited to, restrictions on distributions that would either violate any contract or agreement to which vTv Therapeutics LLC is then a party, including potential debt agreements, or any applicable law, or that would have the effect of rendering vTv Therapeutics LLC insolvent. If vTv Therapeutics LLC does not distribute sufficient funds for us to pay our taxes or other liabilities, we may have to borrow funds, which could adversely affect our liquidity and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid.

***Our organizational structure confers certain benefits upon the vTv Therapeutics Holdings that will not benefit Class A common stockholders to the same extent as it will benefit the vTv Therapeutics Holdings.***

Our organizational structure, including the fact that vTv Therapeutics Holdings is expected to own more than 50% of the voting power of our outstanding voting stock and own part of its economic interest in our business through vTv Therapeutics LLC, confers certain benefits upon vTv Therapeutics Holdings that will not benefit the holders of our Class A common stock to the same extent as it will benefit vTv Therapeutics Holdings. For example, the Tax Receivable Agreement will provide for the payment by us to vTv Therapeutics Holdings (or its transferees or other assignees) of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that we actually realize (or, in some circumstances, we are deemed to realize) as a result of (a) the exchange of Class B common stock, together with the corresponding number of vTv Therapeutics Holdings LLC Units, for shares of our Class A common stock (or for cash), (b) tax benefits related to imputed interest deemed to be paid by us as a result of the Tax Receivable Agreement and (c) certain tax benefits attributable to payments under the Tax Receivable Agreement. Although we will retain 15% of the amount of such tax benefits, it is possible that the interests of vTv Therapeutics Holdings may in some circumstances conflict with our interests and the interests of our other stockholders, including you. For example, vTv Therapeutics Holdings may have different tax positions from us, especially in light of the Tax Receivable Agreement, that could influence their decisions regarding whether and when we should dispose of assets, whether and when we should incur new or refinance existing indebtedness, and whether and when we should terminate the Tax Receivable Agreement and accelerate our obligations thereunder. In addition, the determination of future tax reporting positions, the structuring of future transactions and the handling of any future challenges by any taxing authority to our tax reporting positions may take into consideration vTv Therapeutics Holdings's tax or other considerations, which may differ from the considerations of us or our other stockholders.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements, which involve risks and uncertainties. These forward-looking statements can be identified by the use of forward-looking terminology, including the terms “anticipate,” “believe,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and, in each case, their negative or other various or comparable terminology. All statements other than statements of historical facts contained in this prospectus, including statements regarding the timing of our clinical trials, our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. The forward-looking statements are contained principally in the sections entitled “Prospectus Summary,” “Risk Factors,” “Use of Proceeds,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.”

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Important factors that could cause our results to vary from expectations include, but are not limited to:

- our ability to raise sufficient capital to complete the STEADFAST Study and to complete the development and commercialization of *azeliragon* and of our other drug candidates;
- failure of *azeliragon* or our other drug candidates to advance through clinical trials with favorable results;
- delays in the commencement, enrollment or completion of our clinical trials;
- our ability to satisfy domestic and international regulatory requirements with respect to *azeliragon* and our other drug candidates and the labeling under any approval we may obtain;
- the performance of contract research organizations who conduct our clinical trials for us;
- our ability to establish relationships with third-party manufacturers for supplying or manufacturing our products and drug candidates;
- our ability to develop commercialization and marketing capabilities or to enter into strategic partnerships to develop and commercialize *azeliragon* or any of our other drug candidates;
- the timing and success of the commercialization of *azeliragon* or any of our other drug candidates;
- the rate and degree of market acceptance of *azeliragon* or any of our other drug candidates;
- the size and growth of the potential markets for *azeliragon* or any of our other drug candidates and our ability to serve those markets;
- our plans to expand the indications of *azeliragon* or our other drug candidates;
- regulatory developments in the United States and foreign countries;
- competition from existing drugs or new drugs that may emerge;
- cost containment initiatives and growth of managed care;
- potential product liability claims;
- our ability to attract and retain a sufficient number of scientists, clinicians, sales personnel and other key personnel;
- our ability to obtain, maintain, defend and enforce intellectual property rights protecting *azeliragon* and our other drug candidates;
- our ability to obtain patent term extensions;
- liabilities due to our use of hazardous materials and our uninsured liabilities;

[TABLE OF CONTENTS](#)

- our estimates regarding expenses, future revenues, capital requirements and needs for additional financing; and
- our ability to adequately support future growth.

These forward-looking statements reflect our views with respect to future events as of the date of this prospectus and are based on assumptions and subject to risks and uncertainties. Given these uncertainties, you should not place undue reliance on these forward-looking statements. These forward-looking statements represent our estimates and assumptions only as of the date of this prospectus and, except as required by law, we undertake no obligation to update or review publicly any forward-looking statements, whether as a result of new information, future events or otherwise after the date of this prospectus. We anticipate that subsequent events and developments will cause our views to change. You should read this prospectus and the documents referenced in this prospectus and filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. Our forward-looking statements do not reflect the potential impact of any future acquisitions, merger, dispositions, joint ventures or investments we may undertake. We qualify all of our forward-looking statements by these cautionary statements.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of our Class A common stock in this offering before the payment of expenses will be approximately \$       million (\$       million if the underwriters exercise their over-allotment option in full) based on an assumed initial public offering price of \$       per share (the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus).

Each \$1.00 increase or decrease in the assumed initial public offering price of \$       per share would increase or decrease the net proceeds to us from this offering by \$       million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. We may also increase or decrease the number of shares we are offering. Each increase or decrease of 1.0 million in the number of shares we are offering would increase or decrease the net proceeds to us from this offering by \$       million, assuming no change in the assumed initial public offering price of \$       per share and after deducting the estimated underwriting discounts and commissions.

vTv Therapeutics Inc. will use the net proceeds of this offering to acquire vTv Therapeutics LLC Units from vTv Therapeutics LLC. We intend to use such proceeds to fund the STEADFAST Study, further clinical development of our drug candidates and for working capital and other general corporate purposes. Entities affiliated with MacAndrews will initially bear certain costs and expenses of this offering, including the fees of attorneys, consultants, financial printers and auditors incurred by us, currently estimated to be approximately \$       million in the aggregate. We will reimburse such MacAndrews affiliates using a portion of the gross proceeds of this offering.

This expected use of net proceeds from this offering and our existing cash, cash equivalents and marketable securities represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from clinical trials, as well as any collaborations that we may enter into with third parties for our drug candidates, and any unforeseen cash needs.

As a result, our management will have broad discretion in the application of the net proceeds from this offering, and investors will be relying on the judgment of our management regarding the application of those net proceeds. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Pending these uses, we plan to invest these net proceeds in short-term, interest bearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States.



**DIVIDEND POLICY**

We have never declared or paid any cash dividends on our Class A common stock, and currently do not plan to declare cash dividends on shares of our Class A common stock in the foreseeable future. We expect that we will retain all of our available funds and future earnings, if any, for use in the operation and expansion of our business. Subject to the foregoing, the payment of cash dividends in the future, if any, will be at the discretion of our Board of Directors and will depend upon such factors as earnings levels, capital requirements, restrictions imposed by applicable law, our overall financial condition and any other factors deemed relevant by our Board of Directors.

**CAPITALIZATION**

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2014:

- on an actual basis;
- on a reorganization pro forma basis to reflect the Reorganization Transactions; and
- on a pro forma basis to further reflect the issuance and sale by us of \_\_\_\_\_ shares of our Class A common stock in this offering at an initial public offering price of \$ \_\_\_\_\_ per share, after deducting the underwriting discount and estimated offering expenses payable by us, including the reimbursement of certain costs and expenses borne by entities affiliated with MacAndrews, and the receipt by us of the expected net proceeds of such sale, and assuming no exercise of the underwriters' over-allotment option.

You should read this information together with the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Unaudited Pro Forma Condensed Combined Consolidated Financial Information" and "Selected Financial Data" as well as our financial statements and the related notes, which appear elsewhere in this prospectus.

(unaudited, dollars in thousands, except per unit and per share data)	As of December 31, 2014		
	Actual	Reorganization Pro Forma <sup>(1)</sup>	Pro Forma <sup>(1)</sup>
Cash and cash equivalents	\$ 1,384	\$ 1,384	\$ _____ <sup>(2)</sup>
Long-term debt, including current portion	29,575	—	—
Redeemable convertible preferred units:			
vTvx Holdings I:			
Series A redeemable convertible preferred units, no par value, 8,571,337 units authorized, issued and outstanding	2,847	—	—
Series B redeemable convertible preferred units, no par value, 2,547,593 units authorized, issued and outstanding	3,500	—	—
Series C redeemable convertible preferred units, no par value, 2,343,922 units authorized, and 2,243,922 issued and outstanding	7,781	—	—
Series D redeemable convertible preferred units, no par value, 2,442,361 units authorized, issued and outstanding	9,556	—	—
Series E redeemable convertible preferred units, no par value, 32,789,595 units authorized, issued and outstanding	86,700	—	—
Series F redeemable convertible preferred units, no par value, 1,367,157,023 units authorized and 1,145,947,422 issued and outstanding	312,232	—	—
Total vTvx Holdings I redeemable convertible preferred units	422,616	—	—
vTvx Holdings II:			
Series A redeemable convertible preferred units, no par value; 49,766,563 units authorized, issued and outstanding	1,194	—	—
Series B redeemable convertible preferred units, no par value, 704,118,921 units authorized and 594,834,833 issued and outstanding	14,276	—	—
Total vTvx Holdings II redeemable convertible preferred units	15,470	—	—
vTvx Holdings I:			
Members' (deficit) equity	(454,315)	87	—
Common member units, no par value; 1,512,722,844 units authorized, 4,188,607 issued and outstanding as of December 31, 2014	—	—	—
Total vTvx Holdings I members' (deficit) equity	(454,315)	87	—

[TABLE OF CONTENTS](#)

(unaudited, dollars in thousands, except per unit and per share data)	As of December 31, 2014		
	Actual	Reorganization Pro Forma <sup>(1)</sup>	Pro Forma <sup>(1)</sup>
vTv Holdings II:			
Members' deficit	(44,491)	—	
Common member units, no par value; 805,219,377 units authorized; 5,148,485 issued and outstanding as of December 31, 2014	—	—	
Total vTv Holdings II members' deficit	(44,491)	—	
Class A - Common stock, \$0.01 par value; no shares authorized, issued and outstanding as of December 31, 2014 (actual and reorganization pro forma), shares authorized and shares outstanding (pro forma)	—	—	
Class B - Common stock, \$0.01 par value; no shares authorized, issued and outstanding as of December 31, 2014 (actual and reorganization pro forma), shares authorized and shares outstanding (pro forma)	—	—	
Additional paid in capital	—	—	
Total (deficit) equity	(498,806)	87	
Total capitalization	<u>\$ (31,145)</u>	<u>\$ 87</u>	<u>\$</u>

<sup>(1)</sup>No vTv Holdings I or vTv Holdings II units authorized or issued or outstanding on a reorganization pro forma or a pro forma basis for vTv Therapeutics Inc.

<sup>(2)</sup>Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share would increase or decrease the net proceeds to us from this offering by \$ million, assuming that the number of shares of Class A common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. We may also increase or decrease the number of shares for Class A common stock we are offering. Each increase or decrease of 1.0 million in the number of shares of Class A common stock we are offering would increase or decrease the net proceeds to us from this offering by \$ million, assuming no change in the assumed initial public offering price of \$ per share and after deducting the estimated underwriting discounts and commissions.

The pro forma share information in the table above is based on shares of our Class A common stock being issued in this offering, as if they were outstanding as of December 31, 2014 on a pro forma basis, and excludes the following:

- shares issuable under options to purchase shares of Class A common stock, restricted stock units or other similar awards, including those that may be granted in connection with this offering under the 2015 Plan; and
- shares of Class A common stock reserved for issuance upon the exchange of vTv Therapeutics LLC Units (along with the corresponding number of shares of our Class B common stock).

**DILUTION**

If you invest in our Class A common stock, you will experience dilution to the extent of the difference between the initial public offering price per share of our Class A common stock and the pro forma net tangible book value per share of our Class A common stock. Dilution results from the fact that the per share offering price of the Class A common stock is substantially in excess of the book value per share attributable to the Class A common stock held by us (including all shares issuable upon exchange and/or conversion).

Our pro forma net tangible book value as of December 31, 2014 would have been a deficit of approximately \$ million, or \$ per share of our Class A common stock. Pro forma net tangible book value represents the amount of total tangible assets less total liabilities, and pro forma net tangible book value per share represents pro forma net tangible book value divided by the number of shares of our Class A common stock outstanding, in each case after giving effect to the Reorganization Transactions (based on an assumed initial public offering price of per share (the midpoint of the estimated initial public offering price range on the cover page of this prospectus)) assuming that all of the Class B common stock is exchanged for newly-issued shares of our Class A common stock, on a one-for-one basis.

After giving effect to the Reorganization Transactions, assuming all of the Class B common stock is exchanged for newly-issued shares of Class A common stock, on a one-for-one basis, and after giving further effect to the sale of shares of Class A common stock in this offering at the assumed initial public offering price of \$ per share (the midpoint of the estimated initial public offering price range on the cover page of this prospectus) and the application of the net proceeds from this offering, our pro forma as adjusted net tangible book value would have been a deficit of approximately \$ million, or \$ per share, representing an immediate increase in net tangible book value of \$ per share to us and an immediate dilution in net tangible book value of \$ per share to new investors in this offering.

The following table illustrates the dilution per share of our Class A common stock, assuming the underwriters do not exercise their option to purchase additional shares of our Class A common stock:

Assumed initial public offering price per share	\$
Pro forma net tangible book value per share as of December 31, 2014 <sup>(1)</sup>	\$
Increase in pro forma net tangible book value per share attributable to this offering	
Pro forma as adjusted net tangible book value per share after this offering <sup>(2)</sup>	_____
Dilution in pro forma net tangible book value per share to new investors	\$ _____

<sup>(1)</sup>Reflects outstanding shares of Class A common stock immediately prior to this offering, equal to the shares of Class A common stock issuable upon the exchange of the Class B common stock.

<sup>(2)</sup>Reflects outstanding shares, consisting of (i) shares of Class A common stock to be issued in this offering and (ii) the outstanding shares described in note (1) above issuable upon the exchange of Class B common stock.

Dilution is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share of Class A common stock.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share would increase (decrease) our pro forma as adjusted net tangible book value after this offering by \$ million and the dilution per share to new investors by \$ , in each case assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The following table sets forth, on a pro forma basis as of December 31, 2014, the number of shares of Class A common stock purchased from us, the total consideration paid to us and the average price per share paid by the existing equity holders and by new investors purchasing shares of Class A common stock in this offering, at the assumed initial public offering price of \$ per share (the midpoint of the estimated initial public offering price range on the cover page of this prospectus), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, including the reimbursement of certain costs and expenses borne by entities affiliated with MacAndrews, and after giving effect to the Reorganization Transactions, assuming that all of the Class B common stock are exchanged for

[TABLE OF CONTENTS](#)

newly-issued shares of our Class A common stock, on a one-for-one basis, and after giving further effect to this offering and the application of the net proceeds from this offering:

	Shares of Class A Common Stock Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per Share
New investors in this offering <sup>(1)</sup>					
vTv Therapeutics Holdings					
Total		100%	\$	100%	\$

<sup>(1)</sup>Includes shares of Class A common stock to be sold in this offering, the net proceeds of which we intend to use to acquire vTv Therapeutics LLC Units from vTv Therapeutics LLC, as described under "Use of Proceeds."

To the extent the underwriters' option to purchase additional shares is exercised, there will be further dilution to new investors.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share of Class A common stock (the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus) would increase (decrease) total consideration paid by new investors in this offering by \$ million and would increase (decrease) the average price per share paid by new investors by \$1.00, assuming the number of shares offered, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

**UNAUDITED PRO FORMA CONDENSED COMBINED CONSOLIDATED  
FINANCIAL INFORMATION**

vTv Therapeutics Inc. was formed in April 2015 and does not have historical financial data. The historical financial data presented in this prospectus are the historical combined consolidated financial data of our Predecessors, vTv Holdings I and vTv Holdings II. The unaudited pro forma condensed combined consolidated statement of operations data for the year ended December 31, 2014 gives pro forma effect to the Reorganization Transactions, this offering and the application of the net proceeds from this offering to purchase units of vTv Therapeutics LLC as if they had been completed as of January 1, 2014, and the unaudited pro forma condensed combined consolidated balance sheet data as of December 31, 2014 gives pro forma effect to the Reorganization Transactions, this offering and the application of the net proceeds from this offering to purchase units of vTv Therapeutics LLC as if they had been completed as of December 31, 2014. The unaudited pro forma condensed combined consolidated financial data are presented for information purposes only and should not be considered indicative of actual results of operations that would have been achieved had the Reorganization Transactions and this offering been consummated on the date indicated, and do not purport to be indicative of statements of financial position or results of operations as of any future date or for any future period. The unaudited pro forma condensed combined consolidated financial statements reflect pro forma adjustments that are described in the accompanying notes and are based on available information and certain assumptions we believe are reasonable, but are subject to change. We have made, in our opinion, all adjustments that are necessary to present fairly the pro forma financial data.

The pro forma adjustments principally give effect to the following items:

- the Reorganization Transactions described in the section entitled "The Reorganization Transactions"; and
- this offering and the use of the net proceeds to purchase units of vTv Therapeutics LLC and its payment of estimated offering expenses from the gross proceeds, including the reimbursement of certain costs and expenses borne by entities affiliated with MacAndrews.

You should read the Unaudited Pro Forma Condensed Combined Consolidated Financial Information and accompanying notes in conjunction with the combined consolidated historical financial statements and related notes and the financial and other information included elsewhere in this prospectus, including the sections entitled "Capitalization," "Selected Financial Data," "Use of Proceeds," and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

**vTv Therapeutics Inc.**  
**Unaudited Pro Forma Condensed Combined Consolidated Statements of Operations**  
**Year ended December 31, 2014**  
**(dollars in thousands except per share data)**

	Predecessors' Combined Actual	Reorganization Adjustments (a)	Reorganization Pro Forma	Offering Adjustments (b)	vTv Therapeutics Inc. Pro Forma
Revenue	\$ 1,549	\$ —	\$ 1,549	\$ —	\$ 1,549
Operating expenses:					
Research and development	17,378	—	17,378	—	17,378
Research and development – related party	1,351	—	1,351	—	1,351
General and administrative	11,717	—	11,717	—	11,717
Total operating expenses	30,446	—	30,446	—	30,446
Operating loss	(28,897)	—	(28,897)	—	(28,897)
Other (expense), net	(503)	—	(503)	—	(503)
Other (expense) – related party	(623)	623	—	—	—
Interest (expense)	(282)	282	—	—	—
Interest (expense), net – related party	(5,727)	5,727	—	—	—
Investment (loss) – related party	(69)	69	—	—	—
Combined consolidated net loss	\$ (36,101)	\$ 6,701	\$ (29,400)	\$ —	\$ (29,400)
Net loss attributable to non-controlling interests	—	—	—	—	—
Net loss available to vTv Therapeutics Inc.	\$ —	\$ —	\$ (29,400)	\$ —	\$ —
Net loss attributable to vTv Therapeutics Inc. per share Class A common stock:					
Basic and diluted					\$
Basic and diluted, pro forma (unaudited)					\$ (c)
Weighted average shares of Class A common stock outstanding:					
Basic and diluted					
Basic and diluted, pro forma (unaudited)					(c)

See accompanying Notes to the Unaudited Pro Forma  
Condensed Combined Consolidated Statement of Operations.

**Notes to the Unaudited Pro Forma Condensed Combined Consolidated Statement of Operations for the Year Ended December 31, 2014**

- (a) Reflects the Reorganization Transactions for the newly formed vTv Therapeutics Inc. These adjustments include:
- removal of interest (expense), net that will not be incurred after the Reorganization Transactions, as the debt and the receivable due from a related party will not be assumed by vTv Therapeutics Inc. and will remain with the Predecessors subsequent to the Reorganization Transactions; and
  - removal of a loss on an investment that will not be held by vTv Therapeutics Inc. subsequent to the Reorganization Transactions.
- (b) Reflects the adjustments as a result of this offering, after deducting the underwriting discount and estimated offering expenses payable by us, including the issuance of shares of Class A common stock in this offering, the reimbursement of certain costs and expenses borne by entities affiliated with MacAndrews, and the receipt by us of the expected net proceeds of such sale, and assuming no exercise of the underwriters' over-allotment option.
- (c) The pro forma earnings per share is calculated using the treasury stock method, using only the Class A common stock. The Class B common stock has no economic rights and therefore is excluded from this calculation.



**vTv Therapeutics Inc.**  
**Unaudited Pro Forma Condensed Combined Consolidated Balance Sheet**  
**As of December 31, 2014**  
**(dollars in thousands, except per unit and per share data)**

	Predecessors' Combined Actual	Reorganization Adjustments (a)	Reorganization Pro Forma	Offering Adjustments (b)	vTv Therapeutics Inc. Pro Forma
<b>Assets</b>					
Current assets:					
Cash and cash equivalents	\$ 1,384	\$ —	\$ 1,384	\$ —	\$ —
Restricted cash and cash equivalents	130	(130)	—	—	—
Prepaid expenses and other current assets	97	—	97	—	—
Total current assets	1,611	(130)	1,481	—	—
Note receivable	6,594	(6,594)	—	—	—
Property and equipment, net	3,778	(2,789)	989	—	—
Receivable due from a related party, net	800	(800)	—	—	—
Employee loans receivable – related party	58	—	58	—	—
Other long-term assets	110	—	110	—	—
<b>Total assets</b>	<b>\$ 12,951</b>	<b>\$ (10,313)</b>	<b>\$ 2,638</b>	<b>\$ —</b>	<b>\$ —</b>
<b>Liabilities, redeemable convertible units, and members' / stockholders' (deficit) equity</b>					
Current liabilities:					
Accounts payable and accrued expenses	\$ 3,079	\$ (615)	\$ 2,464	\$ —	\$ —
Accounts payable and accrued expenses – related party	1,752	(1,752)	—	—	—
Short-term debt	155	(155)	—	—	—
Other liabilities – related party	1,878	(1,878)	—	—	—
Total current liabilities	6,864	(4,400)	2,464	—	—
Debt – related party	27,310	(27,310)	—	—	—
Debt, net of current portion	2,110	(2,110)	—	—	—
Fair value of contingent distribution	26,359	(26,359)	—	—	—
Note payable	6,594	(6,594)	—	—	—
Other liabilities, net of current portion	4,434	(4,347)	87	—	—
Total liabilities	73,671	(71,120)	2,551	—	—
Redeemable convertible preferred units (c)	438,086	(438,086)	—	—	—
Equity:					
Members' (deficit) equity:					
vTvx Holdings I:					
Members' (deficit) equity	(454,315)	454,402	87	—	—
Common member units, no par value; 1,512,722,844 units authorized, 4,188,607 issued and outstanding as of December 31, 2014	—	—	—	—	—
Total vTvx Holdings I (deficit) equity	(454,315)	454,402	87	—	—
vTvx Holdings II:					
Members' (deficit) equity	(44,491)	44,491	—	—	—
Common member units, no par value; 805,219,377 units authorized and 5,148,485 issued and outstanding as of December 31, 2014	—	—	—	—	—
Total vTvx Holdings II (deficit) equity	(44,491)	44,491	—	—	—
Class A - Common stock, \$0.01 par value; no shares authorized, issued and outstanding as of December 31, 2014 (actual and as adjusted before offering), shares authorized and shares outstanding (pro forma)					
	—	—	—	—	—
Class B - Common stock, \$0.01 par value; no shares authorized, issued and outstanding as of December 31, 2014 (actual and as adjusted before offering), shares authorized and shares outstanding (pro forma)					
	—	—	—	—	—
Additional paid in capital	—	—	—	—	—
Total (deficit) equity	(498,806)	498,893	87	—	—
<b>Total liabilities, redeemable convertible units, and members' / stockholders' (deficit) equity</b>	<b>\$ 12,951</b>	<b>\$ (10,313)</b>	<b>\$ 2,638</b>	<b>\$ —</b>	<b>\$ —</b>

See accompanying Notes to the Unaudited Pro Forma  
Condensed Combined Consolidated Balance Sheet.

**Notes to the Unaudited Pro Forma Condensed Combined Consolidated Balance Sheet for the Year Ended December 31, 2014:**

- (a) Reflects the Reorganization Transactions for the newly formed vTv Therapeutics Inc. including the following:
- removal of restricted cash, certain receivables, and land included in property and equipment, net that will not be assets of vTv Therapeutics Inc. subsequent to the Reorganization Transactions;
  - removal of debt, contingent distribution payable and other liabilities that will not be obligations of vTv Therapeutics Inc. subsequent to the Reorganization Transactions;
  - removal of preferred units that will not exist at vTv Therapeutics Inc. but will continue to exist at vTvx Holdings I and vTvx Holdings II; and
  - the issuance of vTv Therapeutics LLC Units to vTv Therapeutics Holdings LLC and the issuance of the corresponding shares of Class B common stock.
- (b) Reflects the adjustments as a result of this offering, after deducting the underwriting discount and estimated offering expenses payable by us, including the issuance of shares of Class A common stock in this offering, the reimbursement of certain costs and expenses borne by entities affiliated with MacAndrews, and the receipt by us of the expected net proceeds of such sale, and assuming no exercise of the underwriters' over-allotment option. Each \$1.00 increase or decrease in the assumed initial public offering price of \$ per share would increase or decrease the net proceeds to us from this offering by \$ million, assuming that the number of shares of Class A common stock offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. We may also increase or decrease the number of shares of Class A common stock we are offering. Each increase or decrease of 1.0 million in the number of shares of Class A common stock we are offering would increase or decrease the net proceeds to us from this offering by \$ million, assuming no change in the assumed initial public offering price of \$ per share and after deducting the estimated underwriting discounts and commissions.
- (c) The redeemable convertible preferred units (none of which will exist at vTv Therapeutics Inc. after the completion of the Reorganization Transactions) include (dollars in thousands):

vTvx Holdings I

- Series A redeemable convertible preferred units, no par value; 8,571,337 units authorized, issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$2,545 at December 31, 2014);
- Series B redeemable convertible preferred units, no par value, 2,547,593 units authorized, issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$3,500 at December 31, 2014);
- Series C redeemable convertible preferred units, no par value, 2,343,922 units authorized and 2,243,922 issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$5,514 at December 31, 2014);
- Series D redeemable convertible preferred units, no par value, 2,442,361 units authorized, issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$9,556 at December 31, 2014);
- Series E redeemable convertible preferred units, no par value, 32,789,595 units authorized, issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$86,700 at December 31, 2014); and
- Series F redeemable convertible preferred units, no par value, 1,367,157,023 units authorized and 1,145,947,422 issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$114,595 at December 31, 2014).

[TABLE OF CONTENTS](#)

vTvx Holdings II

- Series A redeemable convertible preferred units, no par value; 49,766,563 units authorized, issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$1,194 at December 31, 2014); and
- Series B redeemable convertible preferred units, no par value, 704,118,921 authorized 594,834,833 units issued and outstanding as of December 31, 2014 (aggregate liquidation preference of \$14,276 at December 31, 2014).

**SELECTED FINANCIAL DATA**

vTv Therapeutics Inc. was formed in April 2015 and does not have historical financial data. The historical financial data presented in this prospectus are the historical financial data of our Predecessors, vTv Holdings I and vTv Holdings II. The selected statement of operations data for the years ended December 31, 2014 and 2013 are derived from the audited combined consolidated statements of operations of the Predecessors for such periods, which are included in this prospectus. The selected balance sheet data as of December 31, 2014 are derived from the audited combined balance sheet of the Predecessors as of such date, which is included in this prospectus.

Our selected financial data should be read together with the sections entitled “Capitalization” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and with our financial statements and their related notes included elsewhere in this prospectus.

	<u>Years Ended December 31,</u>	
	<u>2013</u>	<u>2014</u>
<b>(dollars in thousands, except for per unit and per share data)</b>	<b>(Predecessor)</b>	
<b>Statement of operations data:</b>		
Revenue	\$ 976	\$ 1,549
Operating expenses:		
Research and development	25,434	18,729
General and administrative	11,375	11,717
Total operating expenses	36,809	30,446
Loss from operations	(35,833)	(28,897)
Other income (expense), net	(12,370)	(7,204)
Combined consolidated net loss	<u>\$ (48,203)</u>	<u>\$ (36,101)</u>
vTv Holdings I:		
Net loss per member unit, basic and diluted	\$ (12.82)	\$ (16.81)
Units used to compute basic and diluted net loss per member unit <sup>(1)</sup>	13,288,327	13,263,676
vTv Holdings II:		
Net earnings (loss) per member unit, basic and diluted	\$ 0.06	\$ (0.64)
Units used to compute basic and diluted net loss per member unit <sup>(1)</sup>	19,597,888	19,570,078

<sup>(1)</sup>See Note 16 for the periods ended December 31, 2013 and 2014 of our Notes to Combined Consolidated Financial Statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per unit.

<b>(dollars in thousands)</b>	<u>As of December 31, 2014</u>	
	<b>(Predecessor)</b>	
<b>Balance sheet data:</b>		
Cash and cash equivalents	\$	1,384
Working capital deficiency		(5,253)
Total assets		12,951
Current liabilities		6,864
Long-term debt, net of current portion		29,420
Other liabilities, net of current portion		37,387
vTv Holdings I and vTv Holdings II redeemable convertible preferred units		438,086
Total members’ deficit		(498,806)

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis should be read in conjunction with "Selected Financial Data" and our combined consolidated financial statements and related notes included elsewhere in this prospectus. This discussion and analysis and other parts of this prospectus contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth under "Risk Factors" and elsewhere in this prospectus. You should carefully read the "Risk Factors" section of this prospectus to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements."*

### Overview

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates to fill significant unmet medical needs. We have a powerful pipeline of clinical drug candidates, led by our programs for the treatment of AD and type 2 diabetes. Our drug candidate for the treatment of AD, *azeliragon*, is an orally administered, small molecule antagonist targeting RAGE, and we have commenced patient enrollment in the STEADFAST Study under an FDA-agreed SPA. Our type 2 diabetes drug candidates include *TTP399*, an orally administered, liver-selective GKA, for which we are currently enrolling patients in the AGATA Study, and *TTP273*, an orally administered, non-peptide agonist that targets the GLP-1r, which we anticipate will enter a Phase 2 clinical trial in early 2016. We have three additional programs in various stages of clinical development for the prevention of muscle weakness and the treatment of inflammatory disorders.

To date, we have devoted substantially all of our resources to our research and development efforts relating to our drug candidates, including conducting clinical trials with our drug candidates, providing general and administrative support for these operations and protecting our intellectual property. We do not have any products approved for sale and have not generated any revenue from drug sales. From our inception through December 31, 2014, we have funded our operations primarily through:

- a series of private placements of preferred equity from 1999 to 2006 totaling \$109.3 million;
- the receipt of \$23.4 million from completed research collaborations with Novo Nordisk, A/S Merck and Boehringer Ingelheim from 2001 to 2006;
- the receipt of \$169.2 million of upfront, milestone and research fees during 2006 to 2010 under a license and research agreement with Pfizer, Inc., which was terminated in 2011;
- the receipt of \$55.7 million of upfront, milestone and research expense reimbursements from 2010 to 2013 under a license agreement for our GKA programs with an affiliate of Forest Laboratories, Inc., which was terminated in 2013;
- various borrowings totaling \$114.7 million from November 2011 through March 2014 from entities affiliated with MacAndrews, which were converted to Series F and Series B preferred units of our Predecessors; and
- borrowings of \$27.3 million from April 2014 to December 2014 from entities affiliated with MacAndrews.

vTv Therapeutics Inc. was formed in April 2015 and does not have historical financial data. The historical financial data discussed in this Management's Discussion and Analysis of Financial Condition and Results of Operations are those of our Predecessors, vTvx Holdings I and vTvx Holdings II. After the completion of the Reorganization Transactions, substantially all of the assets of our Predecessors will be held by vTv Therapeutics LLC, which will be a subsidiary of vTv Therapeutics Inc. We have incurred net losses in each year since the inception of our Predecessor, vTvx Holdings I, in 1998. Our combined consolidated net losses were approximately \$48.2 million and \$36.1 million for the years ended

## TABLE OF CONTENTS

December 31, 2013 and 2014, respectively. As of December 31, 2014, we had a total members' deficit of approximately \$498.8 million. Substantially all our net losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for at least the next several years. We anticipate that our expenses will increase substantially as we:

- continue the development of our lead drug candidate, *azeliragon*, for the treatment of AD;
- seek to obtain regulatory approvals for *azeliragon*;
- prepare for the potential commercialization of *azeliragon*;
- begin outsourcing of the commercial manufacturing of *azeliragon* for any indications for which we receive regulatory approval;
- expand our research and development activities and advance our clinical programs, including our Type 2 diabetes programs *TTP399* and *TTP273*;
- maintain, expand and protect our intellectual property portfolio; and
- add operational, financial and management systems and personnel, including personnel to support our obligations as a public company.

We do not expect to generate revenue from drug sales unless and until we successfully complete development and obtain marketing approval for one or more of our drug candidates, which we expect will take a number of years and will be subject to significant uncertainty. Accordingly, we anticipate that we will need to raise additional capital in addition to the net proceeds of this offering prior to the commercialization of *azeliragon* or any of our other drug candidates. We expect to fund a portion of the STEADFAST Study through licensing or other monetization of our drug candidates, including *TTP399* and *TTP273*. Until such time that we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. Nevertheless, we may be unable to raise additional funds or enter into such other arrangements when needed, on favorable terms or at all, which would have a negative impact on our liquidity and financial condition and could force us to delay, reduce the scope or eliminate one or more of our research and development programs or commercialization efforts. Failure to receive additional funding could cause us to cease operations, in part or in full.

## **Financial Overview**

### **Revenue**

To date, we have not generated any revenue from drug sales. All of our revenue to date has been primarily derived from up-front proceeds and research fees under collaboration and license agreements and government grants.

In the future, we may generate revenue from a combination of product sales, license fees, milestone payments and royalties from the sales of products developed under licenses of our intellectual property. We expect that any revenue we generate will fluctuate from quarter to quarter as a result of the timing and amount of license fees, milestone and other payments, and the amount and timing of payments that we receive upon the sale of our products, to the extent any are successfully commercialized. If we fail to complete the development of our drug candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue and our results of operations and financial position will be materially adversely affected.

### **Research and Development Expenses**

Since our inception, we have focused our resources on our research and development activities, including conducting preclinical studies and clinical trials, manufacturing development efforts and activities

## TABLE OF CONTENTS

related to regulatory filings for our drug candidates. We recognize research and development expenses as they are incurred. Our research and development expenses consist primarily of:

- salaries, benefits and related overhead expenses for personnel in research and development functions;
- fees paid to consultants and CROs, including in connection with our preclinical and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis;
- costs related to acquiring and manufacturing clinical trial materials (including continued testing such as process validation and stability of drug product);
- depreciation of leasehold improvements, laboratory equipment and computers; and
- costs related to compliance with regulatory requirements.

From the inception of our earlier-formed Predecessor, vTvx Holdings I, through December 31, 2014, we have incurred approximately \$426.9 million in research and development expenses. In the years ended December 31, 2013 and 2014 we incurred approximately \$25.4 million and \$18.7 million, respectively, on research and development expenses. We plan to increase our research and development expenses for the foreseeable future as we continue the development of *azeliragon* and to further advance the development of our other drug candidates, subject to the availability of additional funding. Our direct research and development expenses consist principally of external costs, such as fees paid to investigators, consultants, central laboratories and CROs, in connection with our clinical trials, and costs related to acquiring and manufacturing clinical trial materials. We typically use our employee and infrastructure resources across multiple research and development programs.

The successful development of our clinical and preclinical drug candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of any of our clinical or preclinical drug candidates or the period, if any, in which material net cash inflows from these drug candidates may commence. This is due to the numerous risks and uncertainties associated with the development of our drug candidates, including:

- the uncertainty of the scope, rate of progress and expense of our ongoing, as well as any additional, clinical trials and other research and development activities;
- the potential benefits of our candidates over other therapies;
- our ability to market, commercialize and achieve market acceptance for any of our drug candidates that we are developing or may develop in the future;
- future clinical trial results;
- the timing and receipt of any regulatory approvals; and
- the filing, prosecuting, defending and enforcing of patent claims and other intellectual property rights, and the expense of doing so.

A change in the outcome of any of these variables with respect to the development of a drug candidate could mean a significant change in the costs and timing associated with the development of that drug candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development of a drug candidate, or if we experience significant delays in enrollment in any of our clinical trials, we could be required to expend significant additional financial resources and time with respect to the development of that drug candidate.

### **General and Administrative Expenses**

General and administrative expenses consist primarily of salaries, benefits and related costs for employees in executive, finance, corporate development and human resources and administrative support functions. Other significant general and administrative expenses include accounting and legal services, expenses associated with obtaining and maintaining patents, cost of various consultants, occupancy costs and information systems.

We expect that our general and administrative expenses will increase as we operate as a public company and commercialize our drug candidates. We believe that these increases will likely include increased costs for director and officer liability insurance, costs related to the hiring of additional personnel and increased fees for outside consultants, lawyers and accountants. We also expect to incur additional costs related to provide an investor relations function, implement a system of internal control over financial reporting and a system of disclosure controls and procedures that are compliant with applicable requirements, comply with corporate governance requirements and other rules of the stock exchange on which we are listed and other similar requirements applicable to public companies.

### **Other Income (Expense), Net**

Other income (expense), net primarily consists of net interest expense. Interest income consists of interest earned on our cash, cash equivalents and short-term investments. We expect our interest income to increase following the completion of this offering as we invest the net proceeds from this offering pending their use in our operations. Interest expense pertains primarily of interest accrued or paid on amounts outstanding under our loans from affiliates of MacAndrews and a real estate loan with a financial institution. Other significant components of other income (expense), net are bad debt expense and losses on the carrying value of land.

### **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States ("GAAP"). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of our financial statements, as well as the reported revenues and expenses during the reported periods. We evaluate these estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are more fully described in Note 2, "Summary of Significant Accounting Policies," to our audited financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies related to revenue recognition, research and development and redeemable convertible preferred units are the most critical for fully understanding and evaluating our financial condition and results of operations.

### **Basis of Presentation**

The combined consolidated financial statements include the consolidated accounts of vTvx Holdings I, the accounts of its wholly-owned subsidiary (prior to December 31, 2014), High Point Clinical Trials Center, LLC ("HPCTC"), and the combined accounts of vTvx Holdings I. All significant intercompany balances and transactions have been eliminated.

### **Revenue Recognition**

We use the revenue recognition guidance established by ASC Topic 605, "Revenue Recognition." We recognize revenue when there is persuasive evidence of an arrangement, the service has been provided to the customer, the collection of the fee is reasonably assured and the amount of the fee to be paid by the customer is fixed or determinable. In determining the accounting for collaboration and alliance agreements,



## TABLE OF CONTENTS

we follow the provisions of ASC Topic 605, Subtopic 25, "Multiple Element Arrangements" ("ASC 605-25"). ASC 605-25 provides guidance on whether an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes and, if division is required, how the arrangement consideration should be allocated among the separate units of accounting. If a deliverable has value on a standalone basis, we treat the deliverable as a separate unit of accounting. If the arrangement constitutes separate units of accounting according to the separation criteria of ASC 605-25, the consideration received is allocated among the separate units of accounting and the applicable revenue recognition criteria must be applied to each unit. We determine how to allocate amounts received under agreements among the separate units based on the respective selling price of each unit. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement and the consideration received is recognized over the period of inception through the date the last deliverable within the single unit of accounting is expected to be delivered.

Collaboration research and development revenue is earned and recognized as research is performed and related expenses are incurred. Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees and milestones from collaborations on a straight-line basis over the estimated period of our substantive performance obligations. If we do not have substantive performance obligations, we recognize non-refundable upfront fees into revenue through the date the deliverable is satisfied.

Revenue for non-refundable payments based on the achievement of milestone events under collaboration agreements is recognized in accordance with ASC Topic 605, Subtopic 28, "Milestone Method" ("ASC 605-28"). Milestone events under our collaboration agreements may include research, development, regulatory, commercialization, or sales events. Under ASC 605-28, a milestone payment is recognized as revenue when the applicable event is achieved if the event meets the definition of a milestone and the milestone is determined to be substantive. ASC 605-28 defines a milestone event as an event having all of the following characteristics: (1) there is substantive uncertainty regarding achievement of the milestone event at the inception of the arrangement; (2) the event can only be achieved based, in whole or in part, on either our performance or a specific outcome resulting from our performance; and (3) if achieved, the event would result in additional payment due to us. We also treat events that can only be achieved based, in whole or in part, on either a third party's performance or a specific outcome resulting from a third party's performance as milestone events if the criteria of ASC 605-28 are otherwise satisfied.

Research and development costs that are reimbursable under collaboration agreements are recorded in accordance with ASC Topic 605, Subtopic 45, "Principal Agent Considerations." Amounts reimbursed under a cost sharing arrangement are reflected as a reduction of research and development expense.

We entered into contractual arrangements with sponsors wanting to conduct a trial on a drug and recognized study revenue when (i) the identified single subject visit has been completed or (ii) in some cases, all visits required in the trial by the subject matter have been completed, consistent with the requirements of the contractual arrangements. For the years ended December 31, 2013 and 2014, substantially all of our study revenues were from our wholly-owned subsidiary (prior to December 31, 2014), HPCTC.

### ***Research and Development***

Major components of research and development costs include cash compensation, depreciation and amortization expense on research and development property and equipment, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on our behalf. Costs incurred in research and development are expensed as incurred.

We record accruals based on estimates of the services received, efforts expended and amounts owed pursuant to contracts with numerous contract research organizations. In the normal course of business, we contract with third parties to perform various clinical study activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events and the completion of portions of the clinical study or

[TABLE OF CONTENTS](#)

similar conditions. The objective of our accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical studies are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study.

We record nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the statements of operations as we receive the related goods or services.

**Redeemable Convertible Preferred Units**

We initially recorded the redeemable convertible preferred units at their fair values at issuance, net of issuance costs. All of the redeemable convertible preferred units have been presented outside of permanent members' deficit. Our redeemable convertible preferred units are carried at the higher of the fair value at issuance less issuance cost, original cost, or liquidation preference. See discussion and additional detail of the redeemable convertible preferred units at Note 11, "Redeemable Convertible Preferred Units and Warrants," to our audited financial statements, which are contained in this prospectus.

**Results of Operations**

**Comparison of the Years Ended December 31, 2013 and 2014**

The following table sets forth certain information concerning our results of operations for the periods shown:

(dollars in thousands)	Years Ended December 31,		Change
	2013	2014	
<b>Statement of operations data:</b>			
Revenue	\$ 976	\$ 1,549	\$ 573
Operating expenses:			
Research and development	25,434	18,729	(6,705)
General and administrative	11,375	11,717	342
Total operating expenses	36,809	30,446	(6,363)
Operating loss	(35,833)	(28,897)	6,936
Other income (expense), net	(12,370)	(7,204)	5,166
<b>Combined consolidated net loss</b>	<b>\$ (48,203)</b>	<b>\$ (36,101)</b>	<b>\$ 12,102</b>

**Revenues**

Revenues were \$1.0 million and \$1.5 million for the years ended December 31, 2013 and 2014 and primarily related to clinical trial services provided by HPCTC to outside third party customers. HPCTC was sold to a former officer and director on December 30, 2014.

**Research and Development Expenses**

Research and development expenses were \$25.4 million and \$18.7 million for the years ended December 31, 2013 and 2014, respectively. The decrease in research and development expenses during 2014 of \$6.7 million or 26.4% was primarily due to:

- a decrease in clinical trial costs of \$1.9 million due to the completion of the Phase 2 study for *TTP054* in June 2013;
- a decrease in clinical trial costs of \$1.1 million due to the completion of the Phase 1 studies for *TTP273* in November 2013;

## TABLE OF CONTENTS

- a decrease in compound manufacturing costs of \$1.9 million as we completed efforts to make drug supplies for upcoming trials including the STEADFAST Study and type 2 diabetes drug candidate trials; and
- a decrease in compensation costs of \$1.4 million due to a reduction in the number of chemists and biologists focused on early stage discovery.

### **General and Administrative Expenses**

General and administrative expenses were \$11.4 million and \$11.7 million for the years ended December 31, 2013 and 2014, respectively. The increase in general and administrative expenses during this period of \$0.3 million or 3.0% was primarily due to:

- an increase in severance related compensation of \$4.0 million in 2014 primarily related to the departure of a former officer and director,
- partially offset by one time stock compensation expense of \$2.9 million recognized in 2013 attributable to a former officer and director associated with a note and equity issuance agreement entered into by us in 2013.

### **Other Income (Expense), Net**

Other income (expense), net is primarily comprised of net interest expense. During the years ended December 31, 2013 and 2014, our interest expense, net was \$11.8 million and \$6.0 million, respectively, representing a decrease of \$5.8 million. During the year ended December 31, 2014, as compared to the year ended December 31, 2013, the net interest expense decreased primarily due to a \$5.4 million decrease in the amount of amortization of debt discount recognized during the years ending December 31, 2013 and 2014, respectively.

### **Liquidity and Capital Resources**

We have incurred losses since the inception of our earlier-formed Predecessor, vTvx Holdings I, in 1998 and as of December 31, 2014, we had a members' deficit of approximately \$498.8 million. Since our inception, MacAndrews and certain affiliates have provided funding to our Predecessors in the form of debt and equity in excess of \$200 million. M&F TTP Holdings LLC is currently providing funding for the fiscal 2015 operations of our Predecessors, including all operating, investing and financing cash flow needs. Additionally, our Predecessors have obtained a binding commitment from MacAndrews to continue funding their operations at a level necessary for our Predecessors to meet their financial obligations, if necessary, through at least January 1, 2016. vTv Therapeutics Inc. will not have the benefit of this commitment following the completion of the Reorganization Transactions and this offering.

We believe that, after the consummation of this offering, we will continue to meet our liquidity requirements over at least the next 12 months. In the event we are not successful at completing this offering, our shareholders have represented to us that they have the current intent and ability to fund our operations, if necessary, through at least January 1, 2016. We anticipate that we will continue to incur losses for at least the next several years. We expect that our research and development and general and administrative expenses will continue to increase and, as a result, we will need additional capital to fund our operations, which we may obtain through one or more of equity offerings, debt financings, strategic alliances and licensing or collaboration arrangements.

Since our inception through December 31, 2014, we have funded our operations principally through the receipt of funds from the private placement of approximately \$109.3 million of preferred equity securities, approximately \$248.3 million from license and research collaborations and debt financings totaling approximately \$142.0 million. As of December 31, 2014, we had cash and cash equivalents of approximately \$1.4 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view to liquidity and capital preservation.

On August 9, 2013, we refinanced a previously existing \$94.1 million unsecured note, evidencing amounts borrowed from MacAndrews & Forbes Group, LLC, with new promissory notes (the "2013 Promissory Notes") and new redeemable preferred units, pursuant to a Note and Equity Issuance Agreement

## TABLE OF CONTENTS

(the "Note and Equity Issuance Agreement"). The 2013 Promissory Notes, for which M&F TTP Holdings LLC acted as principal lender, had an original principal amount of \$94.1 million and bore interest at an annual rate of LIBOR plus 2%. The 2013 Promissory Notes provided that the outstanding balance plus accrued and unpaid interest was due on December 31, 2014 or earlier upon the occurrence of "prepayment events." The new promissory notes were secured by substantially all of our assets.

On December 24, 2013, we amended the Note and Equity Issuance Agreement to provide for additional advances that could be made at the option of M&F TTP Holdings LLC. The additional advances were also secured by substantially all of our assets and bore interest at an annual rate of LIBOR plus 10%. The additional advances were subject to the same prepayment provisions as the advances made under the initial Note and Equity Issuance Agreement.

On March 28, 2014, we, M&F TTP Holdings LLC and certain of our affiliates and employees agreed to exchange all \$116.2 million of outstanding principal and interest under the Note and Equity Issuance Agreement (including amounts advanced under the initial agreement and the 2013 Promissory Notes and amounts advanced following the December 24, 2013 amendment) for 292,722,844 Series F redeemable convertible preferred units of vTvx Holdings I and 155,219,376 Series B redeemable convertible preferred units of vTvx Holdings II. Concurrently on March 28, 2014, we entered into an Uncommitted Advance Agreement with M&F TTP Holdings LLC and a former officer and director. Under the Uncommitted Advance Agreement, advances are made by M&F TTP Holdings LLC at its discretion periodically at our request. There is no minimum or maximum amount for any advance. Advances made under the Uncommitted Advance Agreement bear interest at an annual rate of LIBOR plus 10%. Principal and interest were originally payable on demand, but on May 4, 2015, M&F TTP Holdings LLC agreed to extend the maturity date of the Uncommitted Advance Agreement to January 15, 2016. Prepayments can be made under the Uncommitted Advance Agreement without penalty. As of December 31, 2013 and 2014, \$2.0 million and \$27.3 million, respectively, of principal was outstanding under the Uncommitted Advance Agreement.

Following the completion of this offering, we will not be an obligor under the Uncommitted Advance Agreement, and advances under the Uncommitted Advance Agreement will not be available to us.

The following table summarizes the balances of our outstanding debt as of December 31, 2014:

	December 31, 2014
(dollars in thousands)	
Promissory note on land	\$ 2,265
Uncommitted Advance Agreement	27,310
<b>Total</b>	<b>\$ 29,575</b>

### Cash Flows

	Years Ended December 31,	
	2013	2014
(dollars in thousands)		
Net cash used in operating activities	\$ (41,684)	\$ (30,779)
Net cash (used in) provided by investing activities	(156)	161
Net cash provided by financing activities	40,805	30,913
(Decrease) increase in cash and cash equivalents	\$ (1,035)	\$ 295

### Operating Activities

For the year ended December 31, 2013, our net cash used in operating of activities of \$(41.7) million consisted of a net loss of \$(48.2) million and changes in assets and liabilities of \$(8.8) million offset by \$15.3 million in adjustments for non-cash items. Adjustments for non-cash items primarily consisted of \$10.2 million of amortization of debt discount and stock-based compensation expense of \$2.9 million.

## TABLE OF CONTENTS

For the year ended December 31, 2014, our net cash used in operating of activities of \$(30.8) million consisted of a net loss of \$(36.1) million and changes in assets and liabilities of \$(1.7) million, offset by \$7.0 million in adjustments for non-cash items. Adjustments for non-cash items primarily consisted of amortization of debt discount of \$4.8 million.

### **Investing Activities**

For the year ended December 31, 2013, net cash used in investing activities was \$0.2 million, which was primarily attributable to the purchases of property and equipment of \$0.2 million.

For the year ended December 31, 2014, net cash provided by investing activities was \$0.2 million, which was primarily attributable to the proceeds from the sale of assets of \$0.3 million, offset by expenses paid related to disposal of HPCTC and purchases of property and equipment totaling \$0.1 million.

### **Financing Activities**

For the year ended December 31, 2013, net cash provided by financing activities was \$40.8 million, which was primarily attributable to proceeds from debt issuances of \$39.2 million, offset by \$0.1 million of repayment of debt and \$1.8 million of preferred stock issuance cost.

For the year ended December 31, 2014, net cash provided by financing activities was \$30.9 million, which was primarily attributable to proceeds from debt issuances of \$33.6 million, offset by \$0.1 million of repayment of debt and \$2.5 million for the repurchase of preferred, common member units and warrants from a former officer and director. For more information, see Note 3, "Repurchase of Former Officer's Interest," to our audited financial statements, which are included in this prospectus.

### **Future Funding Requirements**

To date, we have not generated any revenue from product sales. We do not know when, or if, we will generate any revenue from drug sales. We do not expect to generate significant revenue from drug sales unless and until we obtain regulatory approval of and commercialize *azeliragon* or any of our other drug candidates. At the same time, we expect our expenses to increase in connection with our ongoing development activities, particularly as we continue the research, development and clinical trials of, and seek regulatory approval for, our drug candidates. Upon the closing of this offering, we expect to incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our drug candidates, we expect to incur significant commercialization expenses for product sales, marketing, manufacturing and distribution. We anticipate that we will need substantial additional funding in connection with our continuing operations.

Based upon our current operating plan, we believe that the net proceeds from this offering, together with our existing cash, cash equivalents and short-term investments, will enable us to fund our operating expenses and capital requirements through at least mid-2017. We intend to devote the net proceeds from this offering to fund our Phase 3 clinical trial, the STEADFAST Study, and any additional clinical or preclinical studies necessary to support and to submit an application for *azeliragon*. The expected net proceeds of this offering will not be sufficient for us to complete the STEADFAST Study, and we expect that we will need to raise substantial additional capital to complete the development and commercialization of *azeliragon*. We expect to fund a portion of the cost of the STEADFAST Study through licensing or other monetization of our other drug candidates, including *TTP399* and *TTP273*. We have based our estimates on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development and commercialization of our drug candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures necessary to complete the development of our drug candidates.

Our future capital requirements will depend on many factors, including:

- the progress, costs, results and timing of the STEADFAST Study, and the clinical development of *azeliragon*;
- the willingness of the FDA to accept the STEADFAST Study, as well as our other completed and planned clinical and preclinical studies and other work, as the basis for review and approval of *azeliragon*;

## TABLE OF CONTENTS

- the outcome, costs and timing of seeking and obtaining FDA and any other regulatory approvals;
- the number and characteristics of drug candidates that we pursue, including our drug candidates in preclinical development;
- the ability of our drug candidates to progress through clinical development successfully;
- our need to expand our research and development activities;
- the costs associated with securing, establishing and maintaining commercialization capabilities;
- the costs of acquiring, licensing or investing in businesses, products, drug candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to hire additional management and scientific and medical personnel;
- the effect of competing technological and market developments;
- our need to implement additional internal systems and infrastructure, including financial and reporting systems;
- the economic and other terms, timing and success of our existing licensing arrangements and any collaboration, licensing or other arrangements into which we may enter in the future; and
- the amount of any payments we are required to make to vTv Therapeutics Holdings in the future under the Tax Receivable Agreement.

Until such time, if ever, as we can generate substantial revenue from drug sales, we expect to finance our cash needs through a combination of equity offerings, debt financings, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interests of our common stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or drug candidates or grant licenses on terms that may not be favorable to us.

### Contractual Obligations and Commitments

The following table summarizes our contractual obligations at December 31, 2014:

	Total	Less Than 1 Year	1 – 3 Years	3 – 5 Years	More Than 5 Years
<b>(dollars in thousands)</b>					
Principal payments <sup>(1)</sup>	\$ 29,575	\$ 155	\$ 29,420	\$ —	\$ —
Operating lease commitments	2,653	793	1,860	—	—
Capital lease obligations	18	5	12	1	—
Other liabilities – related party <sup>(2)</sup>	5,000	625	2,500	1,875	—
Total contractual obligations	<u>\$ 37,246</u>	<u>\$ 1,578</u>	<u>\$ 33,792</u>	<u>\$ 1,876</u>	<u>\$ —</u>

<sup>(1)</sup>Following the Reorganization Transactions and this offering, we will not have any obligations for these principal payments.

<sup>(2)</sup>Following the Reorganization Transactions and this offering, we will not have any obligations for other liabilities-related party.

Additionally, we enter into contracts in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes, which generally provide for termination or cancellation within 30 days of notice, and therefore are not included in the table above. We also expect to enter into an employment agreement with our chief executive officer that will require the funding of specific payments, if certain events occur, such as a change in control or the termination of his employment without cause. These potential payment obligations are not included in the table above.

#### **Off-Balance Sheet Arrangements**

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

#### **Recent Accounting Pronouncements**

In April 2014, the FASB issued ASU No. 2014-08, "Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity" ("ASU 2014-08"). The amendments in this ASU change the criteria for reporting discontinued operations and enhance convergence of the FASB's and the International Accounting Standards Board's (the "IASB") reporting requirements for discontinued operations. Under AU 2014-08, elimination of the operations and cash flows of a disposed component from an entity's ongoing operations and the absence of significant continuing involvement in the operations of the component after disposal are no longer pre-conditions to present the component as a discontinued operation. In addition this ASU has resulted in increased disclosure for both disposal activities that do and do not qualify for discontinued operations presentation in its financial statements. ASU 2014-08 is effective for all disposals or classifications as held for sale of components of an entity that occur within annual periods beginning on or after December 15, 2014 and early adoption is permitted. We have elected to early adopt ASU 2014-08 as of January 1, 2014. The transfer of HPCTC during the year ending December 31, 2014 was evaluated under the requirements of ASU No. 2014-08. Management concluded that the disposal of HPCTC does not represent a strategic shift in operations and therefore is not presented as discontinued operations. See Note 3, "Repurchase of Former Officer's Interest," to our audited financial statements, for additional discussion of the transfer of HPCTC.

In June 2014, the FASB issued ASU No. 2014-12, "Compensation-Stock Compensation ('Topic 718'): Accounting for Share-Based Payments when the Terms of an Award Provide that a Performance Target Could Be Achieved After the Requisite Service Period" ("ASU 2014-12"). The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. Entities may apply ASU 2014-12 either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this ASU as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. We adopted this standard effective January 1, 2013. Early adoption did not have a material effect on our financial statements.

#### **Recently Issued Accounting Pronouncements Not Yet Adopted**

In May 2014, the FASB issued guidance codified in ASC Topic 606, "Revenue Recognition—Revenue from Contracts with Customers," which amends the guidance in ASC Topic 605, "Revenue Recognition," and becomes effective beginning January 1, 2017. We are currently evaluating the impact of the provisions of ASC Topic 606 on its financial statements and disclosures.

On August 27, 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements—Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The new standard provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern, and to provide related

footnote disclosure. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The adoption of this standard is not expected to have a material impact on our financial statements.

In January 2015, the FASB issued ASU No. 2015-01, "Income Statement—Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items," which eliminates from GAAP the concept of extraordinary items. This ASU is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, with early adoption permitted provided the guidance is applied from the beginning of the fiscal year of adoption. We do not expect this standard to have an impact on our financial statements upon adoption.

In February 2015, the FASB issued ASU No. 2015-02, "Consolidation—Amendments to the Consolidation Analysis (Topic 810)" ("ASU 2015-02"). This ASU requires reporting entities to reevaluate whether they should consolidate certain legal entities under the revised consolidation model. This standard modifies the evaluation of whether limited partnerships and similar legal entities are variable interest entities (VIEs), eliminates the presumption that a general partner should consolidate a limited partnership, and affects the consolidation analysis of reporting entities that are involved with VIEs, especially those that have fee arrangements and related party relationships. This ASU is effective for fiscal years beginning after December 15, 2015, and for interim periods within those fiscal years. We are in the process of assessing the impact of the adoption of ASU 2015-02 on our combined consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, "Interest - Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs" ("ASU 2015-03"). The update requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. We are in the process of assessing the impact of the adoption of ASU 2015-03 on our combined consolidated financial statements.

#### **Qualitative and Quantitative Disclosures about Market Risk**

Our exposure to market risk is limited to our cash, cash equivalents and marketable securities, all of which have maturities of one year or less. The goals of our investment strategy are preservation of capital, fulfillment of liquidity needs and fiduciary control of cash and investments. We also seek to maximize income from our investments without assuming significant risk. To achieve our goals, we maintain a portfolio of cash equivalents and investments in a variety of securities that management believes to be of high credit quality. The securities in our investment portfolio are not leveraged, are classified as available for sale and are, due to their short-term nature, subject to minimal interest rate risk. We currently do not hedge interest rate exposure. Because of the short-term maturities of our investments, we do not believe that an increase in market rates would have a material negative impact on the value of our investment portfolio.

We do not have any material foreign currency exposure.



## BUSINESS

**Overview**

We are a clinical-stage biopharmaceutical company engaged in the discovery and development of orally administered small molecule drug candidates to fill significant unmet medical needs. We have a powerful pipeline of clinical drug candidates, led by our programs for the treatment of Alzheimer's disease ("AD") and type 2 diabetes. Our drug candidate for the treatment of AD, *azeliragon* (TTP488), is an orally administered, small molecule antagonist targeting the receptor for advanced glycation endproducts ("RAGE"), and we have commenced patient enrollment in a Phase 3 clinical trial (the "STEADFAST Study") under an FDA-agreed Special Protocol Assessment ("SPA"). Our type 2 diabetes drug candidates include TTP399, an orally administered, liver-selective glucokinase activator ("GKA"), for which we are currently enrolling patients in a Phase 2b clinical trial (the "AGATA Study"), and TTP273, an orally administered, non-peptide agonist that targets the glucagon-like peptide-1 receptor ("GLP-1r"), which we anticipate will enter a Phase 2 clinical trial in early 2016. We have three additional programs in various stages of clinical development for the prevention of muscle weakness and the treatment of inflammatory disorders.

***Azeliragon and the Treatment of Alzheimer's Disease***

Alzheimer's disease is a progressive neurodegenerative disorder that slowly destroys memory and thinking skills, with a number of other behavioral and neuropsychiatric symptoms. While estimates of the prevalence of AD vary, the Alzheimer's Association estimates that in 2015 there are 5.3 million people in the United States suffering from AD. According to Decision Resources, in 2013, there were 8.3 million AD patients in the "G7 Pharmaceutical Markets," including 3.1 million in the United States and 5.2 million in Western Europe (France, Germany, Italy, Spain and the United Kingdom) and Japan. Mild AD patients represent approximately 64% of the overall AD population. There are currently no disease-modifying therapies approved for the treatment of AD; however, according to Decision Resources, this segment of the market is expected to grow to \$7.7 billion by 2023, representing approximately 60% of expected 2023 revenues in the global AD market.

*Azeliragon* is an orally administered, small molecule drug candidate that has the potential to be among the first FDA approved disease-modifying AD therapeutics due to its novel mechanism of action of inhibiting RAGE. Because of that potential, *azeliragon* has been awarded Fast Track designation by the FDA. The FDA grants Fast Track designation to facilitate the development and expedite the review of drugs intended to treat serious diseases or conditions and fill an unmet medical need. RAGE is a cell surface receptor that is implicated in many of the processes thought to play a primary role in the development and progression of AD, including amyloid-beta ("A $\beta$ ") transport into the brain, the phosphorylation of tau protein, chronic inflammation, vascular dysfunction, metabolic dysregulation and neurotoxicity. By inhibiting RAGE, *azeliragon* has the potential to slow the progression of cognitive decline in mild and mild-to-moderate AD patients. We are not aware of any other clinical-stage drugs targeting RAGE. Unlike development stage disease-modifying treatments from other companies that target a singular cause of AD, *azeliragon* is designed to interact with multiple aspects of AD etiology.

We are currently enrolling the 800-patient STEADFAST Study, a Phase 3 clinical trial, under an FDA-agreed SPA. The STEADFAST Study includes two sub-studies under one protocol. Each sub-study will enroll 400 patients with mild AD, randomized to receive a 5 mg/day dose of *azeliragon* or placebo on a one-to-one basis, and is powered to achieve statistical significance on the co-primary endpoints—change from baseline in ADAS-COG<sub>11</sub> and CDR-SB scores, which are standard measures of cognitive impairment and global function in AD patients. We expect to report topline data by mid-2018. Our Phase 2b study of *azeliragon* in 399 mild-to-moderate AD patients demonstrated a statistically significant benefit at the 5 mg/day dose versus placebo at 18 months with respect to ADAS-COG<sub>11</sub> and a statistically significant lower frequency of psychiatric adverse events. At the same dose, we identified an even more pronounced benefit in ADAS-COG<sub>11</sub> and CDR-SB scores in an analysis of the sub-population of patients with mild AD. In all of our Phase 1 and 2 clinical trials, *azeliragon* has been shown to be generally safe and well tolerated at a dose of 5 mg/day.

***TTP399 and TTP273 and the Treatment of Diabetes***

Diabetes is characterized by the body's inability to properly use or produce insulin, the hormone necessary for the uptake of sugar from the bloodstream so that it may be converted into energy. Type 2

diabetes is an inability to properly use insulin to control sugar in the bloodstream, and 90 to 95% of diabetes patients have type 2 diabetes. According to Decision Resources, in 2013, 62.2 million adults in the G7 Pharmaceutical Markets suffered from type 2 diabetes, including 29.8 million adults in the United States aged 20 and over. There are multiple drug classes approved for the treatment of type 2 diabetes, including insulin replacement, metformin, sulfonylureas, thiazolidinedione, SGLT-2 inhibitors, DPP-4 inhibitors and injectable GLP-1r agonists. We expect our type 2 diabetes drug candidates to compete in the non-insulin segment of the market, which, according to Decision Resources, totaled sales of \$13.4 billion in the G7 Pharmaceutical Markets for 2013 and is expected to grow to \$27.0 billion by 2023. Despite the availability of these drugs, a substantial portion of type 2 diabetes patients are unable to maintain adequate control of blood glucose levels and eventually progress to insulin therapy, demonstrating the need for additional therapies with novel mechanisms of action and routes of administration to improve efficacy and patient compliance.

We are currently evaluating our GKA drug candidate, *TTP399*, in a 180-patient Phase 2b trial, the AGATA Study, to assess its ability to improve control of blood glucose levels over a six-month period. The primary endpoint of the AGATA Study is the change from baseline in glycosylated hemoglobin (“HbA<sub>1c</sub>”) levels, and we expect to report topline data in the first half of 2016. *TTP399* is an orally administered, small molecule, liver-selective GKA, which uses a novel mechanism of action for the treatment of type 2 diabetes. Liver-selective activation of glucokinase (“GK”) provides intensive glycemic control without inducing hypoglycemia. Treatment with *TTP399* is designed to avoid the safety and tolerability issues associated with other GKA candidate drugs in clinical development. We completed a six-week Phase 2a clinical trial of *TTP399* in 120 type 2 diabetes patients whose glycemic parameters were not well-controlled on metformin, in which patients treated with *TTP399* showed statistically significant reductions in HbA<sub>1c</sub> levels compared with placebo without induction of hypoglycemia, hyperlipidemia or insulin secretion. If approved, we believe *TTP399* will compete primarily with oral anti-diabetic drugs (“OADs”), including DPP-4 and SGLT-2 inhibitors. Further, we believe that *TTP399* has the potential to demonstrate higher efficacy than competing non-insulin products, the potential to normalize HbA<sub>1c</sub> levels, and the potential for no contraindication for renal impairment and no risk of pancreatitis. We believe that *TTP399* has the potential to be a first-in-class OAD due to its liver-selectivity and novel mechanism of action.

We anticipate commencing a Phase 2 clinical trial for our orally administered GLP-1r agonist drug candidate, *TTP273*, in early 2016, and expect to report topline data in late 2016. *TTP273* is a small molecule, non-peptide GLP-1r agonist. Currently available GLP-1r agonists (which are injectable peptides) are well established in terms of efficacy, including the ability to lower blood glucose, decrease HbA<sub>1c</sub> levels and induce weight loss, but their use has been limited due to their subcutaneous administration and gastrointestinal side effects, including nausea and vomiting. We believe that an orally administered GLP-1r agonist that has the metabolic effects of currently available GLP-1r agonists, without the gastrointestinal side effects typical of this class of compounds, would offer a competitive advantage compared to GLP-1r targeted treatment options currently available. We previously conducted a proof-of-concept study with a first-generation GLP-1r agonist that demonstrated the proof-of-concept for an orally delivered, small molecule GLP-1r agonist with efficacy consistent with marketed GLP-1r agonists. Additionally, we have conducted Phase 1 clinical trials for *TTP273* in healthy volunteers and type 2 diabetics that showed that *TTP273* was safe and well-tolerated. Our trials have indicated that *TTP273* may have superior tolerability compared to competing products and no risk of antibody formation because *TTP273* is a small molecule. For these reasons, we believe *TTP273* has the potential to expand the market of GLP-1r agonist therapies and replace a number of current GLP-1-related therapies, including DPP-4 inhibitors and injectable GLP-1 analogues.

#### **Other Clinical Programs**

We have three additional programs in various stages of clinical development for the prevention of muscle weakness and the treatment of inflammatory disorders. *HPP593* is a functionally selective peroxisome proliferator-activated receptor delta (“PPAR- $\delta$ ”) agonist being developed for the prevention of muscle weakness associated with prolonged mechanical ventilation (“PMV”) and critical injury that has achieved proof-of-concept in a Phase 1b clinical trial. We plan to initiate a Phase 2 clinical trial in late 2015 and expect to report topline data in late 2016. *HPP737* is an orally administered phosphodiesterase-4 (“PDE4”) inhibitor that is being developed for the treatment of chronic obstructive pulmonary disease

## TABLE OF CONTENTS

("COPD"), psoriasis and other inflammatory diseases. *HPP737* was shown to be safe and well tolerated in a Phase 1 clinical trial and we plan to commence a Phase 2 trial in patients with either psoriasis or COPD in early 2016, with topline data anticipated in late 2016. *HPP971*, a Bach1 inhibitor, is being developed for the treatment of inflammation, autoimmune diseases and diseases associated with oxidative stress, and is currently in Phase 1 development.

### Our Pipeline

We discovered our drug candidates (other than *HPP593*) using our proprietary drug discovery platform, TTP Translational Technology. The following table summarizes our current drug candidates and their respective stages of development:

Program	Preclinical	Phase 1	Phase 2	Phase 3	Status	Milestones
<b>Alzheimer's Disease</b>						
Azeliragon (TTP488): RAGE Antagonist					Phase 3 enrolling	Topline results expected mid 2018
<b>Type 2 Diabetes</b>						
TTP399: Glucokinase Activator					Phase 2b enrolling	Topline results expected mid 2016
TTP273: Oral GLP-1r Agonist					Initiation of Phase 2 trial expected early 2016	Topline results expected late 2016
<b>Prevention of Muscle Weakness Associated with PMV and Critical Injury</b>						
HPP593: PPAR-δ Agonist					Initiation of Phase 2 trial expected late 2015	Topline results expected late 2016
<b>Inflammatory Disorders</b>						
HPP737: PDE4 Inhibitor					Initiation of Phase 2 trial expected early 2016	Topline results expected late 2016
HPP971: Bach1 Inhibitor					Phase 1 ongoing	
<b>Cancer</b>						
Hexokinase II Inhibitor					Preclinical	Licensed to Calithera Biosciences, Inc. in 2015
vTv Therapeutics Inc. retains all rights to the programs in its pipeline, except for the Hexokinase II Inhibitor program, which is licensed to Calithera Biosciences, Inc.						

Each of our most advanced drug candidates is the subject of patent and patent applications for composition of matter and method of use in major markets worldwide. Our patents are expected to provide us with intellectual property protection through 2029 for *azeliragon*, 2030 for *TTP399* and 2034 for *TTP273*, in each case, assuming we obtain the maximum possible extensions in the United States.

### Our Strategy

Our goal is to leverage our powerful pipeline of orally administered, small molecule drug candidates to deliver novel, differentiated therapies to fill significant unmet medical needs. As key components of our strategy, we intend to:

- **Continue Phase 3 enrollment and seek regulatory approval of *azeliragon* as a disease-modifying treatment for patients with mild AD.** We initiated the STEADFAST Study in April 2015 after receiving positive results from an analysis of data collected in our Phase 2b clinical trial of *azeliragon* in mild-to-moderate AD patients. The STEADFAST Study is being conducted under an FDA-agreed SPA and will serve as a registration trial for regulatory approval in the United States. We expect to receive data from the STEADFAST Study in mid-2018, and intend to file a new drug application ("NDA") with the FDA by the end of 2018. Additionally, the FDA granted Fast Track designation to *azeliragon* based on its potential as a disease-modifying therapy.
- **Complete Phase 2 development of our type 2 diabetes programs.** We are advancing both *TTP399* and *TTP273* into Phase 2 clinical trials. We initiated the Phase 2b AGATA Study for *TTP399*, our

small molecule liver-selective GKA, in March 2015 with topline data expected in mid-2016. We plan to commence a three month Phase 2 clinical trial for *TTP273*, our orally administered GLP-1r agonist, in early 2016 with topline data expected in late 2016. We believe both compounds have the ability to take significant market share from existing oral and injectable anti-diabetic drugs.

- **Evaluate strategic collaborations for the commercialization of *azelinagon*.** We plan to seek strategic collaborations for the commercialization of and marketing of *azelinagon* in the United States and the rest of the world.
- **Seek strategic collaborations for Phase 3 development and commercialization of our type 2 diabetes programs.** We plan to seek strategic collaborations for the development, commercialization of, and marketing of our type 2 diabetes programs, *TTP399* and *TTP273*, in the United States and the rest of the world.
- **Continue development of additional pipeline programs and seek strategic development partners for those programs.** We intend to continue developing our other drug candidates, including *HPP593*, *HPP737* and *HPP971*, while simultaneously evaluating strategic collaborations as they may arise.
- **Evaluate opportunities to leverage our TTP Translational Technology to discover additional drug candidates for internal or external development.** We will evaluate opportunities to use TTP Translational Technology, our proprietary drug discovery platform, to discover innovative new drug candidates for internal development or to license to third parties, similar to our arrangement with Calithera.

## **Our Alzheimer's Program – *Azelinagon***

### ***Azelinagon* Overview**

*Azelinagon* is a novel small molecule designed to target RAGE, which we believe is a key upstream factor responsible for disease progression in AD patients. We are currently enrolling patients in the STEADFAST Study, a Phase 3 clinical trial for *azelinagon*, which is subject to an FDA-agreed SPA. *Azelinagon* has also received Fast Track designation from the FDA. Results from our Phase 2b study of *azelinagon* demonstrated a statistically significant and clinically meaningful slowing of cognitive decline over 18 months at the 5 mg/day dose. Due to *azelinagon*'s novel mechanistic properties, we believe that it has the potential to provide a disease-modifying benefit to AD patients.

### **Alzheimer's Disease Market Opportunity**

AD is a progressive neurodegenerative disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out simple tasks. Its symptoms include cognitive dysfunction, memory abnormalities, progressive impairment in activities of daily living and a host of behavioral and neuropsychiatric symptoms. The exact cause of AD is unknown, however, genetic and environmental factors are established contributors. A $\beta$  plaques and neurofibrillary tangles of tau protein in the brain are believed to be the main causes of the disease, leading to loss of neuronal connectivity in the brain. There are currently no cures or disease-modifying therapies for AD, as existing agents ease the symptoms of AD but do not address the underlying causes.

While estimates of the prevalence of AD vary, the Alzheimer's Association estimates that in 2015 there are 5.3 million people in the United States suffering from AD. According to Decision Resources, in 2013, there were 8.3 million AD patients in the G7 Pharmaceutical Markets, comprised of 3.1 million in the United States and 5.2 million in Western Europe (France, Germany, Italy, Spain and the United Kingdom) and Japan. Mild AD patients represent approximately 64% of the overall AD population. There are currently no disease-modifying therapies approved for the treatment of AD, however, according to Decision Resources, this segment of the market is expected to grow to \$7.7 billion by 2023, representing approximately 60% of revenues in the global AD market.

### **Generally Accepted Alzheimer's Disease Clinical Measurement Scales**

The following are commonly used measures for assessing the behavior, function and cognitive impairment of AD patients:

- **ADAS-COG<sub>11</sub>**. The Alzheimer's Disease Assessment Scale-Cognitive Subscale ("ADAS-COG<sub>11</sub>") test is one of the most frequently used tests to measure cognition in clinical trials. The ADAS-COG<sub>11</sub> consists of a 70 point scale measured through 11 parts where a higher score indicates more cognitive impairment. A normal score for someone who does not have AD or another type of dementia is five, according to research conducted in 2004 and published in the journal Alzheimer's Disease and Associated Disorders.
- **CDR-SB**. The Clinical Dementia Rating Scale Sum of Boxes ("CDR-SB") score (range 0 to 18) is obtained by summing ratings in each of six cognitive domains or boxes including memory, orientation, judgment/problem solving, community affairs, home and hobbies and personal care. Higher scores reflect more global impairment.
- **MMSE**. The Mini-Mental State Examination ("MMSE") is a sensitive and clinically validated 30-point questionnaire that is often used to measure cognitive impairment. Any score greater than or equal to 27 points (out of 30) indicates normal cognition. Below this, scores can indicate severe ( $\leq 15$  points), moderate (16–20 points) or mild (21–26 points) AD.
- **ADCS-ADL**. The Alzheimer's Disease Cooperative Study Activities of Daily Living ("ADCS-ADL") is designed to assess mild-to-moderate AD, using activities of daily living, such as reading books or magazines, pastime activities or household chores. The scores range from 0 to 78, with higher scores indicating a greater level of function.
- **NPI**. The Neuropsychiatric Inventory ("NPI") is a measurement of AD patients' behavior. It is based on a 144 point scale, where a higher score indicates more behavioral impairment.

### **Current Treatments for Alzheimer's Disease and Their Limitations**

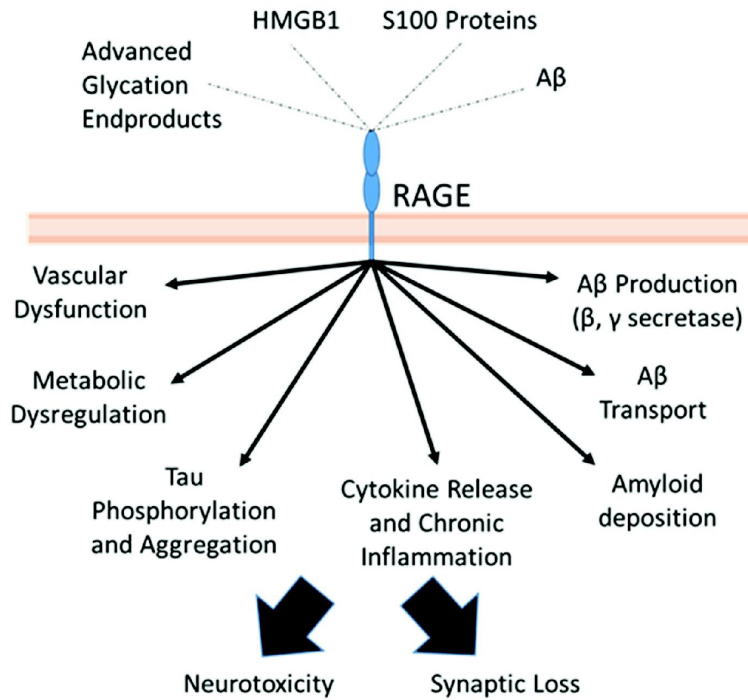
Currently, there are no disease-modifying treatments approved for the treatment of AD, and there are only two classes of approved therapies for the treatment of symptoms of AD: acetylcholinesterase inhibitors ("AChEIs") and glutamatergic modulators. AChEIs are designed to slow the degradation of acetylcholine, helping to preserve neuronal communication and function temporarily, but do not slow or halt neuronal death. Glutamatergic modulators are designed to block sustained, low-level activation of the N-methyl-D-aspartate ("NMDA") receptor without inhibiting the normal function of the receptor in memory and cognition, providing temporary symptomatic relief.

The currently available treatments combat the symptoms of AD rather than the underlying cause, or etiology, and as a result, AD continues to progress in these patients despite treatment. Similarly, the use of antidepressants and antipsychotics are often prescribed off-label to treat the symptoms of severe AD when patients suffer from agitation, aggressive behaviors, psychosis and depression. Recent drug candidates under development include those focused on A $\beta$  synthesis or clearance from the brain, the phosphorylation of tau protein, chronic inflammation, vascular dysfunction, metabolic dysregulation and neurotoxicity.

### **The Role of RAGE in the Onset of Alzheimer's Disease**

RAGE is an immunoglobulin-like cell surface receptor that is overexpressed in brain tissues of patients with AD. We believe that RAGE is an important cellular cofactor that binds with ligands that are implicated in multiple etiologies of AD, including A $\beta$  transport into the brain, the phosphorylation of tau, chronic inflammation, vascular dysfunction, metabolic dysregulation and neurotoxicity. These effects are attenuated following antagonism of the RAGE receptor.

Post-mortem studies in AD patients reveal increased RAGE expression in neuronal, microglial and endothelial cells when compared to similar subjects without AD. Cells around senile plaques express higher levels of RAGE during disease progression. Furthermore, expressed levels of RAGE are correlated with the severity of the disease. The data observed in human AD patients is consistent with the multiple pre-clinical *in-vitro* and *in-vivo* animal models studied by third parties that show RAGE is overexpressed in brain tissue of AD subjects. Taken together, we believe that literature provides substantial support for RAGE inhibition as a validated and promising therapeutic approach in the treatment of AD.



**Our Solution: Azeliragon**

*Azeliragon* is an orally administered, small molecule drug candidate that has the potential to be among the first FDA approved disease-modifying AD therapeutics due to its novel mechanism of action of inhibiting RAGE. We have demonstrated that *azeliragon* is a potent and selective inhibitor of RAGE and, in an analysis of data collected in our Phase 2b clinical trial, *azeliragon* slowed the progression of cognitive decline in mild and mild-to-moderate AD patients. *Azeliragon* has the potential to offer a novel modality in AD therapeutics, and we are not aware of any other clinical-stage drugs targeting RAGE. Because there are currently no approved disease-modifying treatments for AD and since currently approved treatments are focused on symptom relief, we believe that *azeliragon* represents a new approach for the treatment of AD. In addition, we believe that in order to successfully treat and combat the physiological progression of AD, a disease-modifying therapeutic must act on multiple causes, or etiologies, of the disease. Unlike development stage disease-modifying treatments that target a singular cause of AD, *azeliragon* is designed to inhibit RAGE, which affects multiple aspects of AD etiology, including Aβ transport into the brain, the phosphorylation of tau, chronic inflammation, vascular dysfunction, metabolic dysregulation and neurotoxicity.

**Azeliragon Clinical and Regulatory Overview**

We are currently enrolling the 800-patient STEADFAST Study, a Phase 3 clinical trial, under an FDA-agreed SPA. The STEADFAST Study includes two sub-studies under one protocol. Each sub-study will enroll 400 patients with mild AD, randomized to receive a 5 mg/day dose of *azeliragon* or a placebo on a one-to-one basis, and is powered to achieve statistical significance on the co-primary endpoints, with topline data expected by mid-2018. In accordance with the SPA, we expect to be able to file for regulatory approval of *azeliragon* following successful completion of this pivotal trial. *Azeliragon* has been granted Fast Track designation by the FDA. Our Phase 2b clinical trial in mild-to-moderate AD patients showed a statistically significant improvement in its primary endpoint, change from baseline in ADAS-COG<sub>11</sub> for the 5 mg/day dose of *azeliragon* compared with the placebo arm. While the study was not powered to show statistical significance in secondary endpoints, the results also showed improvement in global, functional, behavioral and cognitive secondary endpoints for the 5 mg/day dose of *azeliragon* compared with the placebo arm,

## TABLE OF CONTENTS

though these improvements were not statistically significant. Furthermore, an analysis found *azeliragon* to have greater efficacy in the sub-group of mild AD patients, and it is this population that we are studying in our ongoing Phase 3 registration trial. We have completed six Phase 1 and three Phase 2 clinical trials (two enrolling patients with AD and one enrolling patients with diabetic nephropathy) of *azeliragon*, in which *azeliragon* has been generally safe and well tolerated at the 5 mg/day dose.

The table below sets forth information regarding our ongoing and completed clinical trials of *azeliragon*.

Study	Phase	Objectives	Completion Date
STEADFAST	Phase 3	Efficacy in mild AD for 18 months	Est. mid-2018
TTP488-203	Phase 2b	Safety and efficacy in mild-to-moderate AD for 18 months	December 2010
TTP488-202	Phase 2a	Safety and efficacy in type 2 diabetics with albuminuria	August 2009
TTP488-201	Phase 2a	Safety and efficacy in mild-to-moderate AD for 10 weeks	June 2006
TTP488-106	Phase 1	Evaluate pharmacokinetics ("PK") and its metabolites in plasma, urine and bile	February 2015
TTP488-105	Phase 1	Evaluation of food effect on commercial formulation	July 2014
TTP488-104	Phase 1	Assess concentration in cerebrospinal fluid ("CSF")	March 2006
TTP488-103	Phase 1	Assess concentration in CSF	October 2005
TTP488-102	Phase 1	Dose escalation in elderly for safety, tolerability and PK	August 2005
TTP488-101	Phase 1	Dose escalation for safety and PK	November 2004

### Ongoing Phase 3 STEADFAST Study

We initiated our Phase 3 clinical trial, the STEADFAST Study, in April 2015 pursuant to an SPA with the FDA. The STEADFAST Study is a randomized, double-blind, parallel group, 18-month trial in patients with mild AD, which is the population that showed greater benefit from *azeliragon* in an analysis of our Phase 2b trial, on standard of care of AChEIs and/or memantine. For the purposes of the STEADFAST Study, patients with a MMSE score of 21 to 26 are considered to have mild AD. The study is conducted under a single protocol and will enroll 800 patients in total, divided equally across two independent 400-patient sub-studies, in which each subject will receive either a 5 mg/day dose of *azeliragon* or placebo, randomized on a one-to-one basis, added to the standard of care. The sub-studies are independently powered to demonstrate statistically significant differences in co-primary endpoints at month 18. The STEADFAST Study, if successful, will serve as the basis for filing an NDA in the United States and may also serve as a pivotal trial for marketing applications in other jurisdictions.

The co-primary endpoints for the STEADFAST Study, the change from baseline in ADAS-COG<sub>11</sub> and CDR-SB scores, are designed to establish efficacy by demonstrating a slowing in the loss of cognition and function in AD patients treated with *azeliragon*. We are evaluating multiple secondary endpoints and the key secondary endpoint is MRI brain volumetric measures. We believe that MRI imaging for volumetric measures has the potential to demonstrate modification of the underlying disease by *azeliragon*. Topline results from the STEADFAST Study are expected in mid-2018, and we would expect to file an NDA with the FDA by the end of 2018.

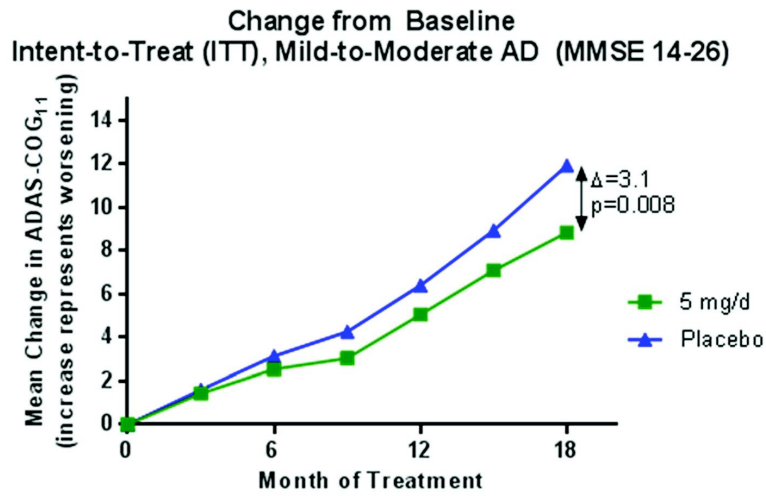
### Completed Phase 2b Trial (TTP488-203)

#### Efficacy in Mild-to-Moderate AD Patients

Our completed Phase 2b clinical trial of *azeliragon*, TTP488-203, was a randomized, double blind, placebo-controlled, 18-month trial assessing the safety and efficacy of *azeliragon* in 399 patients with mild-to-moderate AD, the intent-to-treat ("ITT") population. *Azeliragon* or placebo was added to the standard of care, AChEIs and/or memantine. Patients were randomized to receive an oral dose of 20 mg/day of *azeliragon*, 5 mg/day of *azeliragon* or placebo. Patients in the high dose *azeliragon* arm initially received 60 mg/day of *azeliragon* for six days followed by a daily 20 mg dose, while patients in the low dose arm initially received 15 mg/day of *azeliragon* for six days followed by a 5 mg/day dose.

The primary endpoint of the study was to impede the progression of AD over 18 months as measured by the change from baseline in ADAS-COG<sub>11</sub> score. The secondary endpoints included the changes in global, functional, cognitive and behavioral attributes as measured by CDR-SB, ADCS-ADL, MMSE and NPI.

*Azeliragon*, at the 5 mg/day dose, met its pre-specified ADAS-COG<sub>11</sub> endpoint demonstrating a statistically significant 3.1 point difference ( $p = 0.008$ ) versus placebo at 18 months in patients with mild-to-moderate AD. The results of the primary ADAS-COG<sub>11</sub> endpoint are summarized in the figure below.

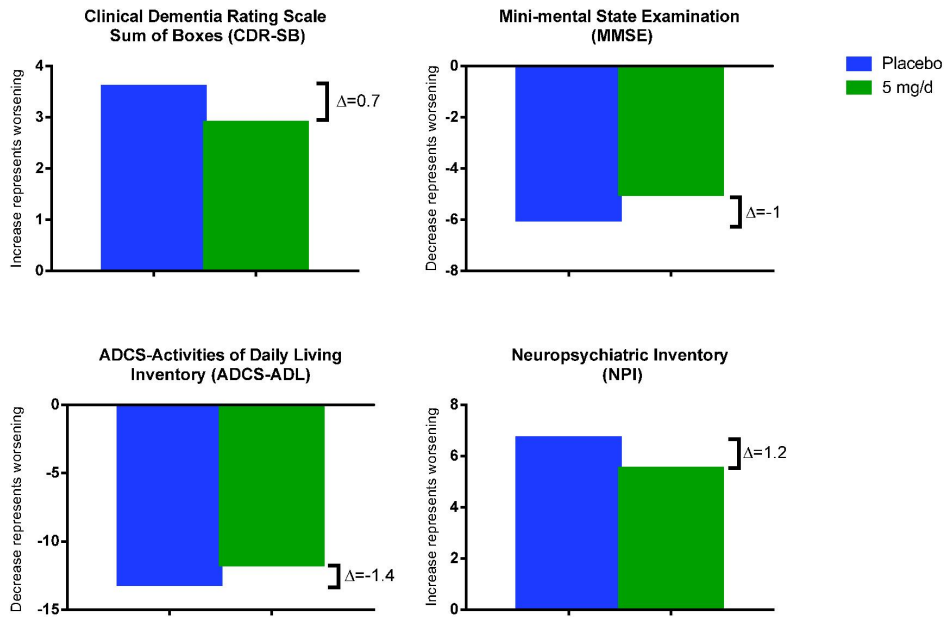


The results for global, functional, cognitive and behavioral secondary endpoints after 18 months were also favorable despite the study not being powered to show significance. In each of the CDR-SB, ADCS-ADL, MMSE and NPI, patients in the 5 mg/day dose arm of *azeliragon* demonstrated numerical improvement compared to the placebo arm. In particular, the CDR-SB score improved by 0.7, the ADCS-ADL score improved by 1.4, the MMSE score improved by 1.0 and the NPI score improved by 1.2. In addition, the 5 mg/day treatment arm of *azeliragon* exhibited a statistically significant decrease in the incidence of psychiatric adverse events, including a statistically significant decrease in anxiety symptoms.



The results of the secondary endpoints in the ITT population are summarized in the following figures, which, in each case, illustrate a potential benefit of *azeliragon* versus placebo.

***Azeliragon* Effects on Global, Functional, Behavioral and Cognitive Secondary Endpoints  
ITT, Mild-to-Moderate AD (MMSE 14-26)**



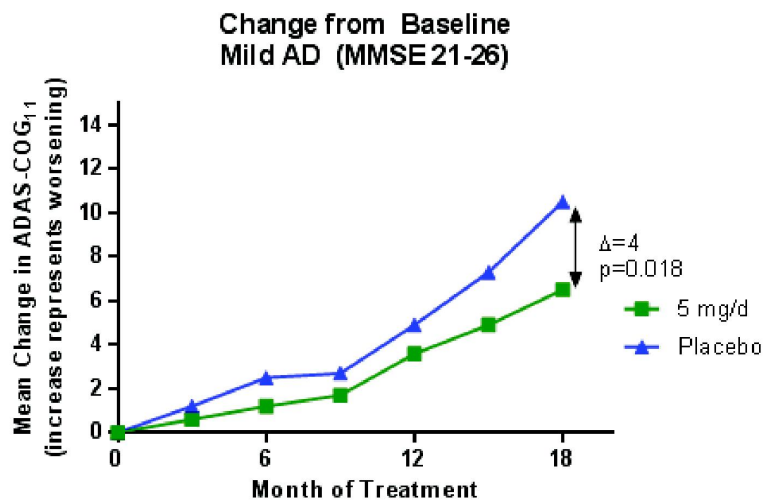
Prior to the completion of the analyses described above, in a pre-specified interim analysis, when 50% of subjects had completed the six-month visit, the high dose was found to be associated with an increased incidence of confusion, falls, and greater ADAS-COG<sub>11</sub> decline than placebo and was discontinued. A second pre-specified interim analysis was conducted approximately 12 months after all subjects were randomized to compare the 5 mg/day dose versus placebo for futility and safety. While this second pre-specified interim analysis raised no concerns regarding safety in the low-dose group, the criterion for futility was met, and the Data Safety Monitoring Board, or DSMB, recommended discontinuation of the study. Treatment was subsequently discontinued.

The futility analysis was conducted using data from only 84 patients, rather than the full population of 266 patients, and the data used in the analysis had not yet undergone quality review. In accordance with the protocol-specified statistical analysis plan, subsequent to the futility analysis, we performed the analysis of the 5 mg/day dose with respect to the primary ADAS-COG<sub>11</sub> endpoint and the secondary endpoints, which produced the results described above.

*Efficacy in Mild AD Patients*

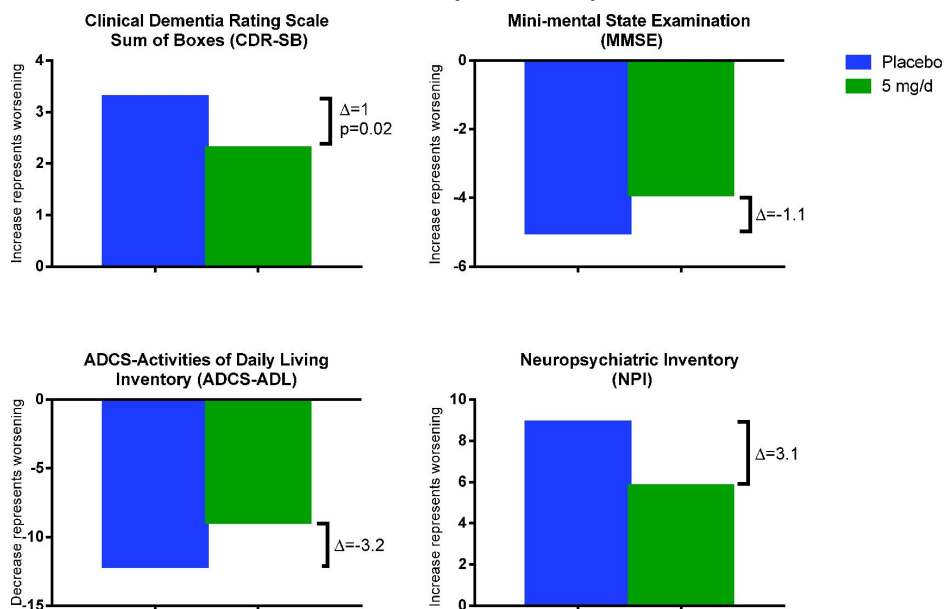
*Azeliragon* at the 5 mg/day dose showed more pronounced efficacy in the mild AD sub-population (MMSE score 21-26) compared to patients with moderate AD (MMSE score 14-20). In the mild AD sub-population, *azeliragon* exhibited a statistically significant 4.0-point difference (p=0.018) in the ADAS-COG<sub>11</sub> score relative to the placebo arm. In addition, while the study was not powered to show statistical significance in global, functional, behavioral and cognitive secondary endpoints, the mild AD sub-population demonstrated more pronounced favorable effects in those endpoints, including a statistically significant 1.0-point difference in the CDR-SB score (p=0.02) compared to the placebo group. The additional secondary endpoints demonstrated numerical improvements of 3.2 for the ADCS-ADL score, 1.1 for the MMSE score and 3.1 for the NPI score.

The results of the primary ADAS-COG<sub>11</sub> endpoint in the mild AD population are summarized in the figure below.



The results of the secondary endpoints in the mild AD population are summarized in the following figures, which, in each case, illustrate potential benefits of *azeliragon* versus placebo.

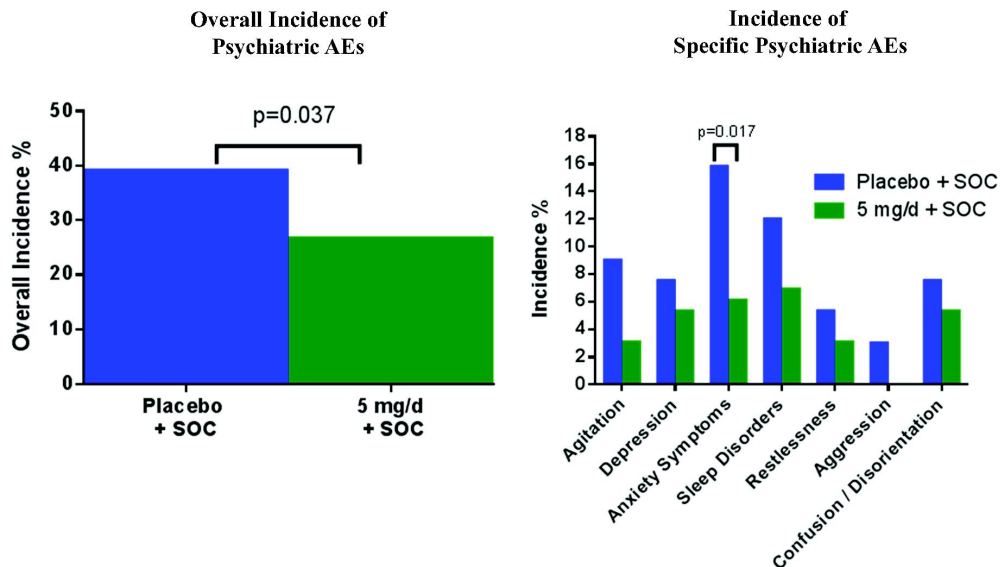
### *Azeliragon* Effects on Global, Functional, Behavioral and Cognitive Secondary Endpoints Mild AD (MMSE 21-26)



**Adverse Events**

Among the most frequent adverse events (“AEs”) in patients who received the high dose (20 mg/day) of *azeliragon* were falls (30 / 22.2%), urinary tract infection (“UTI”) (24 / 17.8%), diarrhea (20 / 14.8%), fatigue (19 / 14.1%), dizziness (12 / 8.9%), confusional state (10 / 7.4%) and headache (9 / 6.7%). Falls and UTI were also among the most frequent AEs in patients who received the low dose (5 mg/day) of *azeliragon* and placebo. The incidences of falls and UTI in the low-dose treatment group were 26 (19.8%) and 21 (16.0%), respectively; the incidences of falls and UTI among patients who received placebo were 26 (19.7%) and 17 (12.9%), respectively.

Of particular note, there was a statistically significant lower incidence of psychiatric AEs in patients receiving 5 mg/day compared to placebo. This was evidenced by a statically significant lower incidence of anxiety symptoms with numerically lower incidence of agitation, depression, sleep disorders, restlessness, aggression and confusion/disorientation.



No marked mean vital signs results or changes from baseline were observed in the active treatment groups compared to subjects who received placebo. There were no significant differences in laboratory blood or urine parameters or ECG changes between the three groups. No MRI findings of amyloid-associated imaging abnormalities (“ARIA”) were seen.

The high dose (20 mg/day) *azeliragon* arm was discontinued due to an increased incidence of confusion, falls, and an apparent accelerated cognitive decline suggested by a greater change over time in ADAS-COG<sub>11</sub> score at a pre-specified interim analysis by an independent DSMB. There were no safety concerns evident in the 5 mg/day dose or placebo and these groups were permitted to continue the trial following re-consenting of subjects. The cognitive impairment and side effects in the 20 mg/day dose were demonstrated to be reversible after discontinuing the study drug. The trajectory of the ADAS-COG<sub>11</sub> change from baseline curve over time not only showed the reversal of the transient cognitive worsening but ultimately crossed the placebo curve suggesting a possible underlying effect on the disease process. The mechanism behind the central nervous system (“CNS”) toxicity is unclear, but there were no signs of increased brain atrophy, no change in CSF and plasma levels of Aβ, and no detected amyloid-related imaging abnormalities in the high-dose group.

## **Our Diabetes Programs – Glucokinase Activator and GLP-1r Agonist**

### **Overview**

Our lead diabetes drug candidates consist of our GKA (*TTP399*), for which we are currently enrolling patients in the Phase 2b AGATA Study, and our GLP-1r agonist (*TTP273*), for which we have completed Phase 1 trials and anticipate commencing a Phase 2 trial in early 2016. In previous studies, both *TTP399* and *TTP273* have been safe and tolerable and have demonstrated early signs of efficacy in both healthy volunteers and diabetes patient populations. We believe that these results show that our diabetes programs have the potential to provide superior efficacy and safety profiles versus existing compounds. We believe that *TTP399* will be a first-in-class OAD due to its liver selectivity and novel mechanism of action. We believe that *TTP273* is positioned as a best-in-class GLP-1r agonist, providing type 2 diabetes patients with the only orally administered, small molecule, non-peptide GLP-1r agonist.

### **Diabetes Market Opportunity**

A person suffering from type 2 diabetes does not produce or properly use insulin (a hormone necessary for allowing uptake of sugar from the bloodstream so that it may be converted into energy). In type 2 diabetes, the secretion of insulin from the pancreas and the action of insulin on tissues such as fat and muscle are both abnormal. Type 2 diabetics produce insulin, but insulin production and use both decrease over time as the disease progresses, ultimately requiring insulin administration to manage the disease. Obesity is generally considered the major contributor to the development of type 2 diabetes. As the global obesity epidemic expands, the increase in the number of type 2 diabetes patients is expected to continue. With the increasing incidence and prevalence of type 2 diabetes, we believe there is a significant unmet medical need for treatment alternatives with improved efficacy and safety.

According to Decision Resources, in 2013, 29.8 million adults in the United States aged 20 and over and 62.2 million adults in the G7 markets suffered from type 2 diabetes. There are multiple approved drug classes approved for the treatment of type 2 diabetes, including insulin replacement, metformin, sulfonylureas, thiazolidinedione, SGLT-2 inhibitors, DPP-4 inhibitors and injectable GLP-1r agonists. We expect our type 2 diabetes drug candidates to compete in the non-insulin segment of the market, which, according to Decision Resources, totaled sales of \$13.4 billion in the G7 Pharmaceutical Markets for 2013 and is expected to grow to \$27.0 billion worldwide by 2023.

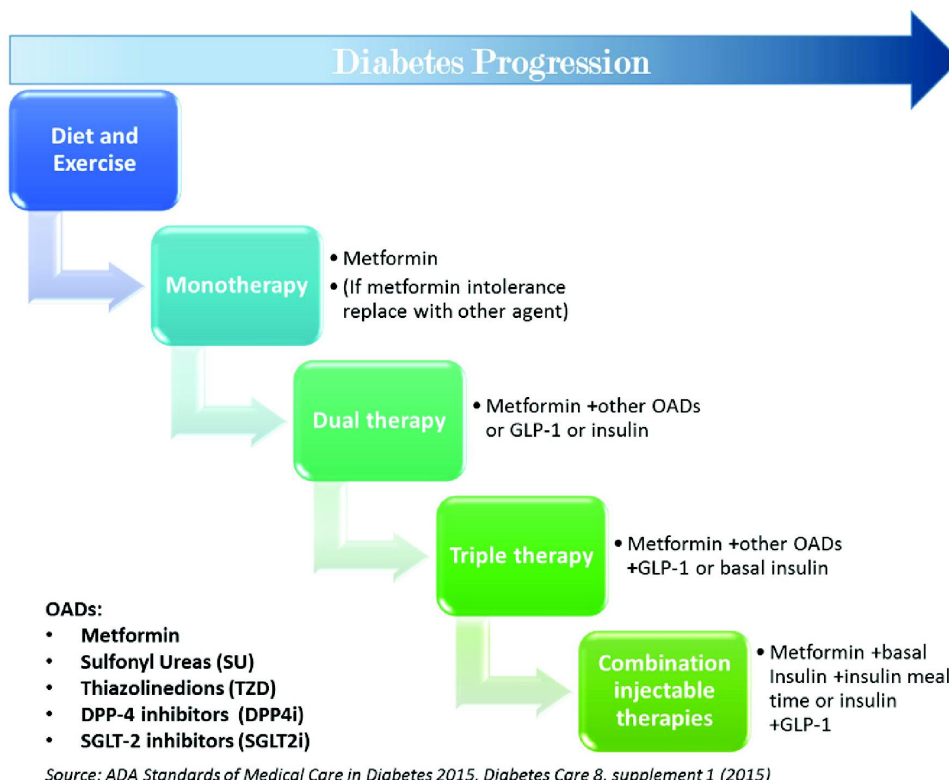
### **Current Treatments for Diabetes and Their Limitations**

The current treatment paradigm for diabetes focuses on lifestyle changes, including weight loss, if applicable, as well as medications to manage blood glucose levels. Obesity is generally considered the major contributor to the development of type 2 diabetes, and weight loss alone is associated with improvements in glycemic parameters. Optimal glycemic control is the treatment goal in diabetic patients to prevent the risk of long-term microvascular complications. There are currently several classes of drugs approved to improve glycemic control in patients with diabetes, including injectable drugs and OADs. Existing injectable therapies include most forms of insulin therapy and GLP-1r agonists. Existing OADs include metformin, sulfonylureas and thiazolidinediones, with the addition of two new classes in the past few years, DPP-4 and SGLT-2 inhibitors, driving the OAD market's growth. Despite the range of available therapies, diabetic patients have difficulty achieving and maintaining consistent glycemic control, defined as HbA<sub>1c</sub> < 7% as recommended by the American Diabetes Association, and eventually progress to insulin use. Failure to attain or maintain glycemic control over time raises a patient's risk of disease progression with the attendant loss of control and progression to potentially serious complications, such as cardiovascular disease, blindness, kidney failure, and nerve damage. We believe the continued and significant unmet medical need for diabetes treatments is demonstrated by the commercial success of DPP-4 inhibitors, a new class of OADs which were first approved in the United States in 2006 and achieved annual sales of \$5.2 billion in 2013.

We expect our diabetes drug candidates to compete in the non-insulin therapy market, currently comprised of OADs and injectable GLP-1r agonists. OADs are the preferred first line treatment by physicians (primary care and endocrinologists), payors and patients given their ease of use, convenience and no training requirements. The goal of these therapies is to delay the progression to insulin dependence (see the figure below). Despite the availability of multiple oral therapies and the introduction of new oral therapies (DPP-4 and SGLT-2 inhibitors) with novel mechanisms, used both as monotherapy and in

combination with other agents, there remains a lack of differentiation and inadequate efficacy. While GLP-1r agonists are generally considered to have superior efficacy compared with OADs, primary care physicians and patients continue to prefer oral agents for their ease of use and improved patient compliance versus injectables. There remains an unmet medical need in the OAD class for a drug that mimics the superiority of GLP-1r agonists and reduces the incidence of hypoglycemia.

Progression of type 2 diabetes and treatment intensification using commonly prescribed oral and injectable diabetes drugs is summarized below.



With the increasing incidence and prevalence of type 2 diabetes, we believe there is a significant unmet medical need for treatment alternatives with improved efficacy and safety. We have chosen two different approaches for the treatment of diabetes: activation of GK, through our drug candidate *TTP399*, and stimulation of GLP-1r, through our drug candidate *TTP273*. If approved, we believe *TTP399* and *TTP273* could offer attractive alternatives as OADs for the treatment of type 2 diabetes.

**Glucokinase Activator**

*The Role of GK Activation in Diabetes*

GK acts as the physiological glucose sensor, changing its conformation, activity and/or intracellular location in parallel with changes in glucose concentrations. GK has two main distinctive characteristics that make it a good choice for blood glucose control. First, its expression is mostly limited to tissues that require glucose-sensing (mainly liver and pancreatic  $\beta$ -cells). Second, GK is able to sense changes in serum glucose levels and modulate changes in liver glucose metabolism that in turn regulate the balance between hepatic glucose production and glucose consumption, and modulate changes in insulin secretion by the  $\beta$ -cells.

Studies in humans, along with numerous animal studies, showing that mutations in the gene encoding GK can cause both hyperglycemia (diabetes mellitus) and hypoglycemia (glucose levels below normal) depending on the mutation, confirm the critical role of GK in the regulation of glucose control. The concept

of GK activation for the treatment of diabetes is attractive because it has proven to be effective and safe in normalizing glycemia in animal models of type 2 diabetes by a mechanism entirely distinct from the action of antidiabetic therapies currently on the market. Moreover, several lines of evidence have suggested that development of type 2 diabetes is related to functional impairment of the GK enzyme. Thus, GK activation may be a way to overcome an important underlying cause of type 2 diabetes progression and hence halt or delay the course of the disease.

Our approach to targeting GK is to use a small molecule, liver-selective compound that only activates GK in the liver without affecting the interaction between GK and glucokinase regulatory protein (“GKRP”). Many competitors have tried to develop drugs that act as GKAs. Previously identified GKAs evaluated in the clinic for the treatment of type 2 diabetes demonstrate improved glucose control; however, these GKAs showed increased incidence of hypoglycemia and hyperlipidemia and an apparent lack of durability. These liabilities have been correlated to hyperstimulation of the  $\beta$ -cells in a glucose independent manner and/or the accumulation of lipids in the liver, consistent with the disruption of GK and the GKRP interaction by these GKAs. Thus, liver-selective compounds that do not activate GK in pancreatic  $\beta$ -cells or affect the GK-GKRP interaction in the liver are expected to demonstrate a superior profile in comparison to previously identified GKAs.

*Our Solution: Glucokinase Activator*

TTP399 is an orally administered, small molecule, liver-selective GKA in development as a new OAD for the treatment of type 2 diabetes with a novel mechanism of action. Activation of GK provides intensive glycemic control without inducing hypoglycemia. If approved, we believe TTP399 would compete primarily with OADs, including DPP-4 and SGLT-2 inhibitors. Our trials for TTP399 suggest that our approach to GK activation has the potential to avoid safety and tolerability issues associated with other GKAs, such as activation of GK in the pancreas, stimulation of insulin secretion independent of glucose, hypoglycemia, increased lipids and liver toxicity. Further, we believe that TTP399, if approved, has the potential to be more effective than competing non-insulin products, the potential to normalize HbA<sub>1c</sub> levels, the potential for no contraindication for renal impairment and no risk of pancreatitis. We believe that TTP399 has the potential to be a first-in-class OAD due to its liver-selectivity and novel mechanism of action.

*Glucokinase Activator Clinical and Regulatory Overview*

We are currently enrolling patients in the AGATA Study, a 180-patient Phase 2b clinical study for TTP399. We initiated the AGATA Study based upon the results of TTP399-201, a Phase 2a clinical trial that demonstrated TTP399 has the ability to improve glycemic control after six weeks of treatment. We have completed ten clinical trials of TTP399, summarized in the table below. In our Phase 1 and 2 clinical trials, TTP399 was safe and well tolerated without any episodes of hypoglycemia.

<b>Study</b>	<b>Phase</b>	<b>Objectives</b>	<b>Completion Date</b>
AGATA	Phase 2b	Multiple site, six-month, double-blind, parallel, repeat-dosing study to evaluate safety and efficacy	Est. mid-2016
TTP399-201	Phase 2a	Multiple site, six-week double-blind, parallel, repeat-dosing study to characterize PK and PD profiles in type 2 diabetes patients not well controlled on metformin	September 2012
GK01-117	Phase 1	A drug-drug interaction study with statins	October 2012
GK01-115	Phase 1	An open-label, single-dose, four-way crossover study in 30 healthy male subjects to compare PK of four formulations	November 2011
GK01-115	Phase 1	Single dose study healthy volunteers (“HV”) absolute and regional bioavailability	August 2011
TTP399-107	Phase 1	Capsule versus tablet bioavailability	May 2010
TTP399-106	Phase 1b	Ten day multi-dose study in diabetic patients not controlled on metformin	November 2010
TTP399-104	Phase 1	Single dose study HV encapsulated tablet	April 2009
TTP399-103	Phase 1	Ten day multi-dose study in HV	June 2009
TTP399-102	Phase 1b	Ten day multi-dose study in naïve diabetics	August 2008
TTP399-101	Phase 1	Single dose study in HV	December 2007

*Ongoing Phase 2b AGATA Study*

In March 2015, we initiated a Phase 2b clinical trial of *TTP399*, the AGATA Study, which is a six-month trial to demonstrate proof-of-concept that the benefits from *TTP399* can be sustained over time. The AGATA Study is a multi-center adaptive Phase 2b, randomized, double-blind, placebo- and active- (sitagliptin) controlled, parallel group trial to evaluate the safety and efficacy of *TTP399* following six months of administration in subjects with type 2 diabetes on a stable dose of metformin. Patients will have a baseline HbA<sub>1c</sub> of 7.5-9.5%. The AGATA Study is expected to include 180 subjects across four arms, including two doses of *TTP399* (400 mg and 800 mg), sitagliptin, which is a DPP-4 inhibitor, and placebo.

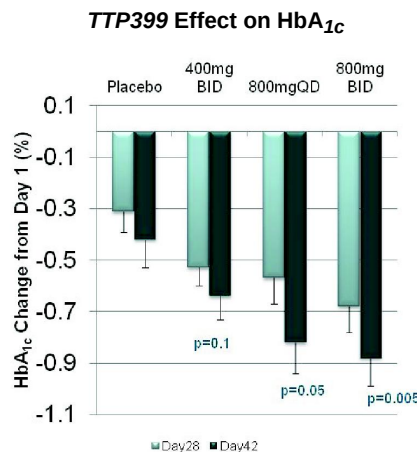
The primary endpoint of the AGATA Study will be the change from baseline in HbA<sub>1c</sub> at six months. The secondary endpoints will include subject achievement of HbA<sub>1c</sub> < 7% at six months, subject achievement of HbA<sub>1c</sub> < 6.5% at six months, plasma glucose, lipids (triglycerides, total cholesterol, HDL cholesterol, and LDL cholesterol), insulin, lactate, C-peptide, glucagon, GLP-1 and body weight. We expect topline data from the AGATA Study in mid-2016.

*Completed Phase 2a Clinical Trial (TTP399-201)*

We completed a six-week Phase 2a clinical trial of *TTP399*, a randomized, double-blind, parallel-group, placebo-controlled, multiple dose study in 120 type 2 diabetes patients whose glycemic parameters were not well-controlled on metformin. The trial was designed to assess the pharmacokinetics, pharmacodynamics, safety and tolerability of *TTP399* and was conducted at 11 centers in the United States. Patients were randomized into four arms: 29 received *TTP399* 400 mg twice a day ("BID"), 31 received *TTP399* 800 mg once a day ("QD"), 30 received *TTP399* 800 mg BID and 30 received placebo. All patients remained on consistent doses of metformin throughout the trial. HbA<sub>1c</sub> was generally consistent across arms in the trial with an average of approximately 8.2%.

In the trial, *TTP399* demonstrated a statistically significant reduction in HbA<sub>1c</sub> levels in all *TTP399* dose groups compared with placebo, without induction of hypoglycemia or hyperlipidemia and with no induction of insulin secretion in patients with type 2 diabetes. Within the high dose arm of *TTP399*, approximately 86% of patients with HbA<sub>1c</sub> levels ≤ 7.5% at baseline achieved blood glucose normalization, defined as HbA<sub>1c</sub> ≤ 6.5%, after six weeks of treatment, while 50% of patients with HbA<sub>1c</sub> levels ≤ 8% at baseline achieved normalization after six weeks. For all doses combined, approximately 40% of patients with HbA<sub>1c</sub> levels ≤ 7.5% at baseline achieved blood glucose normalization while 25% of patients with HbA<sub>1c</sub> levels ≤ 8% at baseline achieved normalization. None of the patients receiving placebo reached HbA<sub>1c</sub> normalization.

The results showing the reduction in HbA<sub>1c</sub> are summarized in the following figure:



Clinical results also showed a statistically significant effect on both postprandial glucose, fasting glucose, average daily glucose and no increases on fasting plasma lipids or plasma lactate.

*Adverse Events*

TTP399 was generally safe and well tolerated at all doses in the trial. The proportion of patients reporting at least one AE was between 42% to 63% in the TTP399 groups compared to 40% in the placebo group. There was no notable imbalance in the reporting of any AE between the active trial and the placebo. There were no AEs that led to discontinuation of study drug. There was no dose-responsive increase in the percentages of subjects with at least one AE. One subject in the 800 mg QD group experienced a moderate severe AE of diverticulitis on Day 15 that was considered not related to study drug. No action was taken with study drug, and the event resolved ten days later.

**GLP-1r Agonist**

*The Role of GLP-1r Activation in Diabetes*

GLP-1r is a class B G protein-coupled receptor that regulates important physiological and pathological processes related to type 2 diabetes. GLP-1r stimulation as a therapeutic modality has been validated by the approval of peptide GLP-1r agonists, such as exenidin-4 (Byetta) and liraglutide (Victoza). Subcutaneous administration of these peptides lowers blood glucose, decreases HbA<sub>1c</sub> levels and reduces weight. This class of peptides is associated with gastrointestinal side effects (nausea and vomiting). Despite the clinical success observed with the injectable peptides, no orally available GLP-1r agonists have demonstrated similar success to date.

*Our Solution: GLP-1r Agonist*

GLP-1r agonists, including exenatide (Byetta, Bydueron), albiglutide (tanzeum) and liraglutide (Victoza), are well established in terms of efficacy, but their use has been limited due to their administration as an injectable. Subcutaneous administration of these peptides lowers blood glucose, decreases HbA<sub>1c</sub> levels and reduces weight. However, this class of peptides is associated with gastrointestinal side effects including nausea and vomiting. TTP273 is a potential first-in-class, orally administered, small molecule, non-peptide GLP-1r agonist. Our past proof-of-concept study with our first generation product, TTP054, demonstrated efficacy consistent with marketed GLP-1r agonists, and our trials indicated that TTP273 may have superior tolerability compared to competing products, as shown through low incidence of gastrointestinal AEs and no antibody formation. We believe an orally administered GLP-1r agonist that mimics the metabolic effects of GLP-1r showing enhanced glycemic control, an improved lipid profile and weight loss, without causing the gastrointestinal side effects typical of this class of compounds, would offer a competitive advantage compared to GLP-1r targeted treatment options currently available. For these reasons, we believe TTP273 has the potential to expand the use of GLP-1r agonists for the treatment of type 2 diabetes.

*GLP-1r Agonist Clinical and Regulatory Overview*

We have completed two Phase 1 clinical trials of TTP273 providing for proof-of-principle achieved in humans. Additionally, we have completed ten Phase 1 and Phase 2 clinical trials of TTP054, which was a predecessor orally administered GLP-1r agonist. In our Phase 1 and Phase 2 clinical trials, TTP273 and TTP054 have been safe and well tolerated. These trials are summarized in the table below.

<b>Study</b>	<b>Phase</b>	<b>Objectives</b>	<b>Completion Date</b>
<b><u>TTP273</u></b>			
TTP273-102	Phase 1b	14-day multiple dose (“MD”) study in diabetic patients not controlled on metformin	November 2013
TTP273-101	Phase 1	Single dose (“SD”) study in healthy volunteers	October 2012
<b><u>TTP054</u></b>			
TTP054-201	Phase 2	12-week MD in patients with type 2 diabetes on stable doses of metformin	June 2013
TTP054-111	Phase 1	SD, crossover, in HV to compare table formulations	August 2012
TTP054-110	Phase 1	SD in patients with type 2 diabetes	March 2012
TTP054-109	Phase 1	SD in HV to compare table formulations	October 2011



**TABLE OF CONTENTS**

<b>Study</b>	<b>Phase</b>	<b>Objectives</b>	<b>Completion Date</b>
TTP054-108	Phase 1b	28-day MD in patients with type 2 diabetes on stable doses of metformin	November 2011
TTP054-106	Phase 1	SD in HV (tablet formulation)	December 2010
TTP054-104	Phase 1b	14-day MD in patients with type 2 diabetes (liquid formulation)	August 2010
TTP054-103	Phase 1	SD, crossover, modified-glucose-infusion in HV to study insulin secretion	March 2009
TTP054-102	Phase 1b	10-day multi-dose study in naïve diabetics	July 2010
TTP054-101	Phase 1	Single dose study in healthy volunteers	July 2008

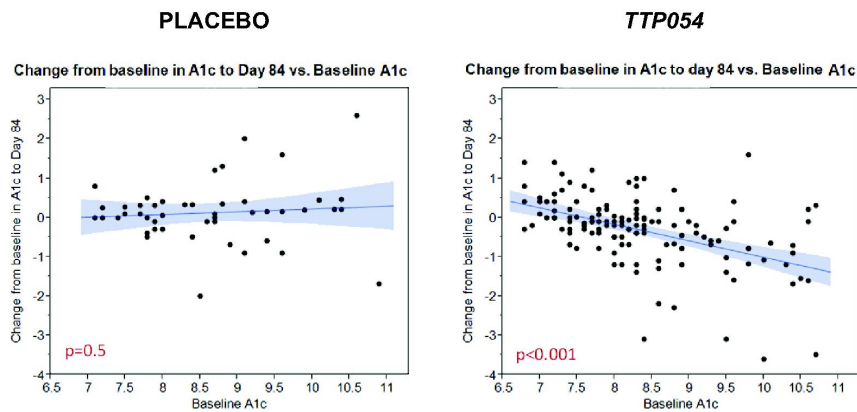
*Upcoming Clinical Trial*

Based on the results of our completed Phase 1 and 2 clinical trials of *TTP273* and *TTP054*, we believe our orally administered GLP-1r agonists have the potential to provide both superior efficacy and tolerability versus peptide GLP-1r analogues. We plan to initiate a Phase 2 clinical trial of *TTP273* to show proof-of-concept that *TTP273* can significantly reduce HbA<sub>1c</sub> and body weight over a twelve week period. The trial is expected to include approximately 180 subjects in three different groups, including two arms that will receive *TTP273* and a placebo arm. We expect to initiate this trial in early 2016 and to report topline data in late 2016.

*Completed Phase 2 Clinical Trial*

Our completed Phase 2 clinical trial of *TTP054* was a randomized, double-blind, parallel-group, placebo-controlled, 12-week, multiple dose study in 187 randomized type 2 diabetic patients who were not well-controlled on metformin. The trial was designed to assess the safety and efficacy of *TTP054*. The trial was conducted at 19 centers in the United States. Patients were randomized into four arms: 28 to receive *TTP054* 200 mg/day, 51 to receive *TTP054* 400 mg/day, 56 to receive *TTP054* 800 mg/day and 52 to receive placebo. The primary efficacy endpoint of the trial was change from baseline in HbA<sub>1c</sub> as compared to placebo. The secondary endpoints included change from baseline in fasting plasma glucose, subject achievement of HbA<sub>1c</sub> <7%, change from baseline in body weight, and subject achievement of body weight loss ≥ 2%.

Our proof-of-concept trial showed statistically significant placebo-corrected reductions in the average level of blood sugar as measured by HbA<sub>1c</sub>. In the trial, there was a reduction of 1% HbA<sub>1c</sub> in subjects not well-controlled on metformin after 12 weeks of treatment. The efficacy demonstrated was consistent with published data for marketed GLP-1 mimetics (exenatide) in studies of similar duration.



### Adverse Events

These clinical trials showed that our GLP-1r agonists have negligible incidences of AEs and no increased risk of hypoglycemia when compared to placebo. In our completed Phase 2 trial, a total of 178 AEs were reported by 69 of 184 patients, or 38%. The proportion of patients reporting at least one AE was highest in the *TTP054* 800 mg/day dose group at 45% versus 40% in the placebo group. The proportion of patients that reported at least one AE were lowest in the 400 mg and 200 mg dose groups at 27% and 37%, respectively.

Overall, in our Phase 2 trial, *TTP054* was safe and well-tolerated. There were no hypoglycemia AEs, and GI AEs, including nausea and vomiting, were minimal and similar in incidence and severity in active and placebo groups. There were five subjects with AEs that were considered serious and led to discontinuation from the study. Among these subjects, only two AEs occurred in *TTP054*-treated subjects (increases in LFTs without increased bilirubin) and were considered related to *TTP054*. All of these AEs resolved with no sequelae.

*TTP273* was generally safe and well-tolerated in our completed Phase 1 clinical trials, with no severe AEs reported after up to 14 days of dosing. There was no apparent dose relationship and no hypoglycemic incidents.

### Additional Pipeline Opportunities

We are also developing a portfolio of additional clinical drug candidates for the prevention of muscle weakness associated with PMV and critical injury, as well as the treatment of inflammatory disorders.

#### **Muscle Weakness Associated With PMV and Critical Injury – HPP593**

*HPP593* is a functionally selective PPAR- $\delta$  agonist that is expected to begin a Phase 2 trial for the prevention of muscle weakness associated with PMV and critical injury. Muscular weakness is a nearly universal outcome after critical illness involving acute respiratory failure. Due to PMV and acute critical illness, immobility leads to the clinical state of weakness, muscle atrophy, physical dependence, susceptibility to new complications, hospital readmission, healthcare resource consumption, poor quality of life and decreased survival. Impaired physical function after critical illness is a robust observation documented in diverse study samples across many different investigators and countries. According to an August 2010 paper by Cox et al. in *Annals of Internal Medicine*, the number of PMV recipients will likely exceed 600,000 per year by 2020. There are currently no therapies (other than physical therapy) to improve outcomes for patients receiving PMV, and *HPP593* presents an opportunity to address this unmet medical need.

*HPP593* is designed to be a selective PPAR- $\delta$  agonist that does not exhibit off-target activity. In late 2015, we intend to initiate an adaptive Phase 2 trial that includes a learning phase (with 40 patients) and a confirming phase (in 160 patients) in five medical centers across the United States with a total of 200 subjects. *HPP593* has demonstrated a lowering of low-density lipoprotein cholesterol and triglycerides in animal models and humans, with a significant increase in high-density lipoprotein cholesterol. *HPP593* has also demonstrated an antidiabetic effect in several animal models of type 2 diabetes. In a 28-day randomized, double-blind, placebo controlled Phase 1b study, *HPP593* showed a statistically significant effect on maintaining muscle strength during limb immobilization and regaining muscle strength after limb immobilization. These data suggest that *HPP593* has the potential to be a good treatment option for the prevention of muscle weakness associated with PMV and critical injury, if the data continue to be favorable and the product is approved.

#### **Inflammatory Diseases – HPP737**

Inhibitors of PDE4 act by increasing intracellular concentrations of cyclic adenosine monophosphate (“cAMP”), which has a broad range of anti-inflammatory effects. However, the therapeutic potential of PDE4 inhibitors has been limited by dose limiting AEs such as nausea and emesis. *HPP737* is a PDE4 inhibitor that addresses inflammatory diseases and offers an improved tolerability profile based on reduced CNS penetrance.

*HPP737* has shown potent inhibition of Interleukin-23 (“IL23”) and tumor necrosis factors (“TNF”) production and therapeutic in vivo activity in several animal models of inflammation. *HPP737* has

completed Phase 1, in which it was safe and well tolerated at all doses tested. In this study, *HPP737* demonstrated a favorable safety profile and comparable target engagement at much lower doses than marketed PDE4 inhibitors. Preclinical and clinical data suggests that *HPP737* may not have the side effects common to other PDE4 inhibitors in development.

We plan to commence a Phase 2 trial in patients with either psoriasis or COPD in early 2016.

### ***Inflammatory Diseases – HPP971***

Small molecules that function as inhibitors of Bach1 activity may be able to block oxidative stress and the associated fibrosis leading to organ failure. The development of a synthetic small molecule that can regulate the oxidative-stress response transcriptional network, in particular the Nrf2 pathway, is thought to be of therapeutic value. To date, however, this approach has relied on pharmacophores having reactive, electrophilic groups which may present safety and tolerability issues, such as Bordoxolone or Tecfidera. Targeting the Bach1 transcriptional repressor provides an alternative mechanism by which antioxidant response elements (“ARE”) genes are controlled.

Bach1 is a transcriptional repressor that controls the expression of ARE containing genes. Genetic deletion of Bach1 has been shown to lead to a significant level of tissue and organ protection in a wide variety of murine disease and trauma models. Hemin and the hemin mimetic cobalt protoporphyrin IX (“CoPP”) are Bach1 ligands that have served as useful tool compounds to probe the role of Bach1 inhibition in a variety of disease settings. Both molecules have been shown to have beneficial effects on oxidative stress-mediated pathologies in a number of animal models. Further, the ubiquity of the response suggests that the observed tissue protective effects are not related to disease etiology, but instead are an intrinsic outcome of Bach1 modulation.

Our candidate, *HPP971*, is a Bach1 inhibitor that represents a novel therapeutic approach that has the potential to be used in the treatment of chronic diseases associated with oxidative stress. *HPP971* is in Phase 1 and has completed single ascending dose and multiple ascending dose studies, in each case showing it was safe and well-tolerated.

### ***Oncology – Hexokinase II Inhibitors***

The field of tumor metabolism seeks to exploit the unique ways in which cancer cells take up and utilize nutrients in order to grow and proliferate. Cancer cells have altered cellular metabolic pathways to acquire and utilize these nutrients and redirect them to provide the necessary building blocks for growth. When these metabolic pathways are blocked, cancer cells are essentially starved of critical nutrients and stop growing or die, whereas normal cells are largely unaffected.

Most cancer cells have increased uptake of the sugar glucose relative to surrounding normal cells. This phenomenon forms the basis for the widely used tumor imaging procedure known as 18F-2-deoxyglucose (FDG)/PET. Tumors take up more FDG, a radioactive glucose analog, than the surrounding normal tissue and this differential can be visualized with PET imaging. Not only do tumors take up more glucose, they also utilize the nutrient in a unique way. Tumors convert glucose into lactic acid in a process known as aerobic glycolysis or the “Warburg effect,” a route rarely utilized in normal cells. This unique uptake and processing of glucose by tumors relative to normal tissue creates an opportunity to selectively target tumors by cutting off their ability to use this fuel.

In many cancers, hexokinase II is overexpressed and has been linked to more aggressive and invasive tumors. Pre-clinical studies in mice have confirmed that the reduction of hexokinase II activity through genetic deactivation (siRNA knockdown studies) results in a significant reduction of tumor growth. Our hexokinase inhibitors may provide an opportunity to inhibit the unique way cancer cells utilize glucose, and the overall Warburg effect, which could result in new treatments for cancer.

Calithera Biosciences, Inc. (“Calithera”) has exclusive, worldwide rights to our hexokinase II inhibitors for research, development and commercialization. We will receive an initial license fee from Calithera, and potentially development and regulatory milestone payments and royalty payments. See “Business—Intellectual Property—License Agreements.”

## Our Proprietary Technology Platform

We use a proprietary drug discovery platform that facilitates the discovery of novel drug candidates in a time- and cost-efficient manner. Using this discovery technology, we have completed the discovery phase for some of its most promising candidate drugs in weeks and months, as compared to an industry average of two to three years, and with this technology, we expect to similarly be able to reduce the discovery phase for any future drug candidates.

### **TTP Translational Technology**

We developed a proprietary drug discovery platform called TTP Translational Technology, which we use to discover novel small molecule therapeutics for major diseases and to validate biological pathways and targets. All of the small molecule drug candidates in our pipeline (other than *HPP593*) were discovered using TTP Translational Technology.

TTP Translational Technology is a fully integrated drug discovery process, amenable to automation, which works to translate genomic and proteomic data into safe and effective small molecule therapeutics in high-throughput fashion, bypassing most of the classical requirements and bottlenecks in drug discovery. We have used this technology to discover drugs for our internal pipeline and in research collaborations with pharmaceutical and biotechnology companies.

### **Our Integrated Platform**

TTP Translational Technology consists of three modules that are fully integrated with an informatics system that captures data from each optimization cycle of the drug discovery process. This informatics system is built with a sophisticated architecture that supports various computing platforms and provides automatic archiving and storage capabilities. The three modules comprising TTP Translational Technology are:

- **TTPredict** provides modeling tools, simulations, statistical and analysis algorithms and visualization in one package. The resulting molecular discovery process couples high throughput *in silico* and *in biologic* screening data with extensive automation in a parallel and integrated fashion in order to rapidly develop hypotheses concerning novel protein structures and potential ligand binding sites. The system uses high-throughput virtual docking, ranking and screening and employs multiple scoring methods. These operations are encompassed within component modules known as TTPostGene, TTPSite, TTPDock and TTPSelect.
- **TTPSpace** is a proprietary library of diverse, drug-like, well characterized compounds (TTProbes and related compound libraries) that can be used in our automated drug discovery processes. We have the capacity to synthesize hundreds if not thousands of well-characterized compounds per day in milligram quantities. TTProbes are an ensemble of functionally diverse, structurally unique and nested low molecular weight molecules exemplifying key recognition elements that enable an immediate interpretation and subsequent extrapolation of the geometric, stereo-electronic and physiochemical requirements for binding to target proteins. These molecular probes deliver a focused yet adjustable technique for lead discovery or target validation, especially when coupled to the computational capabilities embodied in TTPredict. TTProbes are tools for rapid biological target validation, bypassing the often time-consuming process of classical pharmacology requirements, quickly producing data about essential binding elements between biological targets and small molecule modulators. Selectivity and specificity data is generated much earlier compared to hits against a classical library, while minimizing negative prior art issues.
- **TTPScreen** consists of novel translational biology techniques, including genomic and high-content imaging processes and proprietary tools built with a sophisticated architecture that supports various computing platforms and utilizes dynamic scripting and parallel execution, allowing management of large amounts of biological data generated from high-throughput screening, including complex experimental protocols, flexible and dynamic assay layouts, multiple IC50 determinations, interactive profiling and kinetic studies. TTPScreen allows full utilization and access to all the available biological and chemical data and information in a highly integrated fashion.

TTP Translational Technology reduces manual tasks, provides rapid validation, lead discovery and optimization of novel clinical candidates, reduces prior art issues associated with leads pulled from classical sources and is capable of addressing the need and demand for complex, non-traditional biological targets such as protein-protein interactions.

Our average time from biological concept through completion of Phase I trials is about four to five years, which is half of the industry average, helping to lower costs and enhance the speed of drug development. Our development methods can be used to identify targets in various therapeutic areas and are scalable to support a large number of programs.

### **Third-Party Suppliers and Manufacturers**

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties to manufacture clinical supplies of our drug candidates and for our other research and discovery programs.

### **Intellectual Property**

#### **Patents**

The IP portfolio for *azeliragon* includes a patent family covering *azeliragon* as a composition of matter, a patent family covering polymorphs of *azeliragon* and a patent family covering select methods of treatment using *azeliragon*. *Azeliragon* as a composition of matter is covered by issued patents in the United States, Europe, Japan, Canada, Australia, China and Hong Kong. The issued U.S. patent covering *azeliragon* as a composition of matter is expected to expire in 2029, assuming we obtain the maximum possible extension. Patents covering *azeliragon* as a composition of matter outside the United States will expire no earlier than 2023 and may expire much later as a result of patent term extensions based on patent office delays, regulatory delays, or a combination thereof.

The IP portfolio for *TTP399* includes a patent family covering *TTP399* as a composition of matter, a patent family covering combinations of *TTP399* and metformin, a patent family covering combinations of *TTP399* and DPP-4 inhibitors or GLP-1r agonists, and patent families covering two different solid formulations of *TTP399*. The patent family covering *TTP399* as a composition of matter was filed in multiple jurisdictions around the world including the United States, Europe, Japan and Canada. The issued U.S. patent covering *TTP399* as a composition of matter is expected to expire in 2030, assuming we obtain the maximum possible extension. Patents covering *TTP399* as a composition of matter outside the United States will expire no earlier than 2025 and may expire much later as a result of patent term extensions based on patent office delays, regulatory delays, or a combination thereof. Some patents and patent applications covering *TTP399* as a composition of matter are licensed from Novo Nordisk A/S, while others are owned by us.

The IP portfolio for the GLP-1r program includes a patent family covering *TTP054* as a composition of matter, a patent family covering *TTP273* as a composition of matter, a patent family covering specific salts of *TTP054*, a patent family covering combinations of *TTP054*, or *TTP273*, and metformin, and a patent family covering methods of synthesizing precursors to *TTP054* and *TTP273*. The patent family covering *TTP054* as a composition of matter was filed in multiple jurisdictions around the world including the United States, Europe, Japan and Canada. The issued U.S. patent covering *TTP054* as a composition of matter is expected to expire in 2034, assuming we obtain the maximum possible extension. Patents covering *TTP054* as a composition of matter outside the United States will expire no earlier than 2029 and may expire much later as a result of patent term extensions based on patent office delays, regulatory delays, or a combination thereof. The patent family covering *TTP273* as a composition of matter was filed in multiple jurisdictions around the world including the United States, Europe, Japan and Canada. The issued U.S. patent covering *TTP273* as a composition of matter is expected to expire in 2034, assuming we obtain the maximum possible extension. Patents covering *TTP273* as a composition of matter outside the United States will expire no earlier than 2030 and may expire much later as a result of patent term extensions based on patent office delays, regulatory delays or a combination thereof.

#### **Trade Secrets**

In addition to patents, we rely on trade secrets and know-how to develop and maintain our competitive position. For example, significant aspects of our TTP Translational Technology are based on unpatented

trade secrets and know-how. Trade secrets and know-how can be difficult to protect, and a number of the individual components of our TTP Translational Technology are now commercially available. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements and invention assignment agreements with our employees, consultants, scientific advisors, contractors and commercial partners. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed by employees or through a relationship with a third party. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become publicly known or be independently discovered by competitors. To the extent that our contractors use or incorporate intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

### **License Agreements**

#### *Calithera*

In March 2015, we entered into a License and Research Agreement with Calithera (the "License Agreement"), under which Calithera obtained an exclusive, worldwide, sublicensable license to develop and commercialize certain of our hexokinase II inhibitors for any therapeutics, prophylactic, preventative or diagnostic use.

Under the terms of the License Agreement, Calithera will pay us an initial license fee of \$600,000, and potential development and regulatory milestone payments totaling up to \$30.5 million for the first licensed product. We are eligible for an additional \$77.0 million in potential sales-based milestones, as well as royalty payments, at mid-single digit royalty rates, based on tiered sales of the first commercialized licensed product. In addition, Calithera will fund up to \$1.1 million during the first 12 months of the License Agreement for the costs associated with up to four of our full-time employee equivalents to develop additional hexokinase inhibitors. If Calithera develops additional licensed products, after achieving regulatory approval of the first licensed product, Calithera would owe additional regulatory milestone payments and additional royalty payments based on sales of such additional licensed products.

Except for the research program funded by Calithera with us, Calithera will be responsible for the worldwide development and commercialization of the licensed products, at its cost, is required to use commercially reasonable efforts with respect to such development and commercialization activities, and must meet certain specified diligence obligations. Calithera holds the first right to prosecute and to enforce all licensed patents under the License Agreement throughout the world, and we will retain certain step-in prosecution and enforcement rights.

The License Agreement, unless terminated earlier, will continue on a product-by-product and country-by-country basis until expiration of the royalty obligations Calithera owes to us on such licensed product, which extend until the later of the expiration of certain patent or data exclusivity rights covering such licensed product in such country or ten years after the first commercial sale of such product in such country. Either party may terminate the License Agreement for the other party's uncured material breach. Calithera may terminate the License Agreement at will upon prior written notice. Either party may terminate the License Agreement for the other party's insolvency.

#### *Novo Nordisk*

In February 2007, we entered into an Agreement Concerning Glucokinase Activator Project with Novo Nordisk A/S whereby we obtained an exclusive, worldwide, sublicensable license under certain Novo Nordisk intellectual property rights to discover, develop, manufacture, have manufactured, use and commercialize products for the prevention, treatment, control, mitigation or palliation of human or animal diseases or conditions. As part of this license grant, we obtained certain worldwide rights to Novo Nordisk's GKA program, including rights to preclinical and clinical compounds such as *TTP399*.

## Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. We believe the key competitive factors that will affect the development and commercial success of our drug candidates are efficacy, safety and tolerability profile, mechanism of action, control and predictability, convenience of dosing and price and reimbursement.

Many of the companies against which we may compete have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

### *Potential Competing Products – Alzheimer's Disease*

There are currently no approved disease-modifying treatments for AD in the United States, as existing therapies treat only the symptoms of the disease, rather than targeting the underlying mechanisms. The approved symptomatic AD therapies in the United States fall into two classes, AChEIs and glutamatergic modulators. If *azeliragon* is approved, it may potentially compete with drug candidates with differentiated mechanisms currently in development as potential disease modifying treatments for AD, including anti-A $\beta$  monoclonal antibodies, BACE inhibitors, tau aggregation inhibitors and monoamine oxidase-b inhibitors. We are not aware of any other clinical-stage RAGE inhibitors for the treatment of AD.

### *Potential Competing Products – Type 2 Diabetes*

We expect that our type 2 diabetes drug candidates will compete with currently available non-insulin medication products for type 2 diabetes. These products include the following:

- Injectable GLP-1r agonists, such as exenatide or liraglutide, which mimic a naturally occurring hormone that stimulates the pancreas to secrete insulin when blood glucose levels are high.
- DPP-4 inhibitors, such as sitagliptin or saxagliptin, are a class of drugs that work by blocking the enzyme that normally degrades GLP-1.
- Sulfonylureas and meglitinides, which are classes of drugs that act on the pancreatic cells to stimulate the secretion of insulin.
- Thiazolidinediones, such as pioglitazone, and biguanides, such as metformin, which lower blood glucose by improving the sensitivity of cells to insulin, or diminishing insulin resistance.
- Alpha-glucosidase inhibitors, which lower the amount of glucose absorbed from the intestines, thereby reducing the rise in blood glucose that occurs after a meal.
- SGLT-2 inhibitors, such as dapagliflozin and canagliflozin, are a class of medications that lower blood glucose by increasing glucose excretion in urine.

In addition to existing marketed products, there are a number of product candidates currently in development focusing on the same mechanisms as our programs for the treatment of type 2 diabetes, including:

- **Glucokinase activators:** Advinus Therapeutics Ltd., Eli Lilly and Company, Pfizer Inc., Hua Medicine Ltd. and Teijin Pharma Limited are among the companies evaluating glucokinase activators in clinical or preclinical studies.
- **Oral GLP-1r agonists:** Diabetology Ltd., Novo Nordisk, Oramed Pharmaceuticals Inc., Poxel SA and Receptos, Inc. are among the companies evaluating oral GLP-1r agonists in clinical or preclinical studies.

We believe that our drug candidates may offer key potential advantages over these competitive products that could enable our drug candidates, if approved, to capture meaningful market share from our

competitors. Nevertheless, many of our potential competitors have substantially greater financial, technical and human resources than we do, as well as greater experience in the discovery and development of drug candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our competitors may be more successful than us in obtaining regulatory approval for drugs and achieving widespread market acceptance. Our competitors' drugs may be more effective, or more effectively marketed and sold, than any drug candidate we may commercialize and may render our drug candidates obsolete or non-competitive before we can recover the expenses of their development and commercialization. We anticipate that we will face intense and increasing competition as new drugs enter the market and advanced technologies become available. Finally, the development of new treatment methods for the diseases we are targeting could render our drug candidates non-competitive or obsolete.

### **Government Regulation and Product Approval**

Government authorities in the United States at the federal, state and local level extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. Our drug candidates must receive final approval from the FDA before they may legally be marketed in the United States.

### ***U.S. Drug Development Process***

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations. The process of obtaining regulatory approvals and ensuring compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a hold on clinical trials, warning letters, product seizures, product detention, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies according to Good Laboratory Practices or other regulations, as well as formulation studies;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to Good Clinical Practices, or GCP, to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity; and
- FDA review and approval of the NDA.

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

Once a pharmaceutical drug candidate is identified for development, it enters the preclinical testing stage. The preclinical testing stage includes laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies. An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical trial lends itself to an efficacy evaluation. Preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that



30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance.

All clinical trials must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent. Further, an institutional review board, or IRB, must review and approve the plan for any clinical trial before it commences at any institution. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical trial and the consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRBs for approval.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The drug candidate is initially introduced into healthy human subjects and tested for tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing may be conducted in patients having the specific disease.
- *Phase 2.* Phase 2 trials involve investigations in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the drug candidate for specific targeted diseases and to determine optimal dosage and schedule.
- *Phase 3.* Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in a larger patient population, generally at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the drug candidate and provide an adequate basis for regulatory approval and product labeling.

Post-approval studies, also called Phase 4 trials, may be conducted after initial marketing approvals. These studies are used to obtain additional experience from the treatment of patients in the intended therapeutic indication and may be required by the FDA as part of the approval process.

Progress reports detailing the results of the clinical trials must be submitted annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected side effects. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution on various grounds, including if the research subjects are being exposed to an unacceptable health risk.

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

### ***Special Protocol Assessment***

The special protocol assessment, or SPA, process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial design and data analysis plans, within 45 days of receipt of the request.

The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the drug candidate with respect to effectiveness of the indication studied. All agreements and disagreements between the FDA and the sponsor regarding an SPA must be clearly documented in an SPA letter or the minutes of a meeting between the sponsor and the FDA.

Even if the FDA agrees to the design, execution and analyses proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement under the following circumstances:

- public health concerns emerge that were unrecognized at the time of the protocol assessment, or the director of the review division determines that a substantial scientific issue essential to determining safety or efficacy has been identified after testing has begun;
- a sponsor fails to follow a protocol that was agreed upon with the FDA; or
- the relevant data, assumptions or information provided by the sponsor in a request for SPA change, are found to be false statements or misstatements, or are found to omit relevant facts.

A documented SPA may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. We have obtained an SPA with the FDA for our Phase 3 STEADFAST Study of *azeliragon*. Agreement by the FDA to an SPA does not guarantee that the results of a study conducted in accordance with the agreement will be successful.

### **United States Review and Approval Processes**

The results of product development, preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA, requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees which may be waived under certain limited circumstances.

#### *FDA Review of New Drug Applications*

The FDA reviews all NDAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA has ten months from the date the application is accepted for filing in which to complete the initial review of a standard NDA and respond to the applicant and six months for a priority NDA. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether the chemistry, manufacturing and control documentation is adequate to assure and preserve the product's identity, strength, quality and purity. Before approving an NDA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. The FDA may refer the NDA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of independent experts who provide advice and recommendations when requested by the FDA on matters of importance that come before the agency. The FDA is not bound by the recommendation of an advisory committee.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other data and information.

Even if such data and information are submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than we interpret the same data. The FDA will issue a complete response

letter if the agency decides not to approve the NDA in its present form. The complete response letter usually describes all of the specific deficiencies that the FDA identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to conform the application to a condition suitable for approval. If a complete response letter is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, withdraw the application, or request an opportunity for a hearing.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug's safety and effectiveness after NDA approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized.

#### *Special FDA Expedited Review and Approval Programs*

The FDA has various programs, including Fast Track designation, accelerated approval and priority review, that are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

To be eligible for a Fast Track designation, the FDA must determine, based on the request of a sponsor, that a product is intended to treat a serious or life threatening disease or condition and demonstrates the potential to address an unmet medical need. The FDA may determine that a product will fill an unmet medical need if it is expected to provide a therapy where none exists or provide a therapy that may be potentially superior to existing therapy based on efficacy or safety factors.

The FDA may give a priority review designation to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. A priority review means that the goal for the FDA to review an application is six months, rather than the standard review of ten months from the date of filing of the NDA. Most products that are eligible for Fast Track designation are also likely to be considered appropriate to receive a priority review.

In addition, products studied for their safety and effectiveness in treating serious or life-threatening diseases or conditions and that provide meaningful therapeutic benefit over existing treatments may be eligible to receive accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require a sponsor of a drug receiving accelerated approval to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug may be subject to accelerated withdrawal procedures.

Moreover, under the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, a sponsor can request designation of a drug candidate as a "breakthrough therapy." A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Drugs designated as breakthrough therapies are also eligible for accelerated approval. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We have obtained Fast Track designation for *azeliragon* for the treatment of dementia of the Alzheimer's type.

#### *Patent Term Restoration and Marketing Exclusivity*

Depending upon the timing, duration and specifics of FDA marketing approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally (a) one-half the time between the effective date of an IND and the submission date of an NDA plus (b) the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within 60 days of approval of the drug. The PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration.

Data and market exclusivity provisions under the FDCA can also delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent data and marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active pharmaceutical ingredient, or active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a Section 505(b)(2) NDA submitted by another company that references the previously approved drug with exclusivity. Section 505(b)(2) generally permits the submission of an NDA where at least some of the information required for approval comes from clinical trials not conducted by or for the applicant and for which the applicant has not obtained a right of reference. However, an ANDA or Section 505(b)(2) application may be submitted after four years if it contains a Paragraph IV certification claiming that the patents covering the drug are either invalid or not infringed by the drug described in the ANDA or 505(b)(2) application.

The FDCA also provides three years of marketing exclusivity for an NDA, Section 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application. Such clinical trials may, for example, support new indications, dosages, routes of administration or strengths of an existing drug, or a new use. This exclusivity, which is sometimes referred to as clinical investigation exclusivity, prevents the FDA from approving an ANDA or an application under Section 505(b)(2) for the same conditions of use associated with the new clinical investigations before the expiration of three years from the date of approval. Such three-year exclusivity, however, would not prevent the approval of another application if the applicant submits a Section 505(b)(1) NDA and has conducted its own adequate, well-controlled clinical trials demonstrating safety and efficacy, nor would it prevent approval of an ANDA or Section 505(b)(2) application for a product that did not incorporate the exclusivity-protected changes of the approved drug product.

#### *Post-Approval Requirements*

Any drugs for which we receive FDA approval are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse effects with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, complying with certain electronic records and signature requirements and complying with FDA promotion and advertising requirements. In September 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-marketing authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and implementation of risk evaluation and mitigation strategies, or REMS programs, mandated by the FDA. The FDA strictly regulates labeling, advertising, promotion and other types of

information on products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. Further, manufacturers of drugs must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, certain changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to prior FDA review and approval.

Drug manufacturers and other entities involved in the manufacturing and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the drug. Manufacturers must establish validated systems to ensure that products meet specifications and regulatory standards, and test each product batch or lot prior to its release.

The FDA may restrict market availability or withdraw a product approval if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. Discovery of previously unknown problems with a product subsequent to its approval may result in restrictions on the product or even complete withdrawal of the product from the market. Further, the failure to maintain compliance with regulatory requirements may result in administrative or judicial actions, such as fines, warning letters, holds on clinical trials, product seizures, product detention or refusal to permit the import or export of products, refusal to approve pending applications or supplements, restrictions on marketing or manufacturing, injunctions or civil or criminal penalties.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. For example, in July 2012, FDASIA was enacted, which, among other things, expanded drug supply chain requirements and strengthened FDA's response to drug shortages. In addition to new legislation, the FDA regulations and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in mandatory revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals; and
- product seizure or detention, or refusal to permit the import or export of products; or injunctions or the imposition of civil or criminal penalties.

### ***Foreign Regulation***

In addition to regulations in the United States, we will be subject to a variety of foreign regulations governing clinical trials and commercial sales and distribution of our drug candidates to the extent we choose to clinically evaluate or sell any products outside of the United States. Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing,

pricing and reimbursement vary greatly from country to country. As in the United States, post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution would apply to any product that is approved for sale outside the United States.

### ***Third-Party Payor Coverage and Reimbursement***

Significant uncertainty exists as to the coverage and reimbursement status of any of our drug candidates for which we obtain regulatory approval. In both the United States and foreign markets, our ability to commercialize our drug candidates successfully, and to attract commercialization partners for our drug candidates, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. Medicare is a federally funded program managed by the Centers for Medicare and Medicaid Services, or CMS, through local administrative contractors that administer coverage and reimbursement for certain healthcare items and services furnished to certain individuals aged 65 or older, disabled or suffering from end-stage renal disease. Medicaid is an insurance program for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured that is both federally and state funded and managed by each state. The federal government sets general guidelines for Medicaid and each state creates specific regulations that govern its individual program. Each payor has its own process and standards for determining whether it will cover and reimburse a procedure or particular product. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Therefore, achieving favorable coverage and reimbursement from government payors is usually a significant gating issue for successful introduction of a new product. The competitive position of some of our products will depend, in part, upon the extent of coverage and adequate reimbursement for such products and for the procedures in which such products are used. Prices at which we or our customers seek reimbursement for our drug candidates can be subject to challenge, reduction or denial by the government and other payors and may require us to pay rebates.

The U.S. Congress and state legislatures may, from time to time, propose and adopt initiatives aimed at cost containment, which could impact our ability to sell our drug candidates profitably. For example, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, which we refer to collectively as the Affordable Care Act, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Effective October 1, 2010, the Affordable Care Act revised the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. The Affordable Care Act also addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, and established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. We will not know the full effects of the Affordable Care Act until applicable federal and state agencies issue regulations or guidance under the new law. Although it is too early to determine the effect of the Affordable Care Act, the new law appears likely to continue the pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction,

tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These automatic reductions include aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures.

The cost of pharmaceuticals continues to generate substantial governmental and other third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures due to the trend toward managed healthcare, the increasing influence of managed care organizations and additional legislative proposals. Our results of operations could be adversely affected by current and future healthcare reforms.

Some third-party payors also require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers that use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, the announcement or adoption of these proposals could have a material adverse effect on our ability to obtain adequate prices for our drug candidates and operate profitably.

#### ***Other Healthcare Laws and Compliance Requirements***

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including CMS, other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments. The laws we are subject to include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The Anti-Kickback Statute is subject to evolving interpretations. In the past, the government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The majority of states also have anti-kickback laws which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

Additionally, the civil False Claims Act prohibits knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the United States government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the country, for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party

payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of \$150,000 per year (or up to an aggregate of \$1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit reports to the government by the 90th day of each subsequent calendar year. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

### **Employees**

As of May 1, 2015, we had 35 employees, all of whom work in North Carolina, of which at least 16 hold graduate degrees (including 12 doctorate degrees) and 23 are engaged in full-time research and development activities. None of our employees are represented by a labor union, and we consider our employee relations to be good.

### **Properties**

Our corporate headquarters and lab facilities are located in High Point, North Carolina, where we lease 43,040 square feet of mixed laboratory and office space in the Mendenhall Oaks office park. The lease agreement for this space continues through June 2018, with an option for early termination in June 2016.

We believe that our existing facilities are adequate for our current and expected future needs. We may seek to negotiate new leases or look for additional or alternate space for our operations. We believe that appropriate alternative space is readily available at similar rents.

### **Legal Proceedings**

We are not currently a party to any material legal proceedings.



## MANAGEMENT

The following table sets forth the name, age and position of each of our directors and executive officers as of May 1, 2015:

<u>Name</u>	<u>Age</u>	<u>Position(s)</u>
Jeffrey B. Kindler	59	Executive Chairman
Stephen L. Holcombe	58	President and Chief Executive Officer
Paul G. Savas	52	Director

Prior to completion of this offering, we intend to appoint a number of additional directors and executive officers.

### Executive Officers

**Jeffrey B. Kindler** has served as our Executive Chairman since April 2015, and we expect to appoint him to be Chairman of our Board of Directors prior to completion of this offering. Mr. Kindler is currently Chief Executive Officer at Centrexion Corporation, a Venture Partner at Lux Capital, a principal in and senior advisor to Marathon Pharmaceuticals, LLC, a global investment firm that builds and manages innovative pharmaceutical companies, and a Managing Director at Starboard Capital Partners, a Connecticut-based private equity firm. From 2006 to 2010, Mr. Kindler was the Chairman and Chief Executive Officer of Pfizer Inc. Prior to his appointment as Pfizer's CEO, Mr. Kindler served as Pfizer's Executive Vice President and General Counsel as well as a Vice Chairman of the company. Prior to joining Pfizer in 2002, he was Chairman of Boston Market Corporation from 2000 to 2001 and President of the Partner Brands group of McDonalds Corporation during 2001. Mr. Kindler serves on the boards of a number of publicly and privately held healthcare companies, as well as several not-for-profit institutions including Tufts University. Mr. Kindler holds a bachelor's degree from Tufts University and a J.D. from Harvard Law School.

**Stephen L. Holcombe** has served as our President and Chief Executive Officer since April 2015. Mr. Holcombe has been the President of our Predecessors since 2014, where he previously served as Senior Vice President since 2002. He has also served as Chief Financial Officer of our Predecessors since 2002. Mr. Holcombe has over 35 years of experience in financial and managerial roles focusing on the execution of private and public financings, developing corporate alliance and partnership strategies and managing relationships with external constituents. Positions that Mr. Holcombe held prior to joining our Predecessors include Executive Vice President and Chief Financial Officer of Vanguard Cellular Systems, Inc., one of the largest independent wireless operators in the United States, Executive Vice President and Chief Financial Officer of BuildNet Inc., an e-commerce software solutions provider, and various positions with KPMG Peat Marwick Mitchell. He holds a bachelor's degree in Accountancy from Wake Forest University.

### Board of Directors

**Paul G. Savas** has served on our Board of Directors since April 2015. Mr. Savas is Executive Vice President and Chief Financial Officer at MacAndrews. He joined MacAndrews in 1994 as Director of Corporate Finance, served in various positions of increasing responsibility and became Chief Financial Officer in 2007. He also serves as a director of Harland Clarke Holding Corp. and has been a member of the board of directors of our Predecessors since 2007. During the past six years, Mr. Savas also served as a member of the board of managers of REV Holdings LLC. He holds a bachelor's degree in Accounting from Rutgers University and an M.B.A. from Fordham University. Mr. Savas provides our Board of Directors valuable business, leadership and management insights with respect to our strategic, operational and financial direction. For these reasons, we believe he is well qualified to serve on our Board of Directors.

### Family Relationships

There are no family relationships among any of our directors or executive officers.

### Board Composition

The Board of Directors of vTv Therapeutics Inc. currently consists of \_\_\_\_\_ members. In accordance with our amended and restated certificate of incorporation and our amended and restated bylaws, the number of directors on the Board of Directors will be determined from time to time by the Board of

## TABLE OF CONTENTS

Directors, and only a majority of the Board of Directors may fix the number of directors. Each director is to hold office until his or her successor is duly elected and qualified or until his or her earlier death, resignation or removal. At any meeting of the Board of Directors, except as otherwise required by law, a majority of the total number of directors then in office will constitute a quorum for all purposes. We are currently determining the composition of our Board of Directors in preparation for our initial public offering.

Under the investor rights agreement to be entered into in connection with the Reorganization Transactions, vTv Therapeutics Holdings will be initially entitled to nominate a majority of the members of our Board of Directors. vTv Therapeutics Holdings will initially have the right to nominate \_\_\_\_\_ of our directors and vTv Therapeutics Holdings' initial board nominees are expected to be \_\_\_\_\_. See "Certain Relationships and Related Party Transactions—Investor Rights Agreement."

### **Director Independence**

The Board of Directors of vTv Therapeutics Inc. has determined that \_\_\_\_\_ are "independent directors," as defined by the applicable NASDAQ rules.

### **Board Committees**

Our Board of Directors will establish, upon the completion of this offering, an audit committee, a compensation committee and a nominating and corporate governance committee. Each of these committees will operate under a charter that has been approved by the Board of Directors. We are currently in the process of determining the composition of our Board of Directors and committees in preparation for our initial public offering.

#### ***Audit Committee***

Our Audit Committee will assist the Board of Directors in monitoring the audit of our financial statements, our independent registered public accounting firm's qualifications and independence, the performance of our audit function and independent auditors and our compliance with legal and regulatory requirements. The Audit Committee will have direct responsibility for the appointment, compensation, retention (including termination) and oversight of our independent auditors, and our independent auditors report directly to the Audit Committee. The Audit Committee will also review and approve related party transactions as required by the applicable NASDAQ rules.

Upon completion of this offering, we will have an audit committee consisting of \_\_\_\_\_. The Board of Directors has determined that \_\_\_\_\_ qualifies as an "audit committee financial expert" as such term is defined in Item 407(d)(5) of Regulation S-K and that \_\_\_\_\_ is "independent" for purposes of Rule 10A-3 of the Securities Exchange Act of 1934, as amended, and under the listing standards of NASDAQ. Our Board of Directors has determined that the composition of its audit committee satisfies the independence requirements of the SEC and NASDAQ.

#### ***Compensation Committee***

Following the completion of this offering, our compensation committee will be responsible for reviewing and recommending policies relating to the compensation and benefits of our directors and employees, including our Chief Executive Officer and other executive officers.

Upon completion of this offering, our compensation committee will consist of \_\_\_\_\_. Because we will be a "controlled company" under the rules of NASDAQ, our compensation committee is not required to be fully independent, although if such rules change in the future or we no longer meet the definition of a controlled company under the current rules, we will adjust the composition of the compensation committee accordingly in order to comply with such rules.

The compensation committee will have the sole authority to retain and terminate any compensation consultant to assist in the evaluation of employee compensation and to approve the consultant's fees and the other terms and conditions of the consultant's retention.

#### ***Nominating and Corporate Governance Committee***

Following the completion of this offering, our Nominating and Corporate Governance Committee will be responsible for selecting or recommending that the Board of Directors select candidates for election to

## TABLE OF CONTENTS

our Board of Directors, developing and recommending to the Board of Directors corporate governance guidelines that are applicable to us and overseeing Board of Director and management evaluations.

Upon completion of this offering, our nominating and governance committee will consist of . Because we will be a "controlled company" under NASDAQ rules, our nominating and governance committee is not required to be fully independent, although if such rules change in the future or we no longer meet the definition of a controlled company under the current rules, we will adjust the composition of our nominating and governance committee accordingly in order to comply with such rules.

### ***Compensation Committee Interlocks and Insider Participation***

None of our executive officers serves, or in the past has served, as a member of the Board of Directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more executive officers who serve as members of our Board of Directors or our compensation committee. None of the members of our compensation committee is, or has ever been, an officer or employee of our company.

### ***Code of Business Conduct and Ethics***

Upon consummation of this offering, the Board of Directors will adopt a Code of Business Conduct and Ethics that will apply to all of our directors, officers and employees and is intended to comply with the relevant listing requirements for a code of conduct as well as qualify as a "code of ethics" as defined by the rules of the SEC. The statement will contain general guidelines for conducting our business consistent with the highest standards of business ethics. We intend to disclose future amendments to certain provisions of our Code of Business Conduct and Ethics, or waivers of such provisions applicable to any principal executive officer, principal financial officer, principal accounting officer and controller, or persons performing similar functions, and our directors, on our website at [www.vtvtherapeutics.com](http://www.vtvtherapeutics.com) under " . Following the consummation of this offering, the Code of Business Conduct and Ethics will be available on our website identified above under " ."

### ***Board Leadership Structure and Board's Role in Risk Oversight***

The Board of Directors has an oversight role, as a whole and also at the committee level, in overseeing management of its risks. The Board of Directors regularly reviews information regarding our credit, liquidity and operations, as well as the risks associated with each. The compensation committee of the Board of Directors is responsible for overseeing the management of risks relating to its employee compensation plans and arrangements and the audit committee of the Board of Directors oversees the management of financial risks. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire Board of Directors is regularly informed through committee reports about such risks.

### ***Executive Compensation***

Prior to this offering, we did not pay compensation to any of our executive officers, and accordingly, we did not have compensation policies or objectives governing our named executive officer compensation. Our Board of Directors has not yet formed our compensation committee. Accordingly, we have not adopted compensation policies with respect to, among other things, setting base salaries, awarding bonuses or making future grants of equity awards to our executive officers. We anticipate that our compensation committee, once formed, will design a compensation program that rewards, among other things, favorable stockholder returns, our company's competitive position within the biopharmaceutical industry, our operating results and contributions to our company.

The following is a non-exhaustive list of items that we expect our compensation committee will consider in formulating our compensation philosophy and apply that philosophy to the implementation of our overall compensation program for named executive officers and other employees:

- attraction and retention of talented and experienced executives in our industry;
- motivation of our executives whose knowledge, skills and performance are critical to our success;
- alignment of the interests of our executive officers and stockholders by motivating executive officers to increase stockholder value and rewarding executive officers when stockholder value increases; and

## TABLE OF CONTENTS

- encouragement of our executives to achieve meaningful levels of ownership of our stock.

We expect that our compensation committee, once formed, may retain a compensation consultant to review our policies and procedures with respect to executive compensation and assist our compensation committee in implementing and maintaining compensation plans.

### **Employment Agreements**

We intend to enter into employment agreements with our Chief Executive Officer and our Chief Financial Officer.

### **2015 Omnibus Equity Incentive Plan**

We intend to adopt and implement the 2015 Omnibus Equity Incentive Plan (the "2015 Plan") at or around the date we complete the initial public offering to provide equity-based compensation for our directors and employees. We are currently in the process of determining the terms of the 2015 Plan.

### **Tax Considerations**

Section 162(m) of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the "Code," limits the amount that we may deduct from our Federal income taxes for remuneration paid to our named executive officers (other than the chief financial officer) to one million dollars per named executive officer per year, unless certain requirements are met. Section 162(m) provides an exception from this deduction limitation for certain forms of "performance-based compensation," as well as for the gain recognized by named executive officers upon the exercise of qualifying compensatory stock options. In addition, transition provisions under Section 162(m) may apply for a period of three years following the consummation of this offering to certain compensation arrangements that were entered into by us before we were publicly held. After this offering, our board of directors may generally seek to structure performance-based, equity and equity-based compensation for the named executive officers in a manner that complies with Section 162(m) in order to provide for the deductibility of such compensation. While our board of directors intends to be mindful of the full deductibility of compensation, our board of directors believes that it should not be constrained by the requirements of Section 162(m) of the Code where those requirements would impair flexibility in compensating our named executive officers in a manner that can best promote our corporate objectives. We have not adopted a policy that requires that all compensation be deductible.

Section 409A of the Code. Section 409A of the Code requires that "nonqualified deferred compensation" be deferred and paid under plans or arrangements that satisfy the requirements of the statute with respect to the timing of deferral elections, timing of payments and certain other matters. Failure to satisfy these requirements can expose employees and other service providers to accelerated income tax liabilities, penalty taxes and interest on their vested compensation under such plans. Accordingly, as a general matter, it is our intention to design and administer our compensation and benefits plans and arrangements for all of our employees and other service providers, including our named executive officers, so that they are either exempt from, or satisfy the requirements of, Section 409A.

### **Director Compensation**

We anticipate that each director will receive compensation for attending meetings of the Board of Directors as well as committee meetings. We expect that directors will each receive a director fee of \$        per year (and an additional \$        per year for committee chairmen). In addition, each director will be reimbursed for out-of-pocket expenses in connection with their services. We are currently in the process of determining the specific terms of our director compensation.

## **CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS**

Other than compensation arrangements for our named executive officers and directors, we describe below each transaction or series of similar transactions, since our incorporation, to which we were a party or will be a party, in which:

- the amounts involved exceeded or will exceed \$120,000; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Compensation arrangements for our named executive officers and directors are described in the sections entitled “Management—Executive Compensation” and “Management—Director Compensation.”

### **Policies and Procedures for Related Party Transactions**

We have adopted a Related Person Transaction Policy, which sets forth our policy with respect to the review, approval, ratification and disclosure of all related person transactions by our audit committee. In accordance with our Related Person Transaction Policy, our audit committee has overall responsibility for the implementation and compliance with this policy.

For the purposes of our Related Person Transaction Policy, a “related person transaction” is a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we were, are or will be a participant and in which any related person (as defined in our Related Person Transaction Policy) had, has or will have a direct or indirect material interest, in excess of \$120,000. A “related person transaction” does not include any employment relationship or transaction involving an executive officer and any related compensation resulting solely from that employment relationship which has been reviewed and approved by our Board of Directors or compensation committee.

Our Related Person Transaction Policy requires that notice of a proposed related person transaction be provided to our legal department prior to entering into such transaction. If our legal department determines that such transaction is a related person transaction, the proposed transaction will be submitted to our audit committee for consideration at its next meeting. Under our Related Person Transaction Policy, only our audit committee will be permitted to approve those related person transactions that are in, or not inconsistent with, our best interests. In the event we become aware of a related person transaction that has not been previously reviewed, approved or ratified under our Related Person Transaction Policy and that is ongoing or is completed, the transaction will be submitted to our audit committee so that it may determine whether to ratify, rescind or terminate the related person transaction.

Our Related Person Transaction Policy also provides that our audit committee will review certain previously approved or ratified related person transactions that are ongoing to determine whether the related person transaction remains in our best interests and the best interests of our stockholders.

### **Exchange Agreement**

At the closing of this offering, we, vTv Therapeutics Holdings, and other existing and future holders of our vTv Therapeutics LLC Units (and corresponding shares of Class B common stock) will enter into the Exchange Agreement under which, from time to time, they (or certain transferees thereof) will have the right to exchange their vTv Therapeutics LLC Units (along with a corresponding number of our Class B common stock) with vTv Therapeutics LLC for (i) shares of our Class A common stock on a one-for-one basis or (ii) cash (based on the market price of the shares of Class A common stock), at our option (as the managing member of vTv Therapeutics LLC), subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications. Any decision to require an exchange for cash rather than shares of Class A common stock will ultimately be determined by our entire Board of Directors.

### **Tax Receivable Agreement**

As described under “Use of Proceeds” we intend to use the net proceeds from this offering to acquire equity interests in vTv Therapeutics LLC. In the future, Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, may be exchanged for shares of our Class A

common stock, or for cash, at our option (as the managing member of vTv Therapeutics LLC). See “Certain Relationships and Related Party Transactions—Exchange Agreement.” These future exchanges of Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, may result in increases in the tax basis of the assets of vTv Therapeutics LLC that otherwise would not have been available. Such increases in tax basis are likely to increase (for tax purposes) depreciation and amortization deductions and therefore reduce the amount of income tax we would otherwise be required to pay in the future and may also decrease gain (or increase loss) on future dispositions of certain assets to the extent the increased tax basis is allocated to those assets. The IRS may challenge all or part of these tax basis increases and a court could sustain such a challenge.

We intend to enter into a Tax Receivable Agreement with vTv Therapeutics Holdings that will provide for the payment by us to vTv Therapeutics Holdings (or its transferees or other assignees) of 85% of the amount of cash savings, if any, in U.S. federal, state and local income tax or franchise tax that we actually realize (or, in some circumstances, we are deemed to realize) as a result of (a) the exchange of Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, for shares of our Class A common stock (or for cash), (b) tax benefits related to imputed interest deemed to be paid by us as a result of the Tax Receivable Agreement and (c) certain tax benefits attributable to payments under the Tax Receivable Agreement. Although the actual increase in tax basis and the amount and timing of any payments under the Tax Receivable Agreement will vary depending upon a number of factors, including the timing of exchanges, the price of shares of our Class A common stock at the time of the exchange, the nature of the assets, the extent to which such exchanges are taxable, the tax rates then applicable, and the amount and timing of our income, we expect that the payments that we may make to vTv Therapeutics Holdings could be substantial.

vTv Therapeutics Holdings generally will not reimburse us for any payments that may previously have been made under the Tax Receivable Agreement even if the IRS subsequently disallows the tax basis increase or any other relevant tax item. Instead, any excess cash payments made by us to vTv Therapeutics Holdings will be netted against any future cash payments that we might otherwise be required to make under the terms of the Tax Receivable Agreement. However, we might not determine that we have effectively made an excess cash payment to vTv Therapeutics Holdings for a number of years following the initial time of such payment. As a result, in certain circumstances we could make payments to vTv Therapeutics Holdings under the Tax Receivable Agreement in excess of our cash tax savings. Our ability to achieve benefits from any tax basis increase and the payments to be made under the Tax Receivable Agreement, will depend upon a number of factors, including the timing and amount of our future income and the nature of our assets.

To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid. In addition, the Tax Receivable Agreement provides that, upon a merger, asset sale or other form of business combination or certain other changes of control or if, at any time, we elect an early termination of the Tax Receivable Agreement, our (or our successor's) obligations with respect to exchanged or acquired Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units (whether exchanged or acquired before or after such change of control or early termination) would be required to be paid significantly in advance of the actual realization, if any, of any future tax benefits and would be based on certain assumptions, including that we would have sufficient taxable income to fully utilize the deductions arising from the increased tax deductions and tax basis and other benefits related to entering into the Tax Receivable Agreement, and, in the case of certain early termination elections, that any Class B common stock, together with the corresponding number of vTv Therapeutics LLC Units, that have not been exchanged will be deemed exchanged for the market value of the Class A common stock at the time of termination. Consequently, it is possible that the actual cash tax savings realized by us may be significantly less than the corresponding Tax Receivable Agreement payments.

Upon consummation of this offering, vTv Therapeutics Inc. will be a holding company, will have no material assets other than its ownership of vTv Therapeutics LLC Units, and will have no independent means of generating revenue or cash flow. We intend, as its managing member, to cause vTv Therapeutics LLC to make distributions in an amount sufficient to allow us to pay our operating expenses, including any payments due under the Tax Receivable Agreement. However, vTv Therapeutics LLC's ability to make such distributions may be subject to various limitations and restrictions including, but not limited to, restrictions

on distributions that would either violate any contract or agreement to which vTv Therapeutics LLC is then a party, including potential debt agreements, or any applicable law, or that would have the effect of rendering vTv Therapeutics LLC insolvent. If vTv Therapeutics LLC does not distribute sufficient funds for us to pay our operating expenses, including any payments due under the Tax Receivable Agreement, we may have to borrow funds, which could materially adversely affect our liquidity and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid.

Our organizational structure, including the fact that vTv Therapeutic Holdings is expected to own more than 50% of the voting power of our voting stock and own part of its economic interest in our business through vTv Therapeutics LLC, confers certain benefits upon vTv Therapeutics Holdings that will not benefit the holders of our Class A common stock to the same extent as it will benefit vTv Therapeutics Holdings. Although we will retain 15% of the amount of the tax benefits described above, it is possible that the interests of vTv Therapeutics Holdings may in some circumstances conflict with our interests and the interests of our other stockholders, including you. For example, vTv Therapeutics Holdings may have different tax positions from us, especially in light of the Tax Receivable Agreement, that could influence their decisions regarding whether and when we should dispose of assets, whether and when we should incur new or refinance existing indebtedness, and whether and when we should terminate the Tax Receivable Agreement and accelerate our obligations thereunder. In addition, the determination of future tax reporting positions, the structuring of future transactions and the handling of any future challenges by any taxing authority to our tax reporting positions may take into consideration vTv Therapeutics Holdings's tax or other considerations, which may differ from the considerations of us or our other stockholders.

### **Reimbursement of Expenses**

Entities affiliated with MacAndrews will initially bear certain costs and expenses of this offering, including the fees of attorneys, consultants, financial printers and auditors incurred by us. We will reimburse such MacAndrews affiliates using a portion of the gross proceeds of this offering.

### **Investor Rights Agreement**

In connection with this offering, we intend to enter into an investor rights agreement with vTv Therapeutics Holdings. The investor rights agreement will provide vTv Therapeutics Holdings with certain demand, shelf and piggyback registration rights with respect to its shares of vTv Therapeutics Inc. common stock and also provide vTv Therapeutics Holdings with certain governance rights, depending on the size of its holdings of vTv Therapeutics Inc. common stock.

Under the registration rights provisions of the investor rights agreement:

- after 180 days after the completion of this offering, vTv Therapeutics Holdings and its affiliates have the right to cause us to conduct an unlimited number of demand registrations, subject to certain customary restrictions, which demand registrations may take the form of a shelf registration;
- once we are eligible to do so, vTv Therapeutics Holdings and its affiliates have the right to cause us to file and have declared effective a shelf registration statement on Form S-3 with respect to all of their shares of vTv Therapeutics Inc. common stock; and
- vTv Therapeutics Holdings and its affiliates have the right to participate in certain registered offerings by us.

The registration rights provisions also contain customary provisions relating to cooperation with the registration process, black-out periods and customary securities law indemnity provisions in favor of the selling stockholders. With certain customary exceptions, we will be required to bear all registration expenses, other than underwriting discounts and commissions and transfer taxes, associated with any registration of shares pursuant to the agreement. Registration rights may be transferred by vTv Therapeutics Holdings and its affiliates, subject to certain restrictions. No predetermined penalties or liquidated damages will be payable by us if we fail to comply with the registration rights provisions of the investor rights agreement.

[TABLE OF CONTENTS](#)

The investor rights agreement also provides that vTv Therapeutics Holdings has the right to designate: (i) directors if it beneficially owns more than % of the outstanding vTv Therapeutics Inc. common stock, (ii) directors if it beneficially owns more than % but % or less, (iii) directors if it beneficially owns more than % but % or less and (iv) one director if it beneficially owns greater than % but % or less. vTv Therapeutics Holdings loses the right to designate directors at % or less. If the number of directors is increased, vTv Therapeutics Holdings' rights to nominate increase proportionally.

The investor rights agreement is expected to be executed at the closing of this offering and will terminate on the anniversary of its execution, unless extended by mutual agreement between the parties.

**Indemnification Agreements**

We have entered into customary indemnification agreements with our executive officers and directors that provide, in general, that we will provide them with customary indemnification in connection with their service to us or on our behalf.

These indemnification agreements require us, among other things, to indemnify our directors and officers against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified and to obtain directors' and officers' insurance, if available on reasonable terms.



**PRINCIPAL STOCKHOLDERS**

The following table sets forth the beneficial ownership of our Class A common stock as of May 1, 2015 by:

- each person, or group of affiliated persons, who we know to beneficially own more than 5% of our Class A common stock;
- each of our named executive officers;
- each of our directors; and
- all of our executive officers and directors as a group.

The number of shares of Class A common stock outstanding and the percentage of beneficial ownership before this offering are based on the number of shares of Class B common stock and vTv Therapeutics LLC Units to be issued and outstanding immediately prior to this offering and after giving effect to the Reorganization Transactions (based on the midpoint of the estimated initial public offering price range set forth on the cover page of this prospectus). Pursuant to the Exchange Agreement, vTv Therapeutics LLC Units may, subject to the terms of the Exchange Agreement and the vTv Therapeutics LLC Operating Agreement, be exchanged at any time (along with a corresponding number of shares of our Class B common stock) with vTv Therapeutics LLC for shares of our Class A common stock on a one-for-one basis, or for cash, at our option (as the managing member of vTv Therapeutics LLC). See “Certain Relationships and Related Party Transactions—Exchange Agreement.”

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to such securities. Except as otherwise indicated, all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. Unless otherwise indicated, the address of each person or entity named in the table below is c/o vTv Therapeutics Inc., 4170 Mendenhall Oaks Pkwy, High Point, North Carolina 27265.

Name of Beneficial owner	Class A Common Stock Owned After Giving Effect to the Reorganization Transactions and Before this Offering		Class A Common Stock Owned After Giving Effect to the Reorganization Transactions and this Offering		Class A Common Stock Owned After Giving Effect to the Reorganization Transactions and this Offering <sup>(1)</sup>	
	Number	Percent	Number	Percent	Number	Percent
<i>5% or Greater Stockholders:</i>						
Ronald O. Perelman						
<i>Named Executive Officers and Directors:</i>						
Jeffrey B. Kindler						
Stephen L. Holcombe						
Paul G. Savas						
All current directors and executive officers as a group (      persons)						

\* Represents beneficial ownership of less than one percent of shares outstanding.

<sup>(1)</sup>Assumes exercise of the underwriters' over-allotment option in full. See “Underwriting.”

## DESCRIPTION OF CAPITAL STOCK

The following is a summary of all material characteristics of our capital stock as set forth in our amended and restated certificate of incorporation and amended and restated bylaws, which will become effective upon the consummation of this offering. The summary does not purport to be complete and is qualified in its entirety by reference to our amended and restated certificate of incorporation and amended and restated bylaws, all of which are incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and the applicable provisions of Delaware law.

### Capital Stock

In connection with the Reorganization Transactions, we intend to amend and restate our certificate of incorporation so that our authorized capital stock will consist of \_\_\_\_\_ shares of Class A common stock, par value \$0.01 per share, \_\_\_\_\_ shares of Class B common stock, par value \$ \_\_\_\_\_ per share, and \_\_\_\_\_ shares of preferred stock, par value \$0.01 per share.

After consummation of this offering and the use of proceeds therefrom, assuming no exercise of the underwriters' over-allotment option, we expect to have \_\_\_\_\_ shares of our Class A common stock outstanding, \_\_\_\_\_ shares of our Class B common stock outstanding, and no shares of preferred stock outstanding.

### Common Stock

*Voting.* Holders of our Class A common stock and Class B common stock will be entitled to one vote for each share held on all matters submitted to stockholders for their vote or approval. The holders of our Class A common stock and Class B common stock will vote together as a single class on all matters submitted to stockholders for their vote or approval, except with respect to the amendment of certain provisions of our amended and restated certificate of incorporation that would alter or change the powers, preferences or special rights of the Class B common stock so as to affect them adversely, which amendments must be approved by a majority of the votes entitled to be cast by the holders of the shares affected by the amendment, voting as a separate class, or as otherwise required by applicable law. The voting power of the outstanding Class B common stock (expressed as a percentage of the total voting power of all common stock) will be equal to the percentage of interests not held directly or indirectly by vTv Therapeutics Holdings.

Following the Reorganization Transactions and this offering, MacAndrews will indirectly control \_\_\_\_\_ shares of Class B common stock held by vTv Therapeutics Holdings and will therefore control approximately \_\_\_\_\_ % of the combined voting power of our outstanding common stock (or \_\_\_\_\_ % if the underwriters exercise their over-allotment option in full). As a result, even if the underwriters chose to exercise their over-allotment option, MacAndrews will be able to control our business policies and affairs and any action requiring the general approval of our stockholders, including the adoption of amendments to our certificate of incorporation and bylaws, the approval of mergers or sales of substantially all of our assets and (prior to the "Triggering Event," or the point in time at which MacAndrews no longer beneficially own shares representing 50% or more of the combined voting power of our common stock) the removal of members of our Board of Directors with or without cause. MacAndrews, through its control of vTv Therapeutics Holdings, will also have the power to nominate a majority of the members to our Board of Directors under our investor rights agreement. The concentration of ownership and voting power of MacAndrews may also delay, defer or even prevent an acquisition by a third party or other change of control of our company and may make some transactions more difficult or impossible without the support of MacAndrews, even if such events are in the best interests of minority stockholders.

*Dividends.* The holders of Class A common stock will be entitled to receive dividends when, as, and if declared by our Board of Directors out of legally available funds. The holders of our Class B common stock will not have any right to receive dividends other than dividends consisting of shares of our Class B common stock paid proportionally with respect to each outstanding share of our Class B common stock.

*Liquidation or Dissolution.* Upon our liquidation or dissolution, the holders of our Class A common stock will be entitled to share ratably in those of our assets that are legally available for distribution to stockholders after payment of liabilities and subject to the prior rights of any holders of preferred stock then

outstanding. Other than their par value, the holders of our Class B common stock will not have any right to receive a distribution upon a liquidation or dissolution of our company.

*Transferability and Exchange.* Subject to the terms of the Exchange Agreement and the vTv Therapeutics LLC Operating Agreement, vTv Therapeutics Holdings may exchange its vTv Therapeutics LLC Units (along with a corresponding number of shares of our Class B common stock) with vTv Therapeutics LLC for (i) shares of our Class A common stock or (ii) cash (based on the market price of the shares of Class A common stock), at our option (as the managing member of vTv Therapeutics LLC). Any decision to require an exchange for cash rather than shares of Class A common stock will ultimately be determined by our entire Board of Directors. Each such exchange will be on a one-for-one equivalent basis, subject to customary conversion rate adjustments for stock splits, stock dividends and reclassifications. Shares of Class B common stock may not be transferred except in connection with an exchange or transfer of vTv Therapeutics LLC Units.

Upon exchange, each share of our Class B common stock will be cancelled.

### **Preferred Stock**

After the consummation of this offering, we will be authorized to issue up to \_\_\_\_\_ shares of preferred stock. Our Board of Directors will be authorized, subject to limitations prescribed by Delaware law and our amended and restated certificate of incorporation, to determine the terms and conditions of the preferred stock, including whether the shares of preferred stock will be issued in one or more series, the number of shares to be included in each series and the powers, designations, preferences and rights of the shares. Our Board of Directors will also be authorized to designate any qualifications, limitations or restrictions on the shares without any further vote or action by the stockholders. The issuance of preferred stock may have the effect of delaying, deferring or preventing a change in control of our company and may adversely affect the voting and other rights of the holders of our Class A common stock and Class B common stock, which could have an adverse impact on the market price of our Class A common stock. We have no current plan to issue any shares of preferred stock following the consummation of this offering.

### **Corporate Opportunities**

Our amended and restated certificate of incorporation will provide that we renounce any interest or expectancy in the business opportunities of MacAndrews and of their officers, directors, agents, stockholders, members, partners, affiliates and subsidiaries and each such party shall not have any obligation to offer us those opportunities unless presented to one of our directors or officers in his or her capacity as a director or officer. See “Risk Factors—Risks Relating to this Offering and Ownership of Our Class A Common Stock—MacAndrews has substantial influence over our business, and their interests may differ from our interests or those of our other stockholders.”

### **Anti-Takeover Effects of our Certificate of Incorporation and Bylaws**

Our amended and restated certificate of incorporation and bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the Board of Directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of us unless such takeover or change in control is approved by our Board of Directors.

These provisions include:

*Action by Written Consent; Special Meetings of Stockholders.* Our amended and restated certificate of incorporation will provide that, following the Triggering Event, stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our amended and restated certificate of incorporation and bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by the chairman or vice-chairman of the board, the chief executive officer, or pursuant to a resolution adopted by a majority of the Board of Directors or, until the Triggering Event, at the request of holders of 50% or more of our outstanding shares of common stock. Except as described above, stockholders will not be permitted to call a special meeting or to require the Board of Directors to call a special meeting.

*Advance Notice Procedures.* Our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of

## TABLE OF CONTENTS

persons for election to the Board of Directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the Board of Directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our Secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws will not give the Board of Directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

*Authorized but Unissued Shares.* Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital, corporate acquisitions and employee benefit plans. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise.

*Business Combinations with Interested Stockholders.* We intend to elect in our amended and restated certificate of incorporation not to be subject to Section 203 of the Delaware General Corporation Law, an antitakeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination, such as a merger, with a person or group owning 15% or more of the corporation's voting stock for a period of three years following the date the person became an interested stockholder, unless (with certain exceptions) the business combination or the transaction in which the person became an interested stockholder is approved in a prescribed manner. Accordingly, we will not be subject to any anti-takeover effects of Section 203. Nevertheless, our amended and restated certificate of incorporation will contain provisions that have the same effect as Section 203, except that they provide that MacAndrews and its affiliates, including Ronald O. Perelman, and transferees will not be deemed to be "interested stockholders," regardless of the percentage of our voting stock owned by them, and accordingly will not be subject to such restrictions.

### **Directors' Liability; Indemnification of Directors and Officers**

Our amended and restated certificate of incorporation will limit the liability of our directors to the fullest extent permitted by the Delaware General Corporation Law and provides that we will provide them with customary indemnification. We expect to enter into customary indemnification agreements with each of our executive officers and directors that provide them, in general, with customary indemnification in connection with their service to us or on our behalf.

### **Transfer Agent and Register**

The transfer agent and registrar for our Class A common stock will be \_\_\_\_\_.

### **Securities Exchange**

We intend to apply to list the shares of Class A common stock on the NASDAQ Global Market under the symbol "VTVT."

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our Class A common stock. Future sales of substantial amounts of our Class A common stock in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our Class A common stock in the public market after the restrictions lapse. This may adversely affect the prevailing market price and our ability to raise equity capital in the future.

All of the shares of Class A common stock (or shares if the underwriters exercise their over-allotment option in full) outstanding following this offering will have been issued in this offering and will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act.

Immediately following the consummation of the Reorganization Transactions and this offering, the members of vTv Therapeutics LLC will consist of the Issuer and vTv Therapeutics Holdings, which will hold vTv Therapeutics LLC Units and the same number of shares of vTv Therapeutics Inc. Class B common stock, which will represent % of the combined voting power of our outstanding common stock (or % if the underwriters exercise their over-allotment option in full). Pursuant to the terms of the Exchange Agreement, the holders of partnership interests in vTv Therapeutics LLC could from time to time exchange their direct or indirect interests in vTv Therapeutics LLC (and corresponding shares of our Class B common stock) for shares of our Class A common stock on a one-for-one equivalent basis. Shares of our Class A common stock issuable to the holders of vTv Therapeutics LLC Units upon an exchange of direct or indirect interests in vTv Therapeutics LLC (along with the corresponding number of shares of Class B common stock) would be considered "restricted securities," as that term is defined in Rule 144 at the time of this offering.

Restricted securities may be sold in the public market only if they qualify for an exemption from registration under Rule 144 under the Securities Act, which is summarized below, or any other applicable exemption under the Securities Act, or pursuant to a registration statement that is effective under the Securities Act. Immediately following the consummation of this offering, the holders of approximately shares of our Class A common stock (on an assumed as-exchanged basis) will be entitled to dispose of their shares following the expiration of an initial 180-day underwriter "lock-up" period pursuant to the holding period, volume and other restrictions of Rule 144. The representatives of the underwriters are entitled to waive these lock-up provisions at their discretion prior to the expiration dates of such lock-up agreements.

### Rule 144

In general, under Rule 144, once we have been subject to the reporting requirements under the Exchange Act for at least 90 days a person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, would be entitled to sell those shares, subject only to the availability of current public information about us. A non-affiliated person who has beneficially owned restricted securities within the meaning of Rule 144 for at least one year would be entitled to sell those shares without regard to the other provisions of Rule 144.

An affiliate of ours who has beneficially owned restricted shares of our Class A common stock for at least 12 months (or six months, provided that such sale occurs after we have been subject to the reporting requirements under the Exchange Act for at least 90 days) would be entitled to sell, within any three-month period, a number of shares that does not exceed the greater of:

- 1% of shares of our Class A common stock then outstanding; or
- the average weekly trading volume of shares of our Class A common stock on the NASDAQ Global Market during the four calendar weeks preceding the date on which notice of the sale is filed with the Securities and Exchange Commission.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to manner of sale provisions, notice requirements and the availability of current public information about us.

#### **Rule 701**

Under Rule 701, Class A common stock acquired upon the exercise of certain currently outstanding options or pursuant to other rights granted under our stock plans may be resold, to the extent not subject to lock-up agreements, (a) by persons other than affiliates, beginning 90 days after the effective date of this offering, subject only to the manner-of-sale provisions of Rule 144 and (b) by affiliates, subject to the manner-of-sale, current public information and filing requirements of Rule 144, in each case, without compliance with the holding period requirement of Rule 144. The Rule 701 shares held by our executive officers, directors and substantially all of our stockholders are, however, subject to lock-up agreements and will only become eligible for sale upon the expiration of the contractual lock-up agreements. The underwriters may release all or any portion of the securities subject to lock-up agreements upon compliance with certain public notification requirements.

#### **Lock-up Agreements**

Our officers and directors and certain holders of our outstanding shares of Class A common stock, Class B common stock or vTv Therapeutics LLC Units have agreed with the underwriters, subject to certain exceptions, not to dispose of or hedge any of their Class A common stock, Class B common stock or vTv Therapeutics LLC Units or securities convertible into or exchangeable for shares of our Class A common stock, subject to specified exceptions, for a period through the date that is 180 days after the date of this prospectus, as modified as described below, except with the prior written consent of the representatives of the underwriters on behalf of the underwriters.

The representatives may, in their sole discretion and at any time or from time to time before the termination of the lock-up period release all or any portion of the securities subject to lock-up agreements; *provided, however*, that, subject to limited exceptions, at least three business days before the release or waiver or any lock-up agreement, the representatives must notify us of the impending release or waiver and we will announce the impending release or waiver through a major news service at least two business days before the effective date of the release or waiver.

#### **Registration Rights**

We intend to enter into an investor rights agreement with vTv Therapeutics Holdings that will provide it and its affiliates with registration rights with respect to shares of our common stock it will hold after the completion of this offering. This agreement will not provide for any maximum cash penalties nor any penalties connected with delays in registering our common stock. See "Certain Relationships and Related Party Transactions—Investor Rights Agreement" for additional information.

## CERTAIN U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership and disposition of our Class A common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax considerations. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local or non-U.S. tax laws are not discussed. This discussion is based on the U.S. Internal Revenue Code of 1986, as amended (the "Code"), U.S. judicial decisions, administrative pronouncements and existing and proposed Treasury regulations, all as in effect as of the date hereof. All of the preceding authorities are subject to change, possibly with retroactive effect, so as to result in U.S. federal income tax consequences different from those discussed below. The following discussion is based upon the Code. We have not requested, and will not request, a ruling from the IRS with respect to any of the U.S. federal income tax consequences described below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership and disposition of our Class A common stock.

This discussion is limited to Non-U.S. Holders that hold our Class A common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons subject to the alternative minimum tax;
- persons holding our Class A common stock as part of a hedge, straddle or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers or traders in securities;
- "controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our Class A common stock under the constructive sale provisions of the Code;
- persons who hold or receive our Class A common stock pursuant to the exercise of any employee stock option or otherwise as compensation; and
- tax-qualified retirement plans.

The following discussion is for general information only and is not intended to be, nor should it be construed to be, legal or tax advice to any holder or prospective holder of our Class A common stock and no opinion or representation with respect to the U.S. federal income tax consequences to any such holder or prospective holder is made. Prospective purchasers are urged to consult their tax advisors as to the particular consequences to them under U.S. federal, state and local, and applicable foreign tax laws of the acquisition, ownership and disposition of our Class A common stock.

## **Non-U.S. Holders**

For purposes of this discussion, a Non-U.S. Holder is a beneficial owner of our Class A common stock that is treated for U.S. federal income tax purposes as:

- a non-resident alien individual;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of a jurisdiction other than the U.S. or any state or political subdivision thereof;
- an estate, other than an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, other than a trust that (i) is subject to the primary supervision of a court within the U.S. and which has one or more U.S. fiduciaries who have the authority to control all substantial decisions of the trust, or (ii) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

For purposes of this discussion, a Non-U.S. Holder does not include any entity that is treated as a partnership for U.S. federal income tax purposes. If a partnership or other pass through entity is a beneficial owner of our Class A common stock, the tax treatment of a partner or other owner will generally depend upon the status of the partner (or other owner) and the activities of the entity. If you are a partner (or other owner) of a pass through entity that acquires our Class A common stock, you should consult your tax advisor regarding the tax consequences of acquiring, owning and disposing of our Class A common stock.

## **Distributions**

As described in the section entitled “Dividend Policy,” we do not currently expect to make any cash distributions to holders of our Class A common stock. However, if we do make distributions of cash or property in respect of our Class A common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Except as described below under “—U.S. Trade or Business Income,” a Non-U.S. Holder generally will be subject to U.S. federal withholding tax at a 30% rate, or at a reduced rate prescribed by an applicable income tax treaty, on any dividends received in respect of our Class A common stock. If the amount of the distribution exceeds our current and accumulated earnings and profits, such excess first will be treated as a return of capital to the extent of the Non-U.S. Holder’s tax basis in our Class A common stock, and thereafter will be treated as capital gain. However, unless we elect (or the paying agent or other intermediary through which a Non-U.S. Holder holds our Class A common stock elects) otherwise, we (or the intermediary) must generally withhold on the entire distribution, in which case the Non-U.S. Holder would be entitled to a refund from the IRS for the withholding tax on the portion of the distribution that exceeded our current and accumulated earnings and profits. In order to obtain a reduced rate of U.S. federal withholding tax under an applicable income tax treaty, a Non-U.S. Holder will be required to provide a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or appropriate successor form) certifying such stockholder’s entitlement to benefits under the treaty. If a Non-U.S. Holder is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty, the Non-U.S. Holder may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for a refund with the IRS. Non-U.S. Holders are urged to consult their own tax advisors regarding possible entitlement to benefits under an income tax treaty.

## **Sale, Exchange or Other Taxable Disposition of our Class A Common Stock**

Except as described below under “—Information Reporting and Backup Withholding Tax,” and “—FATCA,” a Non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax in respect of any gain on a sale, exchange or other disposition of our Class A common stock unless:

- the gain is U.S. trade or business income, in which case, such gain will be taxed as described in “—U.S. Trade or Business Income,” below;



## TABLE OF CONTENTS

- the Non-U.S. Holder is an individual who is present in the U.S. for 183 or more days in the taxable year of the disposition and certain other conditions are met, in which case the Non-U.S. Holder will be subject to U.S. federal income tax at a rate of 30% (or a reduced rate under an applicable tax treaty) on the amount by which certain capital gains allocable to U.S. sources exceed certain capital losses allocable to U.S. sources; or
- we are or have been a “U.S. real property holding corporation” (a “USRPHC”) under section 897 of the Code at any time during the period (the “applicable period”) that is the shorter of the five year period ending on the date of the disposition of our Class A common stock and the Non-U.S. Holder’s holding period for our Class A common stock, in which case, subject to the exception set forth in the second sentence of the next paragraph, such gain will be subject to U.S. federal income tax in the same manner as U.S. trade or business income.

In general, a corporation is a USRPHC if the fair market value of its “U.S. real property interests” equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests and its other assets used or held for use in a trade or business. In the event that we are determined to be a USRPHC, gain will not be subject to tax as U.S. trade or business income under section 897 of the Code if a Non-U.S. Holder’s holdings (direct and indirect) at all times during the applicable period constituted 5% or less of our Class A common stock, provided that our Class A common stock was regularly traded on an established securities market during such period. We believe, and the rest of this discussion assumes, that we are not currently, and we do not anticipate becoming in the future, a USRPHC for U.S. federal income tax purposes.

### ***U.S. Trade or Business Income***

For purposes of this discussion, dividend income and gain on the sale, exchange or other taxable disposition of our Class A common stock will be considered to be “U.S. trade or business income” if (i) such income or gain is effectively connected with the conduct of a trade or business within the U.S. by the Non-U.S. Holder and (ii) if the Non-U.S. Holder is eligible for the benefits of an income tax treaty with the U.S., such income or gain is attributable to a permanent establishment (or, in the case of an individual, a fixed base) that the Non-U.S. Holder maintains in the U.S. Generally, U.S. trade or business income is not subject to U.S. federal withholding tax (provided certain certification and disclosure requirements are satisfied, including providing a properly executed IRS Form W-8ECI (or successor form)); instead, such income is subject to U.S. federal income tax on a net basis at regular U.S. federal income tax rates (in the same manner as a U.S. person). Any U.S. trade or business income received by a foreign corporation may also be subject to a “branch profits tax” at a 30% rate, or at a lower rate prescribed by an applicable income tax treaty.

### ***Information Reporting and Backup Withholding Tax***

We must annually report to the IRS and to each Non-U.S. Holder any dividend income that is subject to U.S. federal withholding tax, or that is exempt from such withholding pursuant to an income tax treaty. Copies of these information returns may also be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which a Non-U.S. Holder resides. Under certain circumstances, the Code imposes a backup withholding obligation on certain reportable payments. Dividends paid to a Non-U.S. Holder of our Class A common stock will generally be exempt from backup withholding if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or IRS Form W-8BEN-E (or appropriate successor form) or otherwise establishes an exemption and the applicable withholding agent does not have actual knowledge or reason to know that the stockholder is a U.S. person or that the conditions of such other exemption are not, in fact, satisfied.

The payment of the proceeds from the disposition of our Class A common stock to or through the U.S. office of any broker (U.S. or non-U.S.) will be subject to information reporting and possible backup withholding unless the stockholder certifies as to such stockholder’s non-U.S. status under penalties of perjury or otherwise establishes an exemption and the broker does not have actual knowledge or reason to know that the stockholder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied. The payment of proceeds from the disposition of our Class A common stock to or through a non-U.S. office of a non-U.S. broker will not be subject to information reporting or backup withholding.

[TABLE OF CONTENTS](#)

unless the non-U.S. broker has certain types of relationships with the U.S. (a "U.S. related financial intermediary"). In the case of the payment of proceeds from the disposition of our Class A common stock to or through a non-U.S. office of a broker that is either a U.S. person or a U.S. related financial intermediary, the Treasury regulations require information reporting (but not backup withholding) on the payment unless the broker has documentary evidence in its files that the beneficial owner is a Non-U.S. Holder and the broker has no knowledge to the contrary. Holders of our Class A common stock are urged to consult their tax advisor on the application of information reporting and backup withholding in light of their particular circumstances.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a stockholder will be refunded by the IRS or credited against such stockholder's U.S. federal income tax liability, if any, provided that the required information is timely furnished to the IRS.

**FATCA**

Pursuant to the Foreign Account Tax Compliance Act ("FATCA") foreign financial institutions (which include most foreign hedge funds, private equity funds, mutual funds, securitization vehicles and any other investment vehicles) and certain other foreign entities that do not otherwise qualify for an exemption must comply with information reporting rules with respect to their U.S. account holders and investors or be subject to a withholding tax on U.S. source payments made to them (whether received as a beneficial owner or as an intermediary for another party). More specifically, a foreign financial institution or other foreign entity that does not comply with the FATCA reporting requirements or otherwise qualify for an exemption will generally be subject to a 30% withholding tax with respect to any "withholdable payments." For this purpose, withholdable payments include generally U.S. source payments otherwise subject to nonresident withholding tax (e.g., U.S. source dividends) and also include the entire gross proceeds from the sale or other disposition of any equity or debt instruments of U.S. issuers. The FATCA withholding tax will apply even if the payment would otherwise not be subject to U.S. nonresident withholding tax (e.g., because it is gross proceeds from a disposition). This withholding obligation is deferred until January 1, 2017 for gross proceeds from dispositions of U.S. common stock.

Non-U.S. Holders are urged to consult with their own tax advisors regarding the effect, if any, of the FATCA provisions to them based on their particular circumstances.

**UNDERWRITING**

The underwriters named below have agreed to buy, subject to the terms of the underwriting agreement, the number of shares of Class A common stock listed opposite their names below. The underwriters are committed to purchase and pay for all of the shares if any are purchased.

Underwriters	Number of Shares
Piper Jaffray & Co.	
Stifel, Nicolaus & Company, Incorporated	
<b>Total</b>	

The underwriters have advised us that they propose to offer the shares to the public at \$ \_\_\_\_\_ per share. The underwriters propose to offer the shares to certain dealers at the same price less a concession of not more than \$ \_\_\_\_\_ per share. The underwriters may allow and the dealers may reallocate a concession of not more than \$ \_\_\_\_\_ per share on sales to certain other brokers and dealers. After the offering, these figures may be changed by the underwriters.

We have granted to the underwriters an option to purchase up to an additional \_\_\_\_\_ shares of Class A common stock from us at the same price to the public, and with the same underwriting discount, as set forth in the table above. The underwriters may exercise this option any time during the 30-day period after the date of this prospectus, but only to cover over-allotments, if any. To the extent the underwriters exercise the option, each underwriter will become obligated, subject to certain conditions, to purchase approximately the same percentage of the additional shares as it was obligated to purchase under the underwriting agreement.

The following table shows the underwriting fees to be paid to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the over-allotment option.

	No Exercise	Full Exercise
Per Share	\$ _____	\$ _____
Total	\$ _____	\$ _____

We have agreed to indemnify the underwriters against certain liabilities, including civil liabilities under the Securities Act, or to contribute to payments that the underwriters may be required to make in respect of those liabilities.

We and each of our directors, executive officers and certain shareholders have agreed to certain restrictions on our ability to sell additional shares of our Class A common stock, Class B common stock or vTv Therapeutics LLC Units for a period of 180 days after the date of this prospectus. We have agreed, subject to certain exceptions, not to directly or indirectly offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, make any short sale or otherwise transfer or dispose of, directly or indirectly, any shares of Class A common stock, Class B common stock or vTv Therapeutics LLC Units, without the prior written consent of each of Piper Jaffray & Co. and Stifel, Nicolaus & Company, Incorporated. The agreements provide for certain exceptions, including, among others, (1) transfers or redemptions of the vTv Therapeutics LLC Units in connection with the Reorganization Transactions and (2) our issuance of shares in connection with the exercise of options granted under, and the granting of options under, the 2015 Plan.

Prior to the offering, there has been no established trading market for the Class A common stock. The initial public offering price for the shares of Class A common stock offered by this prospectus was negotiated by us and the underwriters. The factors considered in determining the initial public offering price include the history of and the prospects for the industry in which we compete, our past and present operations, our historical results of operations, our prospects for future earnings, the recent market prices of securities of generally comparable companies and the general condition of the securities markets at the time

[TABLE OF CONTENTS](#)

of the offering and other relevant factors. There can be no assurance that the initial public offering price of the Class A common stock will correspond to the price at which the Class A common stock will trade in the public market subsequent to this offering or that an active public market for the Class A common stock will develop and continue after this offering.

To facilitate the offering, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the Class A common stock during and after the offering. Specifically, the underwriters may over-allot or otherwise create a short position in the Class A common stock for their own account by selling more shares of Class A common stock than have been sold to them by us. The underwriters may elect to cover any such short position by purchasing shares of Class A common stock in the open market or by exercising the over-allotment option granted to the underwriters. In addition, the underwriters may stabilize or maintain the price of the Class A common stock by bidding for or purchasing shares of Class A common stock in the open market and may impose penalty bids. If penalty bids are imposed, selling concessions allowed to syndicate members or other broker-dealers participating in the offering are reclaimed if shares of Class A common stock previously distributed in the offering are repurchased, whether in connection with stabilization transactions or otherwise. The effect of these transactions may be to stabilize or maintain the market price of the Class A common stock at a level above that which might otherwise prevail in the open market. The imposition of a penalty bid may also effect the price of the Class A common stock to the extent that it discourages resales of the Class A common stock. The magnitude or effect of any stabilization or other transactions is uncertain. These transactions may be effected on the NASDAQ Global Market or otherwise and, if commenced, may be discontinued at any time.

In connection with this offering, some underwriters (and selling group members) may also engage in passive market making transactions in the Class A common stock on the NASDAQ Global Market. Passive market making consists of displaying bids on the NASDAQ Global Market limited by the prices of independent market makers and effecting purchases limited by those prices in response to order flow. Rule 103 of Regulation M promulgated by the SEC limits the amount of net purchases that each passive market maker may make and the displayed size of each bid. Passive market making may stabilize the market price of the Class A common stock at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

The underwriters and certain of their respective affiliates have from time to time provided and may in the future provide investment banking, lending, and other services to the Company and its affiliates, including certain of its shareholders, for which they have received and would receive customary fees and expense reimbursements.

## LEGAL MATTERS

The validity of the shares offered hereby will be passed upon for us by Paul, Weiss, Rifkind, Wharton & Garrison LLP, New York, New York. Latham & Watkins LLP, New York, New York has acted as counsel for the underwriters in connection with certain legal matters related to this offering.

## EXPERTS

Ernst & Young LLP, independent registered public accounting firm, has audited the balance sheet of vTv Therapeutics Inc. at April 30, 2015, as set forth in their report. We have included the balance sheet in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

Ernst & Young LLP, independent registered public accounting firm, has audited the combined consolidated financial statements of TransTech Pharma, LLC and High Point Pharmaceuticals, LLC at December 31, 2014 and 2013, and for each of the two years in the period ended December 31, 2014, as set forth in their report. We have included our financial statements in the prospectus and elsewhere in the registration statement in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1, including exhibits, under the Securities Act that registers the shares of our Class A common stock to be sold in this offering. This prospectus does not contain all the information contained in the registration statement and the exhibits filed as part of the registration statement. For further information with respect to us and our Class A common stock, we refer you to the registration statement and the exhibits filed as part of the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, we refer you to the copies of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon the consummation of this offering, we will file annual, quarterly and current reports, proxy statements and other information with the SEC under the Exchange Act. You can read our SEC filings, including the registration statement, at the SEC's website at [www.sec.gov](http://www.sec.gov).

You may read and copy this information at the SEC's Public Reference Room at 100 F Street, N.E., Washington D.C. 20549, at prescribed rates. You may obtain information regarding the operation of the public reference room by calling the SEC at 1-800-SEC-0330. The SEC also maintains a website (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

Our website address is [www.vtvtherapeutics.com](http://www.vtvtherapeutics.com). The information contained in, and that can be accessed through, our website is not incorporated into and is not part of this prospectus.

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

This prospectus includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that they have gathered their information from sources they believe to be reliable, although they do not guarantee the accuracy or completeness of such information. While we believe that these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data.

INDEX TO FINANCIAL STATEMENTS

	<u>Page</u>
<b>vTv Therapeutics Inc.—Balance Sheet as of April 30, 2015</b>	
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-2
<a href="#">Balance Sheet as of April 30, 2015</a>	F-3
<a href="#">Notes to Balance Sheet</a>	F-4
<b>TransTech Pharma, LLC and High Point Pharmaceuticals, LLC (Predecessor)</b>	
<a href="#">Report of Independent Registered Public Accounting Firm</a>	F-5
<a href="#">Combined Consolidated Balance Sheets as of December 31, 2013 and 2014</a>	F-6
<a href="#">Combined Consolidated Statements of Operations for the years ended December 31, 2013 and 2014</a>	F-8
<a href="#">Combined Consolidated Statements of Changes in Redeemable Convertible Units and Members' Deficit for the years ended December 31, 2013 and 2014</a>	F-9
<a href="#">Combined Consolidated Statements of Cash Flows for the years ended December 31, 2013 and 2014</a>	F-10
<a href="#">Notes to Combined Consolidated Financial Statements</a>	F-11

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Shareholder of vTv Therapeutics Inc.

We have audited the accompanying balance sheet of vTv Therapeutics Inc. (the Company) as of April 30, 2015. This balance sheet is the responsibility of the Company's management. Our responsibility is to express an opinion on this balance sheet based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the balance sheet is free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the balance sheet referred to above presents fairly, in all material respects, the financial position of vTv Therapeutics Inc. at April 30, 2015, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Raleigh, North Carolina  
May 14, 2015

**vTv Therapeutics Inc.**

**Balance Sheet**  
**April 30, 2015**

**Stockholder's Equity**

Common stock, par value \$0.01 per share, 1,000 shares authorized, 100 shares issued and outstanding	\$	1.00
Common stock receivable		<u>(1.00)</u>
Total stockholder's equity	\$	<u><u>—</u></u>

*See accompanying notes to balance sheet.*



**vTv Therapeutics Inc.**

**Notes to Balance Sheet**

**As of April 30, 2015**

**1. Organization**

vTv Therapeutics Inc. (the "Company") is a holding company and was incorporated in the state of Delaware on April 2, 2015 for the sole purpose of becoming the managing member of vTv Therapeutics LLC.

**2. Basis of Presentation**

The Company's balance sheet has been prepared in accordance with U.S. generally accepted accounting principles. Separate statements of operations, cash flows, and changes in stockholder's equity and comprehensive income have not been presented because the Company has had no operations to date.

**3. Stockholder's Equity**

The Company has authorized for issuance 1,000 shares of common stock with a par value of \$0.01 per share (the "Common Stock"). Under a Subscription Agreement dated April 15, 2015, MacAndrews & Forbes Incorporated ("MacAndrews") has agreed to fund \$1.00 to the Company in exchange for 100 shares of Common Stock, which are reflected on the Company's balance sheet as issued and outstanding. The Common Stock receivable from MacAndrews is reflected as a reduction to stockholder's equity on the Company's balance sheet.

Holders of Common Stock are entitled to (i) one vote for each share held of record on all matters submitted to a vote of stockholders and (ii) to receive dividends, when and if declared by the board of directors out of funds legally available therefor, subject to any statutory or contractual restrictions on the payment of dividends.

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors and Members of TransTech Pharma, LLC and HighPoint Pharma LLC

We have audited the accompanying combined consolidated balance sheets of TransTech Pharma, LLC and HighPoint Pharma LLC (collectively, the Company) as of December 31, 2014 and 2013, and the related combined consolidated statements of operations, changes in redeemable convertible units and members' deficit, and cash flows for each of the two years in the period ended December 31, 2014. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the combined consolidated financial position of TransTech Pharma, LLC and HighPoint Pharma LLC at December 31, 2014 and 2013, and the combined consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2014, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Raleigh, North Carolina  
May 14, 2015

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**  
**Combined Consolidated Balance Sheets**  
(dollars in thousands except per member unit data)

	As of December 31,	
	2013	2014
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 1,089	\$ 1,384
Restricted cash and cash equivalents	130	130
Marketable equity securities - related party	69	—
Accounts receivable, net	215	—
Prepaid expenses and other current assets	921	97
Total current assets	2,424	1,611
Note receivable	6,363	6,594
Property and equipment, net	5,786	3,778
Receivable due from a related party, net	800	800
Employee loans receivable - related party	25	58
Other long-term assets	106	110
<b>Total assets</b>	<b>\$ 15,504</b>	<b>\$ 12,951</b>
<b>Liabilities, redeemable convertible preferred units, and members' deficit</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,526	\$ 3,079
Accounts payable and accrued expenses - related party	1,152	1,752
Short-term debt	148	155
Short-term debt - related party, net	80,758	—
Other liabilities	—	1,878
Total current liabilities	87,584	6,864
Debt-related party	—	27,310
Debt, net of current portion	2,265	2,110
Fair value of contingent distribution	—	26,359
Note payable	—	6,594
Other liabilities, net of current portion	18	4,434
Total liabilities	89,867	73,671
Commitments and contingencies (Note 10)		
Redeemable convertible preferred units:		
TransTech Pharma, LLC (TTP):		
Series A redeemable convertible preferred units, no par value; 8,571,337 units authorized, issued and outstanding as of December 31, 2013 and 2014 (aggregate liquidation preference of \$2,545 at December 31, 2014)	2,545	2,847
Series B redeemable convertible preferred units, no par value, 2,547,593 units authorized, issued and outstanding as of December 31, 2013 and 2014 (aggregate liquidation preference of \$3,500 at December 31, 2014)	3,500	3,500
Series C redeemable convertible preferred units, no par value, 2,343,922 units authorized and 2,243,922 units issued and outstanding as of December 31, 2013 and 2014 (aggregate liquidation preference of \$5,514 at December 31, 2014)	5,514	7,781
Series D redeemable convertible preferred units, no par value, 2,442,361 units authorized, issued and outstanding as of December 31, 2013 and 2014 (aggregate liquidation preference of \$9,556 at December 31, 2014)	9,556	9,556

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**  
**Combined Consolidated Balance Sheets(continued)**  
(dollars in thousands except per member unit data)

	As of December 31,	
	2013	2014
Series E redeemable convertible preferred units, no par value, 32,789,595 units authorized, issued and outstanding as of December 31, 2013 and 2014 (aggregate liquidation preference of \$86,700 at December 31, 2014)	86,700	86,700
Series F redeemable convertible preferred units, no par value, 1,074,434,179 and 1,367,157,023 units authorized and 1,072,004,541 and 1,145,947,422 issued and outstanding as of December 31, 2013 and 2014, respectively (aggregate liquidation preference of \$114,595 at December 31, 2014)	107,200	312,232
Total TTP redeemable convertible preferred units	215,015	422,616
High Point Pharmaceuticals, LLC (HPP):		
Series A redeemable convertible preferred units, no par value; 49,766,563 units authorized, issued and outstanding as of December 31, 2013 and 2014 (aggregate liquidation preference of \$1,194 at December 31, 2014)	1,194	1,194
Series B redeemable convertible preferred units, no par value, 548,899,544 and 704,118,921 authorized 548,366,932 and 594,834,833 units issued and outstanding as of December 31, 2013 and 2014 (aggregate liquidation preference of \$14,276 at December 31, 2014)	13,161	14,276
Total HPP redeemable convertible preferred units	14,355	15,470
Total redeemable convertible preferred units	229,370	438,086
Members' deficit:		
TransTech Pharma, LLC:		
Members' deficit	(253,015)	(454,315)
Common member units, no par value; 1,220,000,000 and 1,512,722,844 units authorized; 13,288,608 and 4,188,607 issued and outstanding as of December 31, 2013 and 2014, respectively	—	—
Total TransTech Pharma, LLC members' deficit	(253,015)	(454,315)
High Point Pharmaceuticals, LLC:		
Members' deficit	(50,718)	(44,491)
Common member units, no par value; 650,000,000 and 805,219,377 units authorized; 19,609,698 and 5,148,485 issued and outstanding as of December 31, 2013 and 2014, respectively	—	—
Total High Point Pharmaceuticals, LLC members' deficit	(50,718)	(44,491)
Total members' deficit	(303,733)	(498,806)
<b>Total liabilities, redeemable convertible preferred units, and members' equity</b>	<b>\$ 15,504</b>	<b>\$ 12,951</b>

*The accompanying notes are an integral part of the combined consolidated financial statements.*

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**  
**Combined Consolidated Statements of Operations**  
**(in thousands except per member unit data)**

	Year Ending December 31,	
	2013	2014
Revenue	\$ 976	\$ 1,549
Operating expenses:		
Research and development	22,293	17,378
Research and development - related party	3,141	1,351
General and administrative	11,375	11,717
Total operating expenses	36,809	30,446
Operating loss	(35,833)	(28,897)
Other income (expense), net	41	(503)
Other (expense) - related party	(575)	(623)
Interest (expense)	(476)	(282)
Interest (expense), net – related party	(11,346)	(5,727)
Investment (loss) – related party	(14)	(69)
<b>Combined consolidated net loss</b>	<b>\$ (48,203)</b>	<b>\$ (36,101)</b>
Net loss per TTP member unit:		
Net loss attributable to TTP member units, basic and diluted	\$ (170,335)	\$ (222,955)
Net loss per TTP member unit, basic and diluted	\$ (12.82)	\$ (16.81)
Weighted-average number of TTP common member units, basic and diluted	13,288,327	13,263,676
Net earnings (loss) per HPP member unit:		
Net earnings (loss) attributable to HPP member units, basic and diluted	\$ 1,128	\$ (12,506)
Net earnings (loss) per HPP member unit, basic and diluted	\$ 0.06	\$ (0.64)
Weighted-average number of HPP common member units, basic and diluted	19,597,888	19,570,078

*The accompanying notes are an integral part of the combined consolidated financial statements.*

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**  
**Combined Consolidated Statements of Changes in Redeemable Convertible Units and Members' Deficit**  
(in thousands except per member unit data)

	TTP	HPP	TTP		TTP	TTP	TTP	HPP		HPP	Tot
	Redeemable	Redeemable	Common membership		Additional	Accumulated	Members'	Common membership		Members'	Memk
	Convertible Preferred Units	Convertible Preferred Units	units no par value	units no par value	Paid-in Capital	Deficit	Deficit	units no par value	units no par value	Deficit	Defi
			Units	Amount				Units	Amount		
<b>Balances at December 31, 2012</b>	\$ 107,815	\$ 1,194	13,283,874	\$ 13	\$ 1,293	\$ (107,373)	\$ —	19,466,948	\$ —	\$ (74,105)	\$ (180)
Net (loss) income	—	—	—	—	—	(77,893)	—	—	—	29,690	(48)
Issuance of HPP common units	—	—	—	—	—	—	—	142,750	—	5	
Issuance of HPP Series B redeemable convertible preferred units - related party	—	11,643	—	—	—	—	—	—	—	(11,643)	(11)
Issuance of TTP Series F redeemable convertible preferred units - related party	10,077	—	—	—	19,318	4,063	—	—	—	—	23
Deemed contribution from a related party in a debt extinguishment	—	—	—	—	—	—	—	—	—	6,853	6
Stock-based compensation expense - issuance of TTP management shares - related party	2,584	—	—	—	—	—	—	—	—	—	
Change in TTP par value per common units	—	—	—	(12)	12	—	—	—	—	—	
Issuance of TTP common stock	—	—	4,734	0	6	—	—	—	—	—	
Stock-based compensation expense - issuance of TTP management shares - related party	337	—	—	—	—	—	—	—	—	—	
Reorganization of TTP to LLC	—	—	—	(1)	(20,629)	181,203	(160,573)	—	—	—	
Issuance of TTP Series F and HPP Series B redeemable convertible preferred units - related party	1,760	1,518	—	—	—	—	—	—	—	(1,518)	(1)
Change in redemption value of TTP redeemable convertible preferred units	92,442	—	—	—	—	—	(92,442)	—	—	—	(92)
<b>Balances at December 31, 2013</b>	<b>215,015</b>	<b>14,355</b>	<b>13,288,608</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>(253,015)</b>	<b>19,609,698</b>	<b>—</b>	<b>(50,718)</b>	<b>(303)</b>
Net loss	—	—	—	—	—	—	(25,254)	—	—	(10,847)	(36)
Issuance of TTP Series F redeemable convertible preferred units - related party	52,697	—	—	—	—	—	21,303	—	—	—	21
Deemed contribution from a related party in a debt extinguishment	—	—	—	—	—	—	—	—	—	18,733	18
Issuance of HPP Series B redeemable convertible preferred units - related party	—	3,726	—	—	—	—	—	—	—	(3,726)	(3)
Repurchase of TTP Series F preferred, HPP Series B preferred, HPP and TTP common member units and warrants - related party	(54,394)	(2,611)	(9,100,001)	—	—	—	11,949	(14,462,213)	—	2,067	14
Issuance of HPP common units	—	—	—	—	—	—	—	1,000	—	—	

Change in redemption value of TTP redeemable convertible preferred units	209,298	—	—	—	—	—	(209,298)	—	—	—	—	(209,298)
<b>Balances at December 31, 2014</b>	<b>\$ 422,616</b>	<b>\$ 15,470</b>	<b>4,188,607</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ (454,315)</b>	<b>5,148,485</b>	<b>\$ —</b>	<b>\$ (44,491)</b>	<b>\$ (498)</b>	<b>\$ (498)</b>

The accompanying notes are an integral part of the combined consolidated financial statements.

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**  
**Combined Consolidated Statements of Cash Flows**  
(in thousands)

	Year Ended December 31,	
	2013	2014
<b>Cash flows from operating activities:</b>		
Net loss	\$ (48,203)	\$ (36,101)
Adjustments to reconcile net loss to net cash used in operating activities:		
(Gain) loss on disposal of PP&E, net	(21)	34
Depreciation expense	1,086	864
Stock-based compensation expense – related party Series F	2,921	—
Amortization of debt discount – related party	10,181	4,773
Amortization of deferred financing costs	290	145
Bad debt expenses – related party	656	633
Change in fair value of derivative liability – related party	213	—
Impairment loss of carrying value of land	—	488
Impairment loss of marketable securities – related party	—	30
Change in fair value of marketable securities – related party	14	39
Change in assets and liabilities:		
Accounts receivable	3	(733)
Prepaid expenses and other assets	(95)	62
Employee loans receivable - related party	—	(43)
Receivable due from a related party	(575)	(623)
Notes receivable	(231)	(231)
Other long-term assets	(5)	(4)
Accounts payable and accrued expenses	(6,284)	(2,324)
Accounts payable and accrued expenses – related party	(1,608)	2,144
Other liabilities	(26)	68
<b>Net cash used in operating activities</b>	<b>(41,684)</b>	<b>(30,779)</b>
<b>Cash flows from investing activities:</b>		
Proceeds from sale of assets	25	334
Expenses paid related to disposal of HPCTC – related party	—	(140)
Purchases of property and equipment	(181)	(33)
<b>Net cash (used in) provided by investing activities</b>	<b>(156)</b>	<b>161</b>
<b>Cash flows from financing activities:</b>		
Proceeds from debt issuance – related party	39,175	33,561
Repayment of debt	(141)	(148)
Repurchase of TTP preferred common member units and warrants – related party	—	(2,500)
Issuance of HPP preferred units – related party	5	—
Issuance of TTP common units	6	—
Issuance of Series F preferred units – related party	1,760	—
<b>Net cash provided by financing activities</b>	<b>40,805</b>	<b>30,913</b>
(Decrease) increase in cash and cash equivalents	(1,035)	295
Cash:		
Cash and equivalents, beginning of year	2,124	1,089
Cash and equivalents, end of year	<u>\$ 1,089</u>	<u>\$ 1,384</u>
Supplemental cash flow information:		
Cash paid for interest	\$ 192	\$ 142
Non-cash activities:		
Repurchase of TTP and HPP preferred units, common membership units and warrants, in exchange for HPCTC and other liabilities, net of cash exchanged – related party	\$ —	\$ 40,351
Deemed contribution from related party in a debt extinguishment – related party	\$ 6,853	\$ 18,733
Issuance of TTP Series F redeemable preferred units in exchange for debt – related party	\$ 33,458	\$ 74,000

*The accompanying notes are an integral part of the combined consolidated financial statements.*



**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements**

**1. Description of Business and Basis of Presentation**

TransTech Pharma, Inc. ("TTP Inc.") was incorporated in the State of Delaware on December 3, 1998. TransTech Pharma, Inc., was formed to develop and apply proprietary high-throughput medicinal chemistry approaches as its platform technology to yield clinical drug candidates in a timely and cost effective manner.

In November 2013, TTP Inc. underwent a reorganization by contributing all of its assets to TransTech Pharma, LLC ("TTP," or "TransTech"), a Delaware limited liability company, in exchange for (a) assumption of all liabilities of TTP Inc. and (b) all membership units of the Company. The membership units of the Company were then distributed to the shareholders of TTP Inc. to match in kind and number the shares held by them in TTP Inc.

On March 12, 2008, TTP Inc. formed High Point Pharmaceuticals, LLC ("HPP") and transferred various intellectual property (principally consisting of certain programs) to HPP in exchange for common and preferred units as well as warrants to purchase an additional 6.7 million common units. TTP Inc. subsequently distributed these equity investments to its unit holders on a pro-rata basis, based on the unit holders' ownership in TTP Inc. HPP is primarily responsible for all preclinical and clinical development efforts, as well as maintenance of the intellectual property portfolio for all of their drug candidate programs. TTP funds the development of the programs through the periodic advancement of funds to HPP and provides research employees and facilities, for which TTP charges HPP a maintenance fee. TTP has no further obligation beyond the items described above, and TTP has no obligation to the creditors of HPP as a result of its involvement with HPP. For the years ended December 31, 2013 and 2014, HPP had no revenues, net income of \$29.7 million (primarily due to a \$50 million cancellation of debt owed to TTP which corresponded to an offsetting loss by TTP), and a net loss of \$10.8 million, respectively.

TTP and HPP are collectively referred to as "the Company."

The combined consolidated financial statements include the consolidated accounts of TTP, its wholly-owned subsidiary (prior to December 31, 2014), High Point Clinical Trials Center, LLC ("HPCTC"), and the combined accounts of HPP. All significant intercompany balances and transactions have been eliminated. Combined financial statements are presented as their components are under common ownership and management.

The Company has incurred recurring operating losses and had a consolidated total members' deficit and working capital deficiency of \$(498.8) million and \$(5.3) million, respectively, as of December 31, 2014. The Company expects to incur substantial drug development costs in the foreseeable future and does not expect to generate revenue sufficient to cover these costs. As a result, the Company will require substantial additional cash to fund its continued operations. Company management will continue to seek additional revenue generating license and collaborative agreements, research funding and/or private or public equity or debt financings to meet such needs. Even if the Company does not have an immediate need for additional cash, it may seek access to the private or public equity markets if and when conditions are favorable. Since the Company's inception, MacAndrews & Forbes Incorporated and certain affiliates (collectively, "M&F") have provided funding to the Company in the form of debt and equity in excess of \$200 million. M&F is currently providing funding for the fiscal 2015 operations of the Company, including all operating, investing and financing cash flow needs. Additionally, the Company has obtained a binding commitment from M&F to continue funding its operations at a level necessary for it to meet its financial obligations, if necessary, through at least January 1, 2016.

The accompanying combined consolidated financial statements do not include any adjustments related to the recoverability or classification of asset carrying amounts or the amounts and classification of liabilities that may result should the Company be unable to continue as a going concern.

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

**2. Summary of Significant Accounting Policies**

***Use of Estimates***

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires the Company to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

On an ongoing basis, the Company evaluates its estimates, including those related to the useful lives of property and equipment, the fair value of the Company's membership units, the fair value of redeemable preferred units, the fair value of derivative liabilities, and the fair value of the Company's debt, among others. The Company bases its estimates on historical experience and on various other assumptions that it believes to be reasonable, the results of which form the basis for making judgments about the carrying value of assets and liabilities.

***Concentration of Credit Risk***

Financial instruments that potentially expose the Company to concentrations of credit risk consist principally of cash on deposit with multiple financial institutions, the balances of which frequently exceed insured limits.

Three customers represented 85% of the accounts receivable balance at December 31, 2013 and there is no accounts receivable balance at December 31, 2014.

Four customers represented 100% of the revenue earned during the year ending December 31, 2013 and three customers represented 98% of the revenue earned during the year ending December 31, 2014.

***Cash and Cash Equivalents***

The Company considers any highly liquid investments with an original maturity of three months or less to be cash and cash equivalents.

***Restricted Cash and Cash Equivalents***

Restricted cash and cash equivalents relate to cash and cash equivalents that are pledged as collateral related to the operating lease for HPCTC.

***Investments***

The Company determines the appropriate classification of investments in marketable securities at the time of purchase and reevaluates such designation as of each balance sheet date. All marketable securities owned as of and for the years ended December 31, 2013 and 2014 were classified as trading securities and reported at their fair market value with gains and losses for fair market value adjustments recorded in the combined statements of operations. Interest and dividend income on investments, as well as realized and unrealized gains and losses, are included in interest and investment income. The cost of securities sold is based on the specific identification method. No impairment occurred during the year ended December 31, 2013. The Company recognized an impairment in its investment in marketable securities of \$30 thousand for the year ended December 31, 2014.

***Accounts Receivable***

Accounts receivable consist of amounts billed under the Company's service contracts with its customers. The Company extends credit to customers without requiring collateral. Accounts receivable are stated at net realizable value. The Company does not accrue interest on trade receivables. On a periodic basis, the Company evaluates its accounts receivable and establishes an allowance based on its history of collections and write-offs and the current status of all receivables.

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC****Notes To Combined Consolidated Financial Statements (continued)*****Property and Equipment***

The Company records property and equipment at cost less accumulated depreciation. Costs of renewals and improvements that extend the useful lives of the assets are capitalized. Maintenance and repairs are expensed as incurred. Depreciation is determined on a straight-line basis over the estimated useful lives of the assets, which generally range from three to ten years. Leasehold improvements are depreciated over the shorter of the useful life of the asset or the term of the related lease. Upon retirement or disposition of assets, the costs and related accumulated depreciation are removed from the accounts with the resulting gains or losses, if any, reflected in results of operations.

The estimated useful lives of property and equipment are as follows:

<b>Asset Category</b>	<b>Useful Life (in years)</b>
Laboratory equipment	7
Computers and hardware	3-5
Furniture and office equipment	3-7
Software	3
Leasehold improvements	Shorter of useful life or remaining term of lease

***Impairment of Long-Lived Assets***

Long-lived assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amounts of the assets may not be recoverable. When such events occur, the Company compares the carrying amounts of the assets to their undiscounted expected future cash flows. If the undiscounted cash flows are insufficient to recover the carrying values, an impairment loss is recorded for the difference between the carrying amount and fair value of the assets' group.

***Derivatives***

The Company accounts for derivatives at fair value and any changes in fair value are immediately recognized in earnings. See the Company's fair value policy and Note 13 for additional disclosures regarding the determination of fair value. The Company's derivatives were embedded in the debt instruments described in Note 8. The Double Repayment Feature (as defined in Note 8) was embedded in the Unsecured Note (as defined in Note 8) and was extinguished on August 9, 2013. The prepayment provisions of the 2013 Promissory Notes (as defined in Note 8) were deemed an embedded derivative, because the 2013 Promissory Notes were issued at a significant discount and would have been prepaid at par if a prepayment event had taken place. As of December 31, 2013, the fair value of the prepayment provisions bifurcated from the 2013 Promissory Notes was insignificant. The prepayment provisions were extinguished together with the 2013 Promissory Notes on March 28, 2014.

Changes in fair value of derivatives are presented in "Other Income (expense), net" on the Combined Consolidated Statements of Operations.

***Revenue Recognition***

The Company uses the revenue recognition guidance established by ASC Topic 605, "Revenue Recognition." The Company recognizes revenue when there is persuasive evidence of an arrangement, the service has been provided to the customer, the collection of the fee is reasonably assured and the amount of the fee to be paid by the customer is fixed or determinable. In determining the accounting for collaboration and alliance agreements, the Company follows the provisions of ASC Topic 605, Subtopic 25, "Multiple Element Arrangements" ("ASC 605-25"). ASC 605-25 provides guidance on whether an arrangement that involves multiple revenue-generating activities or deliverables should be divided into separate units of accounting for revenue recognition purposes and, if division is required, how the arrangement consideration should be allocated among the separate units of accounting. If a deliverable has value on a standalone basis,

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC****Notes To Combined Consolidated Financial Statements (continued)**

the Company treats the deliverable as a separate unit of accounting. If the arrangement constitutes separate units of accounting according to the separation criteria of ASC 605-25, the consideration received is allocated among the separate units of accounting and the applicable revenue recognition criteria must be applied to each unit. The Company determines how to allocate amounts received under agreements among the separate units based on the respective selling price of each unit. If the arrangement constitutes a single unit of accounting, the revenue recognition policy must be determined for the entire arrangement and the consideration received is recognized over the period of inception through the date the last deliverable within the single unit of accounting is expected to be delivered.

Collaboration research and development revenue is earned and recognized as research is performed and related expenses are incurred. Non-refundable upfront fees are recorded as deferred revenue and recognized into revenue as license fees and milestones from collaborations on a straight-line basis over the estimated period of the Company's substantive performance obligations. If the Company does not have substantive performance obligations, it recognizes non-refundable upfront fees into revenue through the date the deliverable is satisfied.

Revenue for non-refundable payments based on the achievement of milestone events under collaboration agreements is recognized in accordance with ASC Topic 605, Subtopic 28, "Milestone Method" ("ASC 605-28"). Milestone events under the Company's collaboration agreements may include research, development, regulatory, commercialization, or sales events. Under ASC 605-28, a milestone payment is recognized as revenue when the applicable event is achieved if the event meets the definition of a milestone and the milestone is determined to be substantive. ASC 605-28 defines a milestone event as an event having all of the following characteristics: (1) there is substantive uncertainty regarding achievement of the milestone event at the inception of the arrangement; (2) the event can only be achieved based, in whole or in part, on either the company's performance or a specific outcome resulting from the company's performance; and (3) if achieved, the event would result in additional payment due to the company. The Company also treats events that can only be achieved based, in whole or in part, on either a third party's performance or a specific outcome resulting from a third party's performance as milestone events if the criteria of ASC 605-28 are otherwise satisfied.

Research and development costs that are reimbursable under collaboration agreements are recorded in accordance with ASC Topic 605, Subtopic 45, "Principal Agent Considerations." Amounts reimbursed under a cost sharing arrangement are reflected as a reduction of research and development expense.

The Company entered into contractual arrangements with sponsors wanting to conduct a trial on a drug and recognized study revenue when (i) the identified single subject visit has been completed or (ii) in some cases, all visits required in the trial by the subject matter have been completed, consistent with the requirements of the contractual arrangements. For the years ended December 31, 2013 and 2014, substantially all of the Company's study revenues were from its wholly-owned subsidiary (prior to December 31, 2014), HPCTC.

***Fair Value of Financial Instruments***

The Company uses a three-tier fair value hierarchy to classify and disclose all assets and liabilities measured at fair value on a recurring basis, as well as assets and liabilities measured at fair value on a non-recurring basis, in periods subsequent to their initial measurement. The hierarchy requires the Company to use observable inputs when available, and to minimize the use of unobservable inputs, when determining fair value. The three tiers are defined as follows:

- Level 1—Observable inputs that reflect quoted market prices (unadjusted) for identical assets or liabilities in active markets;
- Level 2—Observable inputs other than quoted prices in active markets that are observable either directly or indirectly in the marketplace for identical or similar assets and liabilities; and
- Level 3—Unobservable inputs that are supported by little or no market data, which require the Company to develop its own assumptions.

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

***Research and Development***

Major components of research and development costs include cash compensation, depreciation expense on research and development property and equipment, costs of preclinical studies, clinical trials and related clinical manufacturing, costs of drug development, costs of materials and supplies, facilities cost, overhead costs, regulatory and compliance costs, and fees paid to consultants and other entities that conduct certain research and development activities on the Company's behalf. Costs incurred in research and development are expensed as incurred.

The Company records accruals based on estimates of the services received, efforts expended and amounts owed pursuant to contracts with numerous contract research organizations. In the normal course of business, the Company contracts with third parties to perform various clinical study activities in the ongoing development of potential products. The financial terms of these agreements are subject to negotiation and variation from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events and the completion of portions of the clinical study or similar conditions. The objective of the Company's accrual policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical studies are recognized based on the Company's estimate of the degree of completion of the event or events specified in the specific clinical study.

The Company records nonrefundable advance payments it makes for future research and development activities as prepaid expenses. Prepaid expenses are recognized as expense in the statements of operations as the Company receives the related goods or services.

***Patent Costs***

Patent costs, including related legal costs, are expensed as incurred and recorded within general and administrative operating expenses on the combined statements of operations.

***Income Taxes***

The Company is treated as a partnership for income tax purposes. Accordingly, the allocated share of taxable income or loss is includable in the income tax returns of the Company's members. The Company recognizes the effect of income tax positions only if these positions are more likely than not of being sustained. Changes in recognition or measurement are reflected in the period in which the change in judgment occurs. The Company has not recognized any uncertain tax positions and no examinations are being conducted by U.S., state, or local taxing authorities.

***Redeemable Convertible Preferred Units***

The Company initially recorded the redeemable convertible preferred units at their fair values at issuance, net of issuance costs. All of the redeemable convertible preferred units have been presented outside of permanent members' deficit as the units are redeemable at holders' option at the greater of (a) such series' liquidation value (i.e., the original cost for each unit of such series (as adjusted for any unit split, unit dividend or other similar events)) plus all declared and unpaid distributions on such series and (b) such series' fair market value (plus all declared but unpaid distributions on such series). The Company's policy is to record changes in the redemption value immediately as they occur and adjust the carrying value to equal the redemption value at each reporting period. See discussion and additional detail of the redeemable convertible preferred units at Note 11.

***Basic and Diluted Net Loss per Common Membership Unit***

The Company uses the two-class method to compute net loss per common unit because the Company has issued securities, other than common membership units, that contractually entitle the holders to participate in dividends and earnings of the Company ("participating securities"). The two-class method requires earnings for the period to be allocated between common membership units and participating

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

securities based upon their respective rights to receive distributed and undistributed earnings. Holders of each series of the Company's redeemable convertible preferred units are entitled to participate in distributions, when and if declared by the board of directors, that are made to common membership unit holders and, as a result, the redeemed convertible preferred units are considered participating securities.

***Segment and Geographic Information***

Operating segments are defined as components of an enterprise (business activity from which it earns revenue and incurs expenses) for which discrete financial information is available and is regularly reviewed by the chief operating decision maker (CODM) in deciding how to allocate resources and in assessing performance. The Company's CODM is its President and Chief Financial Officer. The Company concluded its business operates as one reportable segment.

***Recently Adopted Accounting Pronouncements***

From time to time, the Financial Accounting Standards Board (the "FASB") or other standard-setting bodies issue accounting standards that are adopted by the Company as of the specified effective date.

In April 2014, the FASB issued ASU No. 2014-08, "Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity" ("ASU 2014-08"). The amendments in this ASU change the criteria for reporting discontinued operations and enhance convergence of the FASB's and the IASB's reporting requirements for discontinued operations. Under AU 2014-08, elimination of the operations and cash flows of a disposed component from an entity's ongoing operations and the absence of significant continuing involvement in the operations of the component after disposal are no longer pre-conditions to present the component as a discontinued operation. In addition this ASU has resulted in increased disclosure for both disposal activities that do and do not qualify for discontinued operations presentation in its financial statements. ASU 2014-08 is effective for all disposals or classifications as held for sale of components of an entity that occur within annual periods beginning on or after December 15, 2014 and early adoption is permitted. The Company has elected to early adopt ASU 2014-08 as of January 1, 2014. The transfer of HPCTC during the year ending December 31, 2014 was evaluated under the requirements of ASU No. 2014-08. Management concluded that the disposal of HPCTC does not represent a strategic shift in operations and therefore is not presented as discontinued operations. See Note 3 for additional discussion of the transfer of HPCTC.

In June 2014, the FASB issued ASU 2014-12, "Compensation- Stock Compensation ('Topic 718'): Accounting for Share-Based Payments when the Terms of an Award Provide that a Performance Target Could Be Achieved After the Requisite Service Period" ("ASU 2014-12"). The amendments require that a performance target that affects vesting and that could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for annual periods and interim periods within those annual periods beginning after December 15, 2015. Earlier adoption is permitted. Entities may apply ASU 2014-12 either (a) prospectively to all awards granted or modified after the effective date or (b) retrospectively to all awards with performance targets that are outstanding as of the beginning of the earliest annual period presented in the financial statements and to all new or modified awards thereafter. If retrospective transition is adopted, the cumulative effect of applying this ASU as of the beginning of the earliest annual period presented in the financial statements should be recognized as an adjustment to the opening retained earnings balance at that date. Additionally, if retrospective transition is adopted, an entity may use hindsight in measuring and recognizing the compensation cost. The Company adopted this standard effective January 1, 2013. Early adoption did not have a material effect on the Company's financial statements.

***Recently Issued Accounting Pronouncements Not Yet Adopted***

In May 2014, the FASB issued guidance codified in ASC Topic 606, "Revenue Recognition—Revenue from Contracts with Customers," which amends the guidance in ASC 605, "Revenue Recognition," and becomes effective beginning January 1, 2017. The Company is currently evaluating the impact of the provisions of ASC 606 on its financial statements and disclosures.

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

On August 27, 2014, the FASB issued ASU No. 2014-15, "Presentation of Financial Statements – Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." The new standard provides guidance around management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern, and to provide related footnote disclosure. The new standard is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2016, with early adoption permitted. The adoption of this standard is not expected to have a material impact on the Company's financial statements.

In January 2015, the FASB issued ASU No. 2015-01, "Income Statement - Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items," which eliminates from GAAP the concept of extraordinary items. This ASU is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015, with early adoption permitted provided the guidance is applied from the beginning of the fiscal year of adoption. The Company does not expect this standard to have an impact on its combined financial statements upon adoption.

In February 2015, the FASB issued ASU No. 2015-02, "Consolidation-Amendments to the Consolidation Analysis (Topic 810)" ("ASU 2015-02"). This ASU requires reporting entities to reevaluate whether they should consolidate certain legal entities under the revised consolidation model. This standard modifies the evaluation of whether limited partnerships and similar legal entities are variable interest entities (VIEs), eliminates the presumption that a general partner should consolidate a limited partnership, and affects the consolidation analysis of reporting entities that are involved with VIEs, especially those that have fee arrangements and related party relationships. This ASU is effective for fiscal years beginning after December 15, 2015, and for interim periods within those fiscal years. The Company is in process of assessing the impact of the adoption of ASU 2015-02 on its combined consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, "Interest—Imputation of Interest (Subtopic 835-30): Simplifying the Presentation of Debt Issuance Costs," ("ASU 2015-03") The update requires debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability instead of being presented as an asset. Debt disclosures will include the face amount of the debt liability and the effective interest rate. The update requires retrospective application and represents a change in accounting principle. The update is effective for fiscal years beginning after December 15, 2015. Early adoption is permitted for financial statements that have not been previously issued. The Company is in the process of assessing the impact of the adoption of ASU 2015-03 on its combined consolidated financial statements.

**3. Repurchase of Former Officer's Interest**

On March 28, 2014, the Company entered into a reaffirmation and pledge agreement ("Pledge Agreement") with a former officer and director (the "Former Officer") of the Company. Pursuant to the Pledge Agreement, the Former Officer granted a security interest to the Company in 18,730,276 Series F convertible preferred units of TTP and 9,363,128 Series B convertible preferred units of HPP owned by the Former Officer (the "Pledged Units") to secure the Former Officer's obligations to the Company under a promissory note (the "2007 Note") issued by the Former Officer to the Company. The 2007 Note matures on the earlier of March 30, 2018 or the date on which the Former Officer receives in excess of \$10 million in proceeds from the sale of any shares of capital stock of the Company, PharmaCore, Inc. or any of their subsidiaries. See further discussion of transactions with PharmaCore in Note 14. Interest accrues on the 2007 Note at a rate per annum equal to the lowest rate necessary to meet the Internal Revenue Code requirements for the applicable federal rate and is payable at maturity of the 2007 Note. As of December 31, 2014, the 2007 Note had an aggregate outstanding principal amount of \$4.8 million and \$1.8 million of accrued and unpaid interest. As of December 31, 2013, the 2007 Note had an aggregate outstanding principal amount of \$4.8 million and \$1.6 million of accrued and unpaid interest.

On December 30, 2014, the Company's board of directors authorized a repurchase of units from the Former Officer and entities related to the Former Officer. The terms of the unit repurchase are stipulated in

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

a Letter Agreement (the "Agreement") with the Former Officer and such entities related to him. The Agreement stipulated that the Company would repurchase all of the issued and outstanding units of the Former Officer and his related entities in the Company, including any warrants and options to purchase common units. These included 9,100,001 common units of TTP, 14,462,213 common units of HPP, 108,781,071 Series B convertible preferred units of HPP, 218,818,574 Series F convertible preferred units of TTP, 2,776,522 warrants for common units of TTP, 750,000 warrants for common units of HPP and 58,750 options for common units of HPP (the "Repurchased Units"). All units repurchased by the Company were legally retired and resume the status of authorized and unissued common and preferred units.

In exchange for the Repurchased Units, under the Agreement, the Company agreed to make periodic cash payments totaling \$7.5 million between December 30, 2014 and September 30, 2017. Payments consist of \$2.5 million paid at closing of the agreement on December 30, 2014 and \$5.0 million to be paid in eight equal quarterly installments beginning December 31, 2015. This is recorded in other liabilities in the combined consolidated balance sheet. The Company also transferred 100% of its ownership interests in HPCTC to the Former Officer and agreed to pay to the Former Officer a distribution payable. The distribution payable amounts are payments to the Former Officer in the form of cash or certain securities upon the occurrence of certain operational or transactional events and milestones. This is recorded at fair value on the combined consolidated balance sheet as fair value of contingent distribution as of December 31, 2014. These amounts, if any, payable to the Former Officer are capped at \$150 million in the aggregate and expire upon the occurrence of specified termination events. The Agreement superseded all prior understandings with respect to any sales or other similar transactions relating to the Company.

In addition, the Company exchanged the Pledged Units into TTP Perpetual Securities in the principal amount of approximately \$6.0 million and HPP Perpetual Securities in the principal amount of approximately \$0.5 million (the "Perpetual Securities"). All Pledged Units exchanged by the Company were legally retired and resumed the status of authorized and unissued preferred units. The Perpetual Securities remain subject to the Pledge Agreement, have no fixed maturity date and accrue interest at a rate per annum equal to the 2007 Note. The Perpetual Securities may be prepaid without penalty in whole or in part at any time. Prepayments shall first be applied to accrued interest and then to principal. The Perpetual Securities are reflected as a note payable on the Combined Balance Sheet as of December 31, 2014.

In conjunction with the issuance of the Perpetual Securities, the Company gave the Former Officer an irrevocable right to sell back to the Company all of the Perpetual Securities. This right is exercisable at the discretion of the Former Officer. The exercise price of the put feature for all of the Perpetual Securities is the amount then outstanding on the 2007 Note. The Former Officer also gave the Company an irrevocable right to repurchase all of the Perpetual Securities. This right is exercisable at the earlier to occur of: (1) the maturity of the 2007 Note or (2) the date the Former Officer receives distribution payable payments under the Agreement in excess of \$30 million. The exercise price of the call feature for all of the Perpetual Securities is the amount then outstanding on the 2007 Note. The Company, at its sole discretion, may elect to pay the exercise price in cash or via the extinguishment of the 2007 Note.



**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

**4. Prepaid Expenses and Other Current Assets**

Prepaid expenses and other current assets consist of the following (in thousands):

	December 31,	
	2013	2014
Prepaid insurance	\$ 23	\$ 16
Prepaid service contracts	19	26
Prepaid software license	112	24
Prepaid - other	29	31
Deferred financing costs	738	—
<b>Total</b>	<b>\$ 921</b>	<b>\$ 97</b>

**5. Property and Equipment**

Property and equipment consists of the following (in thousands):

	December 31,	
	2013	2014
Land	\$ 3,277	\$ 2,789
Laboratory equipment	7,844	7,654
Leasehold improvements	4,480	2,231
Computers and hardware	1,094	1,079
Software	1,372	1,352
Furniture and office equipment	1,546	509
Other	448	—
Total property and equipment	20,061	15,614
Less: accumulated depreciation and amortization	(14,275)	(11,836)
Property and equipment, net	<u>\$ 5,786</u>	<u>\$ 3,778</u>

During the year ended December 31, 2014, the Company recognized an impairment loss on land of \$0.5 million. The impairment loss is reflected in other income (expense), net on the combined consolidated statements of operations.

The Company leases various equipment under capital lease agreements. The assets under capital leases are included in property and equipment as follows (in thousands):

	December 31,	
	2013	2014
Computers and hardware	\$ 9	\$ 26
Less: accumulated depreciation and amortization	(3)	(8)
	<u>\$ 6</u>	<u>\$ 18</u>

Depreciation expense, including amounts pertaining to assets held under capital leases, was \$1.1 million and \$0.9 million for the years ended December 31, 2013 and 2014, respectively.

**6. Note Receivable**

On March 30, 2007, the Company entered into the 2007 Note with the Former Officer, pursuant to which the Company loaned \$4.8 million to the Former Officer. Interest accrues on the 2007 Note at a rate per annum equal to the lowest rate necessary to meet the Internal Revenue Code requirements for the applicable federal rate and is payable at maturity of the 2007 Note. Under the original terms of the 2007 Note, the entire principal balance and any accrued but unpaid interest became due on the earlier of March 30, 2017 or the date on which the Former Officer received in excess of \$10 million in proceeds from

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

the sale of any shares of capital stock of the Company, PharmaCore, Inc. or any of their subsidiaries. See Note 14 for additional discussion of PharmaCore, Inc. As of December 31, 2014, the 2007 Note had an aggregate outstanding principal amount of \$4.8 million and \$1.8 million of accrued and unpaid interest.

On March 28, 2014, the Company entered into the Pledge Agreement with the Former Officer. Pursuant to the Pledge Agreement, the Former Officer granted a security interest to the Company in the Pledged Units to secure the Former Officer's obligations to the Company under the 2007 Note and under the Pledge Agreement. The Pledge Agreement also amended the maturity date of the 2007 Note to be the earlier of March 30, 2018 or the date on which the Former Officer receives in excess of \$10 million in proceeds from the sale of any units of the Company, HPP, PharmaCore, Inc. or any of their subsidiaries or from the sale of any assets of any of the foregoing.

As discussed in Note 3, on December 30, 2014, the Company exchanged the Pledged Units into the Perpetual Securities. The Perpetual Securities remain subject to the Pledge Agreement, have no fixed maturity date and accrue interest at a rate per annum equal to the 2007 Note. The Perpetual Securities may be prepaid without penalty in whole or in part at any time. Prepayments shall first be applied to accrued interest and then to principal. The Perpetual Securities have been recorded at their initial fair value of \$6.6 million.

**7. Accounts Payable and Accrued Expenses**

Accounts payable and accrued expenses consist of the following (in thousands):

	December 31,	
	2013	2014
Accounts payable	\$ 4,555	\$ 2,042
Accrued development costs	229	198
Accrued property taxes	137	—
Accrued payroll related costs	407	9
Accrued other	198	830
<b>Total</b>	<b>\$ 5,526</b>	<b>\$ 3,079</b>

Accounts payable and accrued expenses – related party consist of the following (in thousands):

	December 31,	
	2013	2014
Accounts payable – related party	\$ 280	\$ 618
Accrued interest – related party	872	1,134
<b>Total</b>	<b>\$ 1,152</b>	<b>\$ 1,752</b>

**8. Debt Obligations**

Debt due to related party consists of the following (in thousands):

	December 31,	
	2013	2014
Uncommitted Advance Agreement	\$ 2,002	\$ 27,310
2013 promissory notes, net	78,756	—
<b>Total</b>	<b>\$ 80,758</b>	<b>\$ 27,310</b>

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

Debt consists of the following (in thousands):

	December 31,	
	2013	2014
Promissory note on land – current	\$ 148	\$ 155
Promissory note on land – long term	2,265	2,110
<b>Total</b>	<b>\$ 2,413</b>	<b>\$ 2,265</b>

In June 2008, the Company entered into a promissory note with a financial institution secured by a deed of trust on land the Company purchased in 2008. The Company borrowed \$2.8 million at an interest rate of 6.5% per annum. The note principal was to be repaid in one installment on June 20, 2011, with interest payments made monthly during the term of the note. On May 9, 2011, the Company entered into a Debt Modification Agreement to amend the terms of the promissory note, whereby it extended the maturity date to May 20, 2016 and changed the annual interest rate to the prime rate plus 1.250%, with a maximum interest rate of 6.750% and minimum rate of 4.750%. The note is to be repaid in 60 monthly payments of principal and interest, including 59 payments of approximately \$22 thousand and a final payment of the entire unpaid balance of principal and interest.

During 2011, the Company entered into three unsecured promissory notes with MacAndrews & Forbes Holdings Inc., a related party. The annual interest rate was LIBOR plus 2%. Principal and interest were due between December 2011 and December 2012 and on any date on which the Company received any proceeds from (1) the sale of any shares of capital stock or membership units of, (2) any sale of assets of, or (3) a license or collaboration involving the assets of, the Company, HPP, PharmaCore, Inc. or any of their respective subsidiaries or affiliates.

On June 1, 2012, the Company refinanced the three unsecured promissory notes with MacAndrews & Forbes Holdings Inc. with a new unsecured promissory note (the "Unsecured Note") with MacAndrews & Forbes Group LLC, also a related party, that bore interest at an annual rate of LIBOR plus 2%. This new promissory note provided that the outstanding balance plus accrued and unpaid interest was due on January 2, 2013, or earlier upon the occurrence of a "prepayment event." A prepayment event was deemed to have occurred on such date as any of the holders of equity interests in TTP and HPP received proceeds (in the form of cash or securities) of a sale transaction, as defined in the Unsecured Note.

Upon the occurrence of a prepayment event, the Company was required to repay MacAndrews & Forbes Group, LLC an amount equal to two times the amounts advanced under the Unsecured Note, less an amount equal to the amounts advanced less the current balance (if any), plus paid interest (if any) in the event that there was no prepayment event prior to the date of maturity, and at any time on or after the date of maturity but prior to May 2022, if the holders of equity interests in TTP and HPP received proceeds (in the form of cash or securities) pursuant to a sale transaction, as defined in the Unsecured Note, TTP and HPP, jointly and severally, were required to repay an amount equal to two times the amounts advanced, less an amount equal to the amounts advanced, less the current balance (if any), plus unpaid interest (if any) (collectively, the "Double Repayment Feature").

The Company determined that the Double Repayment Feature was an embedded derivative and recognized the fair value of this derivative as a liability on the balance sheet, with subsequent changes to fair value recorded through earnings at each reporting period on the statement of operations as change in fair value of derivative liabilities. The change in fair value of the derivative liabilities of \$0.2 million is reflected as a component of other income (expense), net on the combined consolidated statement of operations for the year ended December 31, 2013. The fair value of this embedded derivative was determined by valuing the hybrid instrument with and without the embedded feature using a probability-weighted expected return model.

On August 9, 2013, TTP, jointly and severally with HPP, refinanced the Unsecured Note with new promissory notes (the "2013 Promissory Notes"), redeemable preferred stock of the Company, and redeemable preferred units of HPP, pursuant to a Note and Equity Issuance Agreement (the "Note and Equity Issuance Agreement"). MacAndrews and Forbes Group, LLC, the lender of the Unsecured

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

Note, consented to an extinguishment of the Double Repayment Feature without payments additional to the principal and interest on the Unsecured Note. The 2013 Promissory Notes had an original principal amount of \$94.1 million and bore interest at an annual rate of LIBOR plus 2%. The 2013 Promissory Notes provided that the outstanding balance plus accrued and unpaid interest was due on December 31, 2014 or earlier upon the occurrence of "prepayment events". The 2013 Promissory Notes were secured by substantially all assets of the TTP, HPP and HPCTC. Prepayment events were defined as any of the following: (a) sale or license of any asset, business, product candidates, technologies, compounds, or similar property; (b) issuance or incurrence of any indebtedness (other than intercompany indebtedness); or (c) issuance of equity interests, other than employee options approved by the board of directors. Upon the occurrence of a prepayment event, the Company was required to repay amounts outstanding under the Note and Equity Issuance Agreement with the proceeds of prepayment events that exceeded \$25 million in the aggregate.

On December 24, 2013, TTP amended the Note and Equity Issuance Agreement to provide for additional advances to the Company that could be made at the option of M&F TTP Holdings LLC, a related party. The additional advances were also secured by substantially all assets of the Company, TTP and HPTC and bore interest at an annual rate of LIBOR plus 10%. The additional advances were subject to the same prepayment provisions as the advances made under the initial Note and Equity Issuance Agreement.

On March 28, 2014, the Company and M&F TTP Holdings LLC agreed to exchange all \$116.2 million of outstanding principal and interest under the Note and Equity Issuance Agreement (including amounts advanced under the initial agreement and the 2013 Promissory Notes and amounts advanced following the December 24, 2013 amendment) for 292,722,844 Series F redeemable convertible preferred units of the Company and 155,219,376 Series B redeemable convertible preferred units of HPP. Concurrently on March 28, 2014, the Company entered into an Uncommitted Advance Agreement with M&F TTP Holdings LLC and the Former Officer. There is no minimum or maximum amount for any advance. Advances made under the Uncommitted Advance Agreement bear interest at an annual rate of LIBOR plus 10%. Principal and interest were originally payable on demand and on May 4, 2015, M&F TTP Holdings LLC agreed to extend the maturity date of the Uncommitted Advance Agreement to January 15, 2016. See Note 18. Prepayments can be made under the Uncommitted Advance Agreement without penalty. As of December 31, 2013 and 2014, \$2.0 million and \$27.3 million of principal was outstanding under the Uncommitted Advance Agreement, respectively.

Based upon the Company's borrowings under the debt agreements as of December 31, 2014, the future principal payments are as follows (in thousands):

Year Ending December 31,	
2015	\$ 155
2016	29,420
<b>Total</b>	<b>\$ 29,575</b>

**9. Other Liabilities**

Other liabilities-current consist of the following (in thousands):

	December 31,	
	2013	2014
Distribution payable	\$ —	\$ 625
Other liabilities	—	1,253
<b>Total</b>	<b>\$ —</b>	<b>\$ 1,878</b>

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

Other liabilities, net of current portion consist of the following (in thousands):

	December 31,	
	2013	2014
Distribution payable, net of current portion	\$ —	\$ 4,273
Other liabilities, net of current portion	18	161
<b>Total</b>	<b>\$ 18</b>	<b>\$ 4,434</b>

**10. Commitments and Contingencies**

**Legal Matters**

From time to time, the Company is involved in various legal proceedings arising in the normal course of business. For some matters, a liability is not probable or the amount cannot be reasonably estimated and therefore an accrual has not been made. However, for such matters when it is probable that the Company has incurred a liability and can reasonably estimate the amount, the Company accrues and discloses such estimates.

**Lease Agreements**

The Company leases various equipment and facilities under operating and capital leases expiring at various dates through 2019. The capital leases are financed through various financial institutions and are collateralized by the underlying assets. As of December 31, 2014, the average interest rate for assets under capital leases was 15.3%.

Rent expense for non-cancelable operating leases was \$1.1 million and \$1.0 million for the years ended December 31, 2013 and 2014, respectively.

Future minimum lease payments under capital leases and non-cancelable operating leases as of December 31, 2014 were as follows (in thousands):

Year Ending December 31,	Capital Leases	Operating Leases
2015	\$ 5	\$ 793
2016	4	787
2017	4	765
2018	4	308
2019	1	—
Total minimum lease payments	18	\$ 2,653
Less: amounts representing interest	(3)	
<b>Total</b>	<b>\$ 15</b>	

TransTech Pharma, LLC and High Point Pharmaceuticals, LLC

Notes To Combined Consolidated Financial Statements (continued)

11. Redeemable Convertible Preferred Units and Warrants

**Authorized, Issued, and Outstanding Redeemable Convertible Preferred Units**

As of December 31, 2013, TTP was authorized to issue 1,123,128,987 preferred units in the aggregate. The following table summarizes authorized, issued and outstanding redeemable convertible preferred units as of December 31, 2013. The preferred units are carried at the greater of the original cost, liquidation preference, or fair value as indicated in the table below (in thousands except per member unit data):

	Member Units		Original Cost	Liquidation Preference	Fair Value	Carrying Value
	Authorized	Outstanding				
Series A Preferred	8,571,337	8,571,337	\$ 2,545	\$ 2,545	\$ 47	\$ 2,545
Series B Preferred	2,547,593	2,547,593	3,500	3,500	50	3,500
Series C Preferred	2,343,922	2,243,922	5,514	5,514	121	5,514
Series D Preferred	2,442,361	2,442,361	9,556	9,556	135	9,556
Series E Preferred	32,789,595	32,789,595	86,700	86,700	1,225	86,700
Series F Preferred	1,074,434,179	1,072,004,541	14,759	107,200	13,098	107,200
<b>Total</b>	<b>1,123,128,987</b>	<b>1,120,599,349</b>	<b>\$ 122,574</b>	<b>\$ 215,015</b>	<b>\$ 14,676</b>	<b>\$ 215,015</b>

As of December 31, 2013, HPP was authorized to issue 598,666,107 preferred units in the aggregate. The following table summarizes authorized, issued and outstanding redeemable convertible preferred units as of December 31, 2013. The preferred units are carried at the greater of the original cost, liquidation preference, or fair value as indicated in the table below (in thousands except per member unit data):

	Member Units		Original Cost	Liquidation Preference	Fair Value	Carrying Value
	Authorized	Outstanding				
Series A Preferred	49,766,563	49,766,563	\$ 1,194	\$ 1,194	\$ —	\$ 1,194
Series B Preferred	548,899,544	548,366,932	13,161	13,161	—	13,161
<b>Total</b>	<b>598,666,107</b>	<b>598,133,495</b>	<b>\$ 14,355</b>	<b>\$ 14,355</b>	<b>\$ —</b>	<b>\$ 14,355</b>

As of December 31, 2014, TTP was authorized to issue 1,415,851,831 preferred units in the aggregate. The following table summarizes authorized, issued and outstanding redeemable convertible preferred units as of December 31, 2014. The preferred units are carried at the greater of the original cost, liquidation preference, or fair value as indicated in the table below (in thousands except per member unit data):

	Member Units		Original Cost	Liquidation Preference	Fair Value	Carrying Value
	Authorized	Outstanding				
Series A Preferred	8,571,337	8,571,337	\$ 2,545	\$ 2,545	\$ 2,847	\$ 2,847
Series B Preferred	2,547,593	2,547,593	3,500	3,500	3,132	3,500
Series C Preferred	2,343,922	2,243,922	5,514	5,514	7,781	7,781
Series D Preferred	2,442,361	2,442,361	9,556	9,556	8,547	9,556
Series E Preferred	32,789,595	32,789,595	86,700	86,700	77,546	86,700
Series F Preferred	1,367,157,023	1,145,947,422	64,476	114,595	312,232	312,232
<b>Total</b>	<b>1,415,851,831</b>	<b>1,194,542,230</b>	<b>\$ 172,291</b>	<b>\$ 222,410</b>	<b>\$ 412,085</b>	<b>\$ 422,616</b>

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

As of December 31, 2014, HPP was authorized to issue 753,885,484 preferred units in the aggregate. The following table summarizes authorized, issued and outstanding redeemable convertible preferred units as of December 31, 2014. The preferred units are carried at the greater of the original cost, liquidation preference, or fair value as indicated in the table below (in thousands except per member unit data):

	Member Units		Original Cost	Liquidation Preference	Fair Value	Carrying Value
	Authorized	Outstanding				
Series A Preferred	49,766,563	49,766,563	\$ 1,194	\$ 1,194	\$ —	\$ 1,194
Series B Preferred	704,118,921	594,834,833	14,276	14,276	—	14,276
<b>Total</b>	<b>753,885,484</b>	<b>644,601,396</b>	<b>\$ 15,470</b>	<b>\$ 15,470</b>	<b>\$ —</b>	<b>\$ 15,470</b>

**Preferred Units Activity**

The following table summarizes TTP redeemable convertible preferred units' activity for the years ended December 31, 2013 and 2014:

	Units of						Total
	Series A Preferred	Series B Preferred	Series C Preferred	Series D Preferred	Series E Preferred	Series F Preferred	
Balance, January 1, 2013 (1)	8,571,337	2,547,593	2,243,922	2,442,361	32,789,595	—	48,594,808
Issuance of Series F Preferred	—	—	—	—	—	1,072,004,541	1,072,004,541
Balance, December 31, 2013	8,571,337	2,547,593	2,243,922	2,442,361	32,789,595	1,072,004,541	1,120,599,349
Issuance of Series F Preferred	—	—	—	—	—	292,761,455	292,761,455
Repurchase of Series F Preferred	—	—	—	—	—	(218,818,574)	(218,818,574)
Balance, December 31, 2014	<u>8,571,337</u>	<u>2,547,593</u>	<u>2,243,922</u>	<u>2,442,361</u>	<u>32,789,595</u>	<u>1,145,947,422</u>	<u>1,194,542,230</u>

(1) Represents Preferred Shares in TTP, Inc. as of January 1, 2013. In November 2013, in connection with the contribution of all TTP Inc.'s assets to TTP, membership units in TTP were distributed to holders of TTP Inc.'s Preferred Shares on a one to one basis.

The following table summarizes HPP redeemable convertible preferred units activity for the years ended December 31, 2013 and 2014.

	HPP Units		
	Series A Preferred	Series B Preferred	Total
Balance, January 1, 2013	49,766,563	—	49,766,563
Issuance of Series B Preferred	—	548,366,932	548,366,932
Balance, December 31, 2013	49,766,563	548,366,932	598,133,495
Issuance of Series B Preferred	—	155,248,972	155,248,972
Repurchase of Series B Preferred	—	(108,781,071)	(108,781,071)
Balance, December 31, 2014	<u>49,766,563</u>	<u>594,834,833</u>	<u>644,601,396</u>

**Conversion Rights**

Each TTP Series A, Series B, Series C, Series D, Series E and Series F preferred unit (collectively, the "TTP Series Preferred") is convertible, at the option of the holder, into common units of TTP based on the total consideration received by TTP for each series of the preferred units (plus declared and unpaid

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

distributions) divided by the conversion price. Initially the conversion prices were \$0.296973, \$1.37385, \$2.457293, \$3.91268996, \$2.64413153 and \$0.10 per common unit for the Series A, Series B, Series C, Series D, Series E and Series F preferred units, respectively. The conversion prices are subject to adjustment for stock splits, stock dividends, combinations or any other similar event.

Subsequently, pursuant to the adjustment formulae, the Series A conversion price was not adjusted and remained at \$0.296973 per common unit, the Series B conversion price was not adjusted and remained at \$1.37385 per common unit, the Series C conversion price was adjusted to \$0.203979 per common unit, the Series D conversion price was adjusted to \$2.644131 per common unit, the Series E conversion price was not adjusted and remained at \$2.64413153 per common unit, and the Series F conversion price was not adjusted and remained at \$0.10 per common unit. The foregoing conversion prices were in effect as of December 31, 2014.

Each HPP Series A and B preferred unit is convertible, at the option of the holder, into HPP common units based on the total consideration received by HPP for each series of the preferred units (plus declared and unpaid distributions) divided by the conversion price. Initially the conversion prices were \$0.024 and \$0.024 per common unit for the Series A and Series B preferred units, respectively.

Each series of preferred units also contains a provision whereby the units shall automatically convert into common units based on the then-effective conversion price upon the occurrence of the closing of a qualified public offering pursuant to an effective registration statement under the Securities Act of 1933.

***Rights to Distributions Prior to Termination of the Company***

Holders of preferred units are entitled to receive distributions of cash or other property prior to termination of the Company when and if declared by the Board of Directors. Such distributions are made to members of the Company on a pro rata basis (and with respect to preferred units, on an as-converted basis). Holders of preferred units are entitled to share in any distribution made upon the common units.

***Voting Rights***

Each holder of TTP and HPP Series Preferred is entitled to vote on all matters on which the holders of common units are entitled to vote, based on the number of common units into which their TTP and HPP Series Preferred units are convertible, respectively. In addition, holders of preferred units are entitled to a separate class vote on certain extraordinary matters.

***Liquidation***

Liquidation is deemed to occur in the event of any liquidation, dissolution or winding up of TTP, whether voluntary or involuntary, as well as (if determined by the Board) any change of control of the Company that includes (i) an acquisition of the Company in which the unit holders of the Company immediately prior to such transaction do not own a majority of the outstanding voting securities of the acquiring entity immediately following such transaction and (ii) a sale of all or substantially all of the assets of the Company.

In the event of any liquidation, dissolution or winding up of TTP, the holders of the TTP Series F units are entitled to receive, prior to the distribution to the other holders, a liquidation amount equal to the TTP Series F consideration paid per unit (\$0.10) plus all declared but unpaid distributions thereon. Thereafter, the holders of all other series of TTP Series Preferred are entitled to receive, prior to distribution to the holders of common units, a liquidation amount equal to the consideration paid per unit (\$0.296973, \$1.37385, \$2.457293, \$3.91268996, \$2.64413153, \$0.024 and \$0.024 for the TTP Series A, TTP Series B, TTP Series C, TTP Series D, TTP Series E, HPP Series A and HPP Series B units, respectively), plus all declared but unpaid distributions thereon.

***Redemption***

Beginning January 1, 2015, the holders of a majority of the outstanding TTP Series F preferred units may demand that TTP redeem up to all of the outstanding TTP Series F preferred units. Beginning January



**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

8, 2015, the holders of a majority of the outstanding TTP Series A preferred units and/or a majority of the outstanding TTP Series B preferred units and/or a majority of the outstanding TTP Series C preferred units may demand that TTP redeem up to all of the outstanding units of each respective series of preferred units. Beginning on November 26, 2015, the holders of a majority of the outstanding shares of TTP Series E preferred units may demand that TTP redeem up to all of the outstanding units of such series of preferred units. Beginning on May 20, 2017, the holders of a majority of the outstanding shares of TTP Series D preferred units may demand that TTP redeem up to all of the outstanding units of such series. The redemption price per unit for each such series is the greater of (a) such series' liquidation value (i.e., the original cost for each unit of such series (as adjusted for any unit split, unit dividend or other similar events) plus all declared and unpaid distributions on such series and (b) such series' fair market value (plus all declared but unpaid distributions on such series).

The redemptions of TTP Series Preferred can only be made out of funds legally available for that purpose (which determination would require the TTP board of directors to consider whether, following such redemption, TTP would be able to continue as a going concern). If TTP has insufficient funds legally available to redeem all TTP Series Preferred required to be redeemed on the mandatory redemption date, those funds legally available for such purpose shall be first used to ratably redeem the maximum number of any Series F preferred units that have properly demanded that TTP redeem such units in accordance with the TTP operating agreement before the units of any other series of TTP Series Preferred are redeemed. As of December 31, 2014 there were no funds legally available for redemption.

Beginning January 1, 2015, the holders of a majority of the outstanding HPP Series B preferred units may demand that HPP redeem up to all of the outstanding units of such series. Beginning April 11, 2015, the holders of a majority of the outstanding HPP Series A preferred units may demand that HPP redeem up to all of the outstanding units of such series. The redemption price per unit for each such series is the greater of (a) such series' liquidation value (i.e., the invested amount for each unit of such series (as adjusted for any unit split, unit dividend or similar events)) and (b) such series' fair market value.

The redemptions of HPP preferred units can only be redeemed out of funds legally available for that purpose (which determination would require the HPP board of directors to consider whether, following such redemption, TTP would be able to continue as a going concern). If HPP has insufficient funds legally available to redeem all of the HPP Series A and Series B units required to be redeemed on the mandatory redemption date, those funds legally available for such purpose shall be first used to ratably redeem the maximum number of any HPP Series B preferred units that have properly demanded that HPP redeem such units in accordance with the HPP operating agreement before the HPP Series A preferred units are redeemed. As of December 31, 2014, there were no funds legally available for redemption.

**Registration Rights Agreement**

Preferred unit holders have certain preferential rights in connection with public offerings and sales of common units.

**Repurchase of Preferred Units**

On December 30, 2014, the Company's board of directors authorized the repurchase of the issued and outstanding preferred units held by the Former Officer and certain entities related to him pursuant to the Agreement. The following table summarizes the repurchase of the redeemable convertible preferred units from the Former Officer and certain entities related to him.

	Series F Preferred	Series B Preferred
TTP	218,818,574	—
HPP	—	108,781,071
	<u>218,818,574</u>	<u>108,781,071</u>

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

See Note 3 for further discussion of the repurchase of the Former Officer's interest.

**12. Common Member Units**

***Authorized, Issued, and Outstanding Common Membership Units***

TTP's common units consist of one class, with no par value, 1,220,000,000 and 1,512,722,844 units authorized, and 13,288,608 and 4,188,607 units issued and outstanding at December 31, 2013 and 2014. At December 31, 2014, the Company had reserved common membership units for future issuance as follows:

	<b>TTP Common Units Reserved</b>
Conversion of TTP Series A Preferred	8,571,337
Conversion of TTP Series B Preferred	2,547,593
Conversion of TTP Series C Preferred	2,243,922
Conversion of TTP Series D Preferred	2,442,361
Conversion of TTP Series E Preferred	32,789,595
Conversion of TTP Series F Preferred	1,145,947,422
Outstanding TTP warrants on common units	991,337
Total common units reserved for future issuance	<u>1,195,533,567</u>

HPP's common units consist of one class, with no par value, 650,000,000 and 805,219,377 units authorized, and 19,609,698 and 5,148,485 units issued and outstanding at December 31, 2013 and 2014. At December 31, 2014, the Company had reserved common membership units for future issuance as follows:

	<b>HPP Common Units Reserved</b>
Conversion of HPP Series A Preferred	49,766,563
Conversion of HPP Series B Preferred	594,834,833
Outstanding HPP warrants on common units	917,587
Options for HPP common units	564,937
Total HPP common shares reserved for future issuance	<u>646,083,920</u>

As of December 31, 2014, HPP had 564,937 options outstanding with a strike price of \$0.024 expiring at various dates in 2018. As of December 31, 2014 the fair value of the options was \$0.

***Liquidation Rights***

In the event of any liquidation or dissolution of the Company, the holders of the common units are entitled to share ratably with holders of the TTP and HPP Series Preferred, on an as-if-converted to common units basis, in the remaining assets of the Company legally available for distribution after the payment of the full liquidation preference for all Series Preferred.

***Distributions Prior to Termination of the Company and Voting Rights***

The holders of the common units are entitled to receive distributions of cash or other property prior to termination of the Company when and if declared by the Board of Directors. Such distributions are made to members of the Company on a pro rata basis.

The holders of the common units have the right to one vote per unit.

TransTech Pharma, LLC and High Point Pharmaceuticals, LLC

Notes To Combined Consolidated Financial Statements (continued)

**Warrants on Common Units**

TTP's outstanding warrants and related exercise price were as follows for the years ending December 31, 2013 and 2014, respectively:

	Warrants	Weighted-Average Exercise Price Per Unit
<b>Outstanding balance at January 1, 2013</b>	6,546,011	\$ 2.74
Granted	—	—
Exercised	—	—
Cancelled	—	—
<b>Outstanding balance at December 31, 2013</b>	<u>6,546,011</u>	<u>\$ 2.74</u>
Granted	—	\$ —
Exercised	—	—
Cancelled	(2,778,152)	2.67
Repurchased	(2,776,522)	2.74
<b>Outstanding balance at December 31, 2014</b>	<u>991,337</u>	<u>\$ 2.94</u>

The following table summarizes information about the outstanding TTP warrants as of December 31, 2014:

Exercise Price	Expiration Date	Warrants Outstanding	Warrants Exercisable
\$2.64	1/1/2015	13,875	13,875
\$2.64	1/1/2016	25,000	25,000
\$2.64	11/22/2016	90,000	90,000
\$2.64	12/31/2016	24,962	24,962
\$3.00	8/27/2017	30,000	30,000
\$3.00	12/17/2017	800,000	800,000
\$3.00	1/1/2018	7,500	7,500
		<u>991,337</u>	<u>991,337</u>

HPP's outstanding warrants and related exercise price were as follows for the years ending December 31, 2013 and 2014, respectively:

	Warrants	Weighted-Average Exercise Price Per Unit
<b>Outstanding balance at January 1, 2013</b>	1,742,117	\$ 0.02
Granted	—	—
Exercised	—	—
Cancelled	—	—
<b>Outstanding balance at December 31, 2013</b>	<u>1,742,117</u>	<u>\$ 0.02</u>
Granted	—	\$ —
Exercised	—	—
Cancelled	(74,530)	0.03
Repurchased	(750,000)	0.02
<b>Outstanding balance at December 31, 2014</b>	<u>917,587</u>	<u>\$ 0.02</u>

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

The following table summarizes information about the outstanding HPP warrants as of December 31, 2014:

Exercise Price	Expiration Date	Warrants Outstanding	Warrants Exercisable
\$0.02	1/1/2015	13,875	13,875
\$0.02	1/1/2016	25,000	25,000
\$0.02	11/22/2016	26,250	26,250
\$0.02	12/31/2016	24,962	24,962
\$0.02	12/17/2017	800,000	800,000
\$0.02	4/11/2018	15,000	15,000
\$0.02	5/15/2019	12,500	12,500
		<u>917,587</u>	<u>917,587</u>

**Repurchase of Common Units, Warrants for Common Units, and Stock Options for Common Units**

On December 30, 2014, the Company's Board of Directors authorized the repurchase of all of the issued and outstanding common units held by the Former Officer and certain entities related to him, including all warrants and options for common units. The following table summarizes such repurchase:

	Common Units	Warrants for Common Units	Stock Options for Common Units	Total
TTP	9,100,001	2,776,522	—	11,876,523
HPP	14,462,213	750,000	58,750	15,270,963
	<u>23,562,214</u>	<u>3,526,522</u>	<u>58,750</u>	<u>27,147,486</u>

See Note 3 for additional discussion of the repurchase of the Former Officer's interest.

**13. Fair Value of Financial Instruments**

The carrying amount of certain of the Company's financial instruments, including cash and cash equivalents, net accounts receivable, accounts payable and other accrued liabilities, approximate fair value due to their short-term nature.

**Assets and Liabilities Measured at Fair Value on a Recurring Basis**

The Company evaluates its financial assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level in which to classify them for each reporting period. This determination requires significant judgments to be made. The following table summarizes the conclusions reached regarding fair value measurements as of December 31, 2013 and 2014:

	Balance at December 31, 2013	Quoted Prices in Active Markets for Identical Assets	Significant Other Observable Inputs	Significant Unobservable Inputs
Marketable securities <sup>(e)</sup>	\$ 69	\$ 69	\$ —	\$ —
TTP redeemable preferred securities <sup>(a)</sup>	14,676	—	—	14,676
HPP redeemable preferred securities <sup>(a)</sup>	—	—	—	—
Debt <sup>(b)</sup>	76,785	—	76,785	—
	<u>\$ 91,530</u>	<u>\$ 69</u>	<u>\$ 76,785</u>	<u>\$ 14,676</u>

TransTech Pharma, LLC and High Point Pharmaceuticals, LLC

Notes To Combined Consolidated Financial Statements (continued)

	Balance at December 31, 2014	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
TTP Redeemable preferred securities <sup>(a)</sup>	\$ 412,085	\$ —	\$ —	\$ 412,085
HPP Redeemable preferred securities <sup>(a)</sup>	—	—	—	—
Debt <sup>(b)</sup>	29,575	—	29,575	—
Consideration payable <sup>(c)</sup>	4,897	—	—	4,897
Note payable <sup>(d)</sup>	6,594	—	—	6,594
Contingent distribution <sup>(a)</sup>	26,359	—	—	26,359
<b>Total</b>	<b>\$ 479,510</b>	<b>\$ —</b>	<b>\$ 29,575</b>	<b>\$ 449,935</b>

<sup>(a)</sup>Allocated the equity fair value using the option pricing method ("OPM"). The value of equity was determined using a discounted cash flow ("DCF") method and adjusted for any applicable separate components of the value such as net operating loss carryforwards, excess or deficit working capital, and fair value of debt instrument.

<sup>(b)</sup>Debt was valued using a yield method, which is the a DCF method applied to debt securities, and a probability-weighted framework based on the expected cash flows to the debt securities under various exit scenarios discounted by the risk-adjusted discount rates.

<sup>(c)</sup>The net present value ("NPV") of the consideration payable was valued using the DCF method.

<sup>(d)</sup>Note payable was valued using a lattice model.

<sup>(e)</sup>Marketable securities are valued at the closing market price reported on the active market on which the securities trade.

Changes in Level 3 Instruments for the years ended December 31, 2014 and 2013

	Net					
	Balance at January 1	change in fair value included in earnings	Net change in fair value <sup>(1)</sup>	Purchases/ Issuance	Sales/ Repurchases	Balance at December 31
<b>2013</b>						
TTP Redeemable preferred units	\$ 8,769	\$ —	\$ (8,851)	\$ 14,758	\$ —	\$ 14,676
HPP Redeemable preferred units	—	—	—	—	—	—
Debt embedded derivatives	4,130	213	—	2,118	(6,461)	—
<b>Total</b>	<b>\$ 12,899</b>	<b>\$ 213</b>	<b>\$ (8,851)</b>	<b>\$ 16,876</b>	<b>\$ (6,461)</b>	<b>\$ 14,676</b>
<b>2014</b>						
TTP Redeemable preferred units	\$ 14,676	\$ —	\$ 399,106	\$ 52,697	\$ (54,394)	\$ 412,085
HPP Redeemable preferred units	—	—	—	—	—	—
Consideration payable	—	—	—	4,897	—	4,897
Note payable	—	—	—	6,594	—	6,594
Contingent distribution	—	—	—	26,359	—	26,359
<b>Total</b>	<b>\$ 14,676</b>	<b>\$ —</b>	<b>\$ 399,106</b>	<b>\$ 90,547</b>	<b>\$ (54,394)</b>	<b>\$ 449,935</b>

(1) The above represents the change in the fair value of the Company's redeemable preferred units. See the Combined Consolidated Statements of Changes in Redeemable Convertible Units and Members' Deficit and Note 11 for additional changes in the carrying value of the Company's redeemable preferred units.

There were no transfers into or out of level 3 and/or between level 1 and level 2.

Significant inputs utilized in the valuation of the Company's redeemable convertible preferred units and contingent distribution were as of December 31:

	2013	2014
Annual volatility	141.30%	65.70%
Annual risk-free rate	0.31%	0.19%

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

In addition to the significant inputs above, the fair values of the redeemable convertible preferred units and the contingent distribution as of December 31, 2013 and 2014 were derived utilizing forecasts through 2030 for use under a discounted cash flow model. These forecasts represent the future expected revenues and costs associated with the drug programs currently under development, adjusted by certain probabilities of successful passage through various developmental hurdles, including successful completion of pre-clinical trials and all three phases of clinical trials, as well as FDA approval of a new drug application.

Changes in the unobservable inputs noted above would impact members' equity. For the Company's redeemable convertible preferred units and contingent distribution, increases (decreases) in the estimates of the Company's annual volatility would increase (decrease) the members' equity and an increase (decrease) in the annual risk free rate would increase (decrease) the members' equity.

**14. Related Party Transactions**

***PharmaCore, Inc.***

Certain unit holders of the Company also control PharmaCore, Inc. (PharmaCore). The Company purchases chemistry and Good Manufacturing Practices (GMP) manufacturing services from PharmaCore. Total purchases from PharmaCore for the years ended December 31, 2013 and 2014 were \$3.1 million and \$1.4 million, respectively.

On April 17, 2007, the Company's Board of Directors approved \$2.0 million of subordinated financing to be provided to PharmaCore. Advances were made and interest accrued before the Company entered into the Subordinated Promissory Note agreement (the "Note Agreement") with PharmaCore on June 9, 2008. The Note Agreement was amended on April 23, 2010 to provide an additional \$2.9 million of subordinated financing, with the same terms as the original note. The Note Agreement has a nine year term, a fixed interest rate of 8.25% per annum, with maturity of June 1, 2017. No payments were required through December 31, 2014 with accrued interest capitalized into the principal balance. Thereafter, interest is to be paid quarterly. As part of the agreement, the Company received a warrant, exercisable for up to ten years, to purchase 370,370 common units of PharmaCore at an exercise price of \$0.54 per unit. During 2013 and 2014, the Company recorded interest income of \$0.6 million related to this financing. The total receivable balance due from PharmaCore financing, accrued interest and cash advance activities was \$9.0 million and \$9.6 million at December 31, 2013 and 2014.

During the years ended December 31, 2013 and 2014, the Company recorded an allowance for uncollectible amounts related to the PharmaCore receivable of \$8.2 million and \$8.8 million, respectively. The change in the allowance during the years ended December 31, 2013 and 2014 are reflected in other income (expense) related party on the combined consolidated statements of operations.

***Notes Receivable from Employees and Officers***

Periodically, the Company has advanced monies to its employees. These advances typically are interest bearing at a rate of 4–5% and payable over a period of 1–3 years. During the years ended December 31, 2013 and 2014, the Company advanced a total of \$10 thousand and \$42 thousand, respectively, to its employees. As of December 31, 2013 and 2014, the Company had \$25 thousand and \$58 thousand due from its employees, respectively. Amounts forgiven during each of the years ended December 31, 2013 and 2014 were \$81 thousand and \$10 thousand, respectively. These amounts due are presented as employee loans receivable, net – related party on the combined consolidated balance sheets.

**15. Income Taxes**

In November 2013, TTP Inc. underwent a reorganization by contributing all of its assets to TTP, in exchange for (a) assumption of all its liabilities and (b) all membership units of TTP. The membership units of TransTech Pharma, LLC, were then distributed to the shareholders of TTP Inc. to match in kind and number the shares previously held by them in TTP Inc. Following the reorganization, the Company, a limited liability company, is treated as a partnership for U.S. federal and state income tax purposes in most

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

jurisdictions. Partnerships generally do not pay income tax, nor recognize income tax expense, but pass their taxable attributes to the partners who pay income tax at the partner level. Prior to the reorganization to an LLC, TTP Inc. had significant deferred tax assets largely comprised of net operating loss carryforwards and research and development credits. As a result of recurring and anticipated future operating losses, a full valuation was established against the net deferred assets prior to the reorganization.

**16. Net Earnings (Loss) per Unit**

Under the two-class method, for periods with net income, basic net income per common unit is computed by dividing the net income attributable to common unit holders by the weighted average number of common units outstanding during the period. Net income attributable to common unit holders is computed by subtracting from net income the portion of current year earnings that participating securities would have been entitled to receive pursuant to their dividend rights had all of the year's earnings been distributed. No such adjustment to earnings is made during periods with a net loss as the holders of the participating securities have no obligation to fund losses. Diluted net loss per common unit is computed under the two-class method by using the weighted average number of common units outstanding plus, for periods with net income attributable to common unit holders, the potential dilutive effects of unit options and warrants. In addition, the Company analyzes the potential dilutive effect of the outstanding participating securities under the if-converted method when calculating diluted earnings per unit in which it is assumed that the outstanding participating securities convert into common units at the beginning of the period. The Company reports the more dilutive of the approaches (two-class or if-converted) as its diluted net income per unit during the period. Due to the existence of net losses for TTP for the years ended December 31, 2013 and 2014 and HPP for the year ended December 31, 2014, basic and diluted loss per unit were the same, as the effect of potentially dilutive securities would have been anti-dilutive.

Undistributed net earnings (loss) for a given period is apportioned to participating securities based on the weighted-average of common membership units outstanding during the applicable period as a percentage of the total weighted-average units outstanding during the same period.

The following table summarizes the computation of basic and diluted net loss (in thousands) and net loss per unit of TTP:

	Year Ended December 31,	
	2013	2014
Net TTP loss	\$ (77,893)	\$ (25,254)
Accretion of TTP redeemable convertible preferred units	(92,442)	(209,298)
Discount on repurchase of TTP redeemable convertible units - Series F	—	11,597
Net loss attributable to TTP member units, basic and diluted	<u>\$ (170,335)</u>	<u>\$ (222,955)</u>
Net loss per TTP member unit, basic and diluted	\$ (12.82)	\$ (16.81)
Weighted-average TTP member units outstanding, basic and diluted	13,288,327	13,263,676

The following table summarizes the computation of basic and diluted net earnings (loss) (in thousands) and net earnings (loss) per unit of HPP:

	Year Ended December 31,	
	2013	2014
Net HPP earnings (loss)	\$ 29,690	\$ (10,847)
Accretion of HPP redeemable convertible preferred units	(13,161)	(3,726)
Undistributed HPP earnings allocated to participating securities	(15,401)	—
Discount on repurchase of HPP redeemable convertible units - Series B	—	2,067
Net earnings (loss) attributable to HPP member units, basic and diluted	<u>\$ 1,128</u>	<u>\$ (12,506)</u>
Net earnings (loss) per HPP member unit, basic and diluted	\$ 0.06	\$ (0.64)
Weighted-average HPP member units outstanding, basic and diluted	19,597,888	19,570,078

**TransTech Pharma, LLC and High Point Pharmaceuticals, LLC**

**Notes To Combined Consolidated Financial Statements (continued)**

The following TTP securities, presented on a common unit equivalent basis, have been excluded from the calculation of weighted average TTP common units outstanding because their effect is anti-dilutive:

	Year Ended December 31,	
	2013	2014
TTP Redeemable convertible preferred units:		
TTP Series A	8,571,337	8,571,337
TTP Series B	2,547,593	2,547,593
TTP Series C	2,243,922	2,243,922
TTP Series D	2,442,361	2,442,361
TTP Series E	32,789,595	32,789,595
TTP Series F	1,072,004,541	1,145,947,422
TTP Warrants to purchase common units	6,546,011	991,337
Total TTP common units reserved for future issuance	<u>1,127,145,360</u>	<u>1,195,533,567</u>

As of December 31, 2013 and 2014, the following HPP securities, presented on a common unit equivalent basis, have been excluded from the calculation of weighted average HPP common units outstanding because their effect is anti-dilutive:

	Year Ended December 31,	
	2013	2014
HPP Redeemable convertible preferred units:		
HPP Series A	49,766,563	49,766,563
HPP Series B	548,366,932	594,834,833
Warrants to purchase HPP common units	1,742,117	917,587
Options to purchase HPP common units	624,687	564,937
Total HPP common units reserved for future issuance	<u>600,500,299</u>	<u>646,083,920</u>

**17. Employee Benefit Plan**

The Company has a 401(k) retirement plan in which all of its full-time employees are eligible to participate. The plan provides for the Company to make discretionary 50% matching contributions up to a maximum of 6% of employees' eligible compensation. The Company contributed \$0.23 million and \$0.17 million to the plan for the years ended December 31, 2013 and 2014, respectively.

**18. Subsequent Events**

On March 6, 2015, Company entered into an exclusive global license agreement (the "License Agreement") with Calithera Biosciences, Inc. (Calithera), a clinical-stage pharmaceutical company focused on discovering and developing novel small molecule drugs directed against tumor metabolism and tumor immunology targets for the treatment of cancer, granting Calithera exclusive world-wide rights to research, develop and commercialize the Company's portfolio of hexokinase II inhibitors. Under the terms of the License Agreement, Calithera will pay the Company an initial license fee of \$0.6 million and potential development and regulatory milestone payments totaling up to \$30.5 million for the first licensed product, an additional \$77.0 million in potential sales-based milestones, as well as royalty payments, based on tiered sales of the first commercialized licensed product. In addition, Calithera will fund up to \$1.1 million during the first 12 months of the License Agreement for the costs associated with up to four full-time employees for the Company to develop additional hexokinase inhibitors. If Calithera develops additional licensed products, after achieving regulatory approval of the first licensed product, Calithera would owe additional regulatory milestone payments and additional royalty payments based on sales of such additional licensed products.

On May 4, 2015, M&F TTP Holdings LLC agreed to extend the maturity date of the Uncommitted Advance Agreement to January 15, 2016.





Shares  
**vTv Therapeutics Inc.**  
Class A Common Stock

---

**PRELIMINARY PROSPECTUS**

---

**Piper Jaffray**

**Stifel**

Until \_\_\_\_\_, 2015 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

---

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

Set forth below is a table of the registration fee for the Securities and Exchange Commission and estimates of all other expenses to be paid by the registrant in connection with the issuance and distribution of the securities described in the registration statement:

SEC registration fee	\$	*
NASDAQ listing fee		*
Financial Industry Regulatory Authority filing fee		*
Printing expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Blue Sky fees and expenses		*
Transfer agent and registrar fees		*
Miscellaneous		*
Total	\$	*

\*To be completed by amendment.

**Item 14. Indemnification of Directors and Officers.**

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending or completed actions, suits or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee or agent to the Registrant. The Delaware General Corporation Law provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise. The Registrant's Bylaws provide for indemnification by the Registrant of its directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions, or (iv) for any transaction from which the director derived an improper personal benefit. The Registrant's Certificate of Incorporation provides for such limitation of liability.

The Registrant maintains standard policies of insurance under which coverage is provided (a) to its directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act, and (b) to the Registrant with respect to payments which may be made by the Registrant to such officers and directors pursuant to the above indemnification provision or otherwise as a matter of law.

The proposed form of Underwriting Agreement filed as Exhibit 1.1 to this Registration Statement provides for indemnification of directors and officers of the Registrant by the underwriters against certain liabilities.

We expect to enter into customary indemnification agreements with our executive officers and directors that provide them, in general, with customary indemnification in connection with their service to us or on our behalf.

**Item 15. Recent Sales of Unregistered Securities**

In connection with the Reorganization Transactions described under “Prospectus Summary—The Reorganization Transactions” in the accompanying prospectus, the Registrant will issue an aggregate of    shares of its Class B common stock to vTv Therapeutics Holdings. The shares of Class B common stock described above will be issued in reliance on the exemption contained in Section 4(a)(2) of the Securities Act of 1933, as amended, on the basis that the transaction will not involve a public offering. No underwriters will be involved in the transaction.

**Item 16. Exhibits and Financial Statement Schedules.**

**(a) Exhibits**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
1.1*	Form of Underwriting Agreement.
3.1*	Articles of Incorporation of vTv Therapeutics Inc.
3.2*	Bylaws of vTv Therapeutics Inc.
3.3*	Form of Amended and Restated Articles of Incorporation of vTv Therapeutics Inc. to be in effect at the closing of the initial public offering.
3.4*	Form of Amended and Restated Bylaws of vTv Therapeutics Inc. to be in effect at the closing of the initial public offering.
4.1*	Specimen of Share Certificate of vTv Therapeutics Inc.
5.1*	Opinion of Paul, Weiss, Rifkind, Wharton & Garrison LLP as to the validity of the securities being offered.
10.1*	Form of Investor Rights Agreement.
10.2*	Form of Amended and Restated vTv Therapeutics LLC Operating Agreement.
10.3*	Form of Exchange Agreement.
10.4*	Form of Tax Receivable Agreement.
10.5*	vTv Therapeutics Inc. 2015 Omnibus Equity Incentive Plan.
10.6*	Form of Indemnification Agreement.
21.1*	List of subsidiaries of the registrant.
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.2*	Consent of Paul, Weiss, Rifkind, Wharton & Garrison LLP (included in Exhibit 5.1 to this Registration Statement).
24.1*	Powers of Attorney (included in signature page).

\*To be filed by amendment.

**(b) Financial Statement Schedules**

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the combined consolidated financial statements or the notes thereto.

**Item 17. Undertakings.**

The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For purposes of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, vTv Therapeutics Inc. has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of High Point, State of North Carolina, on the      day of      2015.

**VTV THERAPEUTICS INC.**

By: \_\_\_\_\_  
Stephen L. Holcombe  
President and Chief Executive Officer

**POWER OF ATTORNEY**

Each person whose signature appears below authorizes Stephen L. Holcombe and Paul G. Savas, or any of them, as his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, to execute in his name and on his behalf, in any and all capacities, this Registrant's registration statement on Form S-1 relating to the Class A common stock and any amendments thereto (and any additional registration statement related thereto permitted by Rule 462(b) promulgated under the Securities Act of 1933 (and all further amendments, including post-effective amendments thereto)), necessary or advisable to enable the registrant to comply with the Securities Act of 1933, and any rules, regulations and requirements of the Securities and Exchange Commission, in respect thereof, in connection with the registration of the securities which are the subject of such registration statement, which amendments may make such changes in such registration statement as such attorney may deem appropriate, and with full power and authority to perform and do any and all acts and things whatsoever which any such attorney or substitute may deem necessary or advisable to be performed or done in connection with any or all of the above-described matters, as fully as each of the undersigned could do if personally present and acting, hereby ratifying and approving all acts of any such attorney or substitute.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

<u>Signature</u>	<u>Capacity</u>	<u>Date</u>
_____ Jeffrey B. Kindler	Executive Chairman	
_____ Stephen L. Holcombe	President and Chief Executive Officer <i>(Principal Executive Officer, Principal Financial Officer, Principal Accounting Officer)</i>	
_____ Paul G. Savas	Director	

---

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Exhibit Description</b>
1.1*	Form of Underwriting Agreement.
3.1*	Articles of Incorporation of vTv Therapeutics Inc.
3.2*	Bylaws of vTv Therapeutics Inc.
3.3*	Form of Amended and Restated Articles of Incorporation of vTv Therapeutics Inc. to be in effect at the closing of the initial public offering.
3.4*	Form of Amended and Restated Bylaws of vTv Therapeutics Inc. to be in effect at the closing of the initial public offering.
4.1*	Specimen of Share Certificate of vTv Therapeutics Inc.
5.1*	Opinion of Paul, Weiss, Rifkind, Wharton & Garrison LLP as to the validity of the securities being offered.
10.1*	Form of Investor Rights Agreement.
10.2*	Form of Amended and Restated vTv Therapeutics LLC Operating Agreement.
10.3*	Form of Exchange Agreement.
10.4*	Form of Tax Receivable Agreement.
10.5*	vTv Therapeutics Inc. 2015 Omnibus Equity Incentive Plan.
10.6*	Form of Indemnification Agreement.
21.1*	List of subsidiaries of the registrant.
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm.
23.2*	Consent of Paul, Weiss, Rifkind, Wharton & Garrison LLP (included in Exhibit 5.1 to this Registration Statement)
24.1*	Powers of Attorney (included in signature page).

---

\* To be filed by amendment.

---